

Medicare Benefit Policy Manual

Chapter 11 - End Stage Renal Disease (ESRD)

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10 - Definitions Relating to ESRD

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End Stage Renal Disease (ESRD) occurs from the destruction of normal kidney tissues over a long period of time. Often there are no symptoms until the kidney has lost more than half its function. The loss of kidney function in ESRD is usually irreversible and permanent.

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

ESRD facilities must be certified by Medicare and are required to comply with the Conditions for Coverage set forth in 42 CFR Part 494. Survey and certification information for ESRD facilities can be found at the following Centers for Medicare and Medicaid Services website: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.

ESRD PPS is covered under Medicare Part B.

Medicare Part B covers the services listed below unless otherwise noted.

A. 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.

1. 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. See §50.A.1 of this chapter for payment information.

2. Peritoneal - 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. See §50.A.4 of this chapter for payment information.

Peritoneal dialysis is particularly suited for:

- Patients without caregivers to assist in self-dialysis;
- Children;

- Patients with no peripheral sites available for fistula or cannula placement;
- Patients who have difficulty learning the more complex hemodialysis technique; and
- Elderly patients with cardiovascular disease who are unable to tolerate intravascular fluid shifts associated with hemodialysis.

The three types of peritoneal dialysis are listed below:

- a. Continuous Ambulatory Peritoneal Dialysis (CAPD) - In CAPD, the patient's peritoneal membrane is used as a dialyzer. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted indwelling catheter that allows the dialysate to pour into the beneficiary's peritoneal cavity. Every 4 to 6 hours the patient drains the fluid out into the same bag and replaces the empty bag with a new bag of fresh dialysate. This is done several times a day.
- b. Continuous Cycling Peritoneal Dialysis (CCPD) - CCPD is a treatment modality that combines the advantages of the long dwell, continuous steady-state dialysis of CAPD, with the advantages of automation inherent in intermittent peritoneal dialysis. The major difference between CCPD and CAPD is that the solution exchanges, which are performed manually during the day by the patient on CAPD, are moved to nighttime with CCPD and are performed automatically with a peritoneal dialysis cyclor. Generally, there are three nocturnal exchanges occurring at intervals of 2 1/2 to 3 hours. Upon awakening, the patient disconnects from the cyclor and leaves the last 2-liter fill inside the peritoneum to continue the daytime long dwell dialysis.
- c. Intermittent Peritoneal Dialysis (IPD) - Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions. See §50.A.5 of this chapter for payment information.

3. Hemofiltration - Hemofiltration is an alternative to peritoneal dialysis and hemodialysis. Hemofiltration (which is also known as diafiltration) removes fluid, electrolytes, and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in three weekly sessions. In contrast to both hemodialysis and peritoneal dialysis treatments, which eliminate dissolved substances via diffusion across semi permeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in an ESRD facility or at home. For payment information see §50 A.2 of this chapter.

4. Ultrafiltration – Ultrafiltration is the process of removing excess fluid from the blood through a dialysis membrane by exerting pressure. This 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 have refractory edema. Occasionally, medical complications may occur which require that ultrafiltration be performed separately from the dialysis treatment. See §50.A.3 of this chapter for payment information.

B. 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).

1. 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. 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>.

CMS determines that an ESRD facility is hospital-based if:

- The ESRD facility and hospital are subject to the bylaws and operating decisions of a common governing board. This governing board, which has final administrative responsibility, approves all personnel actions, appoints medical staff, and carries out similar management functions;
- The ESRD facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through that officer to the governing board;
- The ESRD facility's personnel policies and practices conform to those of the hospital;
- The administrative functions of the ESRD facility (for example, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and

- The ESRD facility and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of hospital overhead to the facility through the required step-down methodology.

CMS does not consider the existence of an agreement between an ESRD facility and a hospital for the referral of patients, a shared service arrangement between a facility and a hospital, or the physical location of a dialysis unit on the premises of a hospital, to mean that an ESRD facility is hospital-based.

2. 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 the following:

- a. Renal Dialysis Center - A hospital-based unit, which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center. Under the ESRD PPS CMS refers to renal dialysis centers as ESRD facilities.
- b. Renal Dialysis Facility - An independent unit that is approved to furnish outpatient maintenance dialysis services directly to ESRD patients. Under the ESRD PPS CMS refers to renal dialysis facilities as ESRD facilities.
- c. Self-Dialysis Unit - A dialysis unit that furnishes self-dialysis services and is part of a Medicare certified ESRD facility.
- d. Home Dialysis Training and Support ESRD Facility – A Medicare certified ESRD facility that furnishes home dialysis training and support services. See 42 CFR 494.100 for more information regarding Medicare certification requirements.
- e. Special Purpose Renal Dialysis Facility – An ESRD facility that is approved to furnish dialysis at special locations, on a short-term basis, to a group of dialysis patients otherwise unable to obtain treatment in their geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

C. Renal Dialysis Services

Renal dialysis services are all items and services used to furnish outpatient maintenance dialysis to individuals for the treatment of ESRD 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 (see §20.2.E, §20.3.F, and §70.B of this chapter for more information);
- Erythropoiesis stimulating agents (ESAs) and their oral or other forms of administration (see §20.3.A of this chapter for more information);
- Injectable drugs and biologicals and their oral or other forms of administration (see §20.3.B, §20.3.C and §20.3.D of this chapter for more information);
- Oral or other forms of non-injectable drugs and biologicals (see §20.3 of this chapter for more information);
- Diagnostic laboratory tests (see §20.2 of this chapter for more information);
- Home and self-dialysis training (see §30.2 of this chapter for more information);
and
- All supplies, equipment, and support services necessary for the effective performance of a patient's dialysis furnished in the ESRD facility or in a patient's home (see §20.4 of this chapter for more information).

See §20 of this chapter for more information regarding renal dialysis items and services.

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.

D. Types of Dialysis

1. Types of Outpatient Maintenance Dialysis - Outpatient maintenance dialysis is furnished on an outpatient basis by a Medicare certified ESRD facility and is paid under the ESRD PPS. 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 and payment instructions of acute dialysis services furnished in the hospital see Pub. 100-04, chapter 4, §200.2 and Pub. 100-02, chapter 1, section 10.

- a. In-facility Dialysis - Dialysis furnished on an outpatient basis in a Medicare certified ESRD facility.
- b. 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).
- c. Staff-Assisted Dialysis - Dialysis performed by the staff of the ESRD facility in the ESRD facility.
- d. Self-Dialysis - Dialysis performed by an ESRD patient in-facility with the expectation that the patient performs their dialysis treatment with little or no professional assistance. The patient must have completed an appropriate course of training as specified at 42 CFR §494.100(a).

NOTE: Self-dialysis and home dialysis include training programs that educate ESRD patients and/or other individuals to assist the patient in performing self-dialysis or home dialysis with little or no professional assistance.

2. 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.

E. Home Dialysis - Supplies, Equipment, and Support Services

ESRD facilities are responsible for furnishing supplies, equipment, and support services for home dialysis. ESRD facilities are financially responsible and may not bill Medicare or the patient for separate payment. If an ESRD facility arranges for a supplier to furnish renal dialysis supplies and equipment, the supplier may seek payment only from the ESRD facility and may not bill Medicare or the patient for separate payment.

Method Selection – For home dialysis services furnished prior to January 1, 2011, a beneficiary selected one of two methods to secure home dialysis items and services. Under Method I, the ESRD facility with which the patient is associated, assumes total responsibility for furnishing all home dialysis items or services. Under Method II, the beneficiary dealt directly with a dialysis supplier to secure home dialysis items and services. Beginning January 1, 2011, Method II is no longer an option for home dialysis items and services under Medicare. Therefore, beginning January 1, 2011, all home dialysis patients are Method I.

Under Method I, Medicare payment for all modalities of home dialysis is made to the ESRD facility under the ESRD PPS. Renal dialysis items and services may be furnished directly by the facility or under arrangement with a supplier.

The ESRD facility or home dialysis supplier may not bill the beneficiary directly for renal dialysis supplies, services, or equipment. For further discussion on Method I payment refer to §20.1 of this chapter.

1. Home Dialysis Equipment - Home dialysis equipment includes all of the medically necessary equipment ordered by the attending physician, including (but not limited to) artificial kidneys, automated peritoneal dialysis machines, and support equipment.

Home dialysis supplies and equipment may be covered if used by an ESRD beneficiary in a nursing home or a SNF. See §40.C and §40.D of this chapter for more information.

2. Installation - Installation includes (but is not limited to) the identification of any minor plumbing and electrical changes required to accommodate the equipment, the ordering and performing of these changes, delivery of the equipment and its actual installation (i.e., hookup), as well as any necessary testing to assure proper installation and function.

Minor plumbing and electrical changes include those parts and labor required to connect the dialysis equipment to plumbing and electrical lines that already exist in the room where the patient will dialyze. Medicare does not cover wiring or rewiring of the patient's home or installing any plumbing to the patient's home or to the room of the home where the patient will dialyze.

3. Maintenance - Maintenance includes (but is not limited to) travel to the patient's home, transportation of the equipment to a repair site, the actual performance of the maintenance or repair, and necessary parts. Water purification equipment maintenance includes replacing the filter on a reverse osmosis device, regenerating the resin tanks on a deionization device, using chemicals in a water softener, and periodic water testing to assure proper performance.

Routine maintenance customarily performed by a patient is not a covered service except for the cost of parts involved in the maintenance furnished by the ESRD facility to the patient.

4. Supplies - Supplies include all durable and disposable items and medical supplies necessary for the effective performance of a patient's dialysis. Supplies include (but are not limited to): dialyzers, forceps, sphygmomanometer with cuff and stethoscope, scales, scissors, syringes, alcohol wipes, sterile drapes, needles, topical anesthetics, and gloves.

5. Support Services – See §30.1.A of this chapter.

6. Support Equipment - Support equipment is equipment used in conjunction with the basic dialysate delivery system. Such equipment includes (but is not limited to) pumps, such as blood and heparin pumps, alarms, such as bubble detectors, water purification equipment used to improve the quality of the water used for dialysis, and adjustable dialysis chairs.

F. Overview of Medicare’s ESRD Payment Policy

1. ESRD Prospective Payment System (ESRD PPS) – Section 153(b) of Pub. L. 110-275, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) amended section 1881(b) of the Social Security Act to require the implementation of an ESRD bundled payment system effective January 1, 2011. Under MIPPA, the ESRD PPS replaced the basic case-mix adjusted composite rate payment system and the methodologies for the reimbursement of separately billable outpatient renal dialysis items and services.

The ESRD PPS provides a case-mix and facility-level adjusted single payment to ESRD facilities for renal dialysis services provided in an ESRD facility or in a beneficiary’s home. (See §10.C of this chapter for the items and services considered to be renal dialysis services.)

To account for higher resource utilization, the ESRD PPS applies case-mix adjusters to the base rate and, when applicable, also includes an add-on for home and self-dialysis training and an outlier payment.

The ESRD PPS provided for a 4 year transition period under which facilities may have received a blend of the payment methodology prior to January 1, 2011 (that is, the basic case-mix adjusted composite rate payment system) and the ESRD PPS. In 2014, all ESRD facilities that receive Medicare payment are paid 100 percent under the ESRD PPS.

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 per dialysis treatment base rate is subsequently adjusted to reflect:

- Patient-level adjustments for:
 - case-mix, (see §60.A.1 of this chapter for adult patient adjustments and §60.A.6 of this chapter for pediatric patient adjustments)
 - An onset of dialysis adjustment for adult patients that have Medicare ESRD coverage during their initial 4 months of dialysis, (see §60.A.4 of this chapter)
- Facility-level adjustments for:
 - A low-volume facility adjustment for ESRD facilities that meet certain criteria, (see §60.B.1 of this chapter)
 - A wage index adjustment to reflect differences in wage levels among the urban and rural areas in which ESRD facilities are located, (see §60.B.2 of this chapter)

- A rural adjustment, effective January 1, 2016
- Other adjustments:
 - A home or self-dialysis training add-on, (see §60.C of this chapter)
 - An outlier payment, (see §60.D of this chapter)

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. The list of renal dialysis services identified for the ESRD PPS consolidated billing may be viewed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Note that this list is not an all-inclusive list, and ESRD facilities are responsible and reimbursed for furnishing all renal dialysis services under the ESRD PPS.

2. Basic Case-Mix Adjusted Composite Rate Payment System – The basic case-mix adjusted composite rate payment system was implemented in CY 2005 and maintained until 2014 for purposes of the blended payment during the ESRD PPS transition period. It applied patient-level case-mix adjusters, additional payment for home and self-dialysis training, and a drug add-on to the composite rate.

The drug add-on accounted for the difference between the methodologies of payment for separately billed drugs and biologicals prior to the enactment of the revised drug pricing specified in the Medicare Modernization Act of 2003 (MMA). For more information on the history of the composite rate see Appendix C and for more information regarding the transition period see §70 of this chapter.

3. Composite Rate –The composite rate was the first step Medicare made toward creating a bundled payment for renal dialysis items and services. It covered routine laboratory testing, certain drugs, equipment and supplies, and support services furnished for outpatient maintenance dialysis in Medicare-certified ESRD facilities. Under the composite rate methodology, separate payment was made to ESRD facilities for most drugs and biologicals furnished to ESRD patients. For more information regarding composite rate items and services, see §20.1, for composite rate laboratory services, see §20.2.E, and for composite rate drugs, see §20.3.F of this chapter.

20 - Renal Dialysis Items and Services

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

Medicare provides payment under the ESRD PPS for all renal dialysis services for outpatient maintenance dialysis when they are furnished to Medicare ESRD patients for the treatment of ESRD by a Medicare certified ESRD facility or a special purpose dialysis facility. Renal dialysis services are the items and services included under the

composite rate and the items and services that were separately paid as of December 31, 2010 that were used for the treatment of ESRD.

Renal dialysis services are furnished in various settings including hospital outpatient ESRD facilities, independent ESRD facilities, or in the patient's home. Renal dialysis items and services furnished at ESRD facilities differ according to the types of patients being treated, the types of equipment and supplies used, the preferences of the treating physician, and the capability and makeup of the staff. Although not all facilities provide an identical range of services, the most common elements of dialysis treatment include:

- Laboratory Tests;
- Drugs and Biologicals;
- Equipment and supplies - dialysis machine use and maintenance;
- Personnel services;
- Administrative services;
- Overhead costs;
- Monitoring access and related dec clotting or referring the patient, and
- Direct nursing services include registered nurses, licensed practical nurses, technicians, social workers, and dietitians.

20.1 - Composite Rate Items and Services

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Beginning January 1, 2011, all renal dialysis services (defined at §10.C of this chapter) are included in the ESRD PPS. Renal dialysis services include, but are not limited to, the items and services included under the composite rate as of December 31, 2010.

The composite payment rate (defined at §10.F.3 of this chapter) was a comprehensive payment for all modes of in-facility and Method I home dialysis. Most items and services related to the treatment of the patient's end-stage renal disease were covered under the composite rate payment with the exception of physicians' professional services, separately billable laboratory services, and separately billable drugs. If a facility failed to furnish, either directly or under an arrangement, any part of the items and services covered under the composite rate, then the ESRD facility could not be paid any amount for the service. This payment was subject to the normal Part B deductible and coinsurance requirements.

Below are examples of items and services included under the composite rate and furnished by the ESRD facility, either directly or under arrangement.

- Dialysate;
- Cardiac monitoring;
- Catheter changes;
- Suture removal;
- Dressing changes;
- Crash cart usage for cardiac arrest;

- Declotting of shunt performed by ESRD facility staff in the dialysis unit;
- All oxygen and its administration furnished in the dialysis unit;
- Staff time to administer blood;
- Staff time used to administer separately billable parenteral items; and
- Staff time used to collect specimens for laboratory tests.

20.2 - Laboratory Services

(Rev. 224, Issued: 06-03-16, Effective: 01-01-16, Implementation: 09-06-16)

All laboratory services furnished to individuals for the treatment of ESRD are included in the ESRD PPS as Part B services and are not paid separately as of January 1, 2011. The laboratory services include but are not limited to:

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

Composite rate laboratory tests are listed in §20.2.E of this chapter. More information regarding composite rate laboratory tests can be found in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.1, §60.1, and §80. As discussed below, composite rate laboratory services should not be reported on claims.

To the extent a laboratory test is performed to monitor the levels or effects of any of the drugs that were specifically excluded from the ESRD PPS, these tests would be separately billable. The following table lists the drug categories that were excluded from the ESRD PPS and the rationale for their exclusion. Laboratory services furnished to monitor the medication levels or effects of drugs and biologicals that fall in those categories would not be considered to be furnished for the treatment of ESRD.

DRUG CATEGORIES EXCLUDED FROM THE ESRD PPS BASE RATE FOR THE PURPOSE OF REPORTING LABS

Drug Category	Rationale for Exclusion
Anticoagulant	Drugs labeled for non-renal dialysis conditions and not for vascular access.
Antidiuretic	Used to prevent fluid loss.
Antiepileptic	Used to prevent seizures.
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.
Antipsychotic	Used to treat psychosis.
Antiviral	Used to treat viral conditions such as shingles.
Cancer management	Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category.

Drug Category	Rationale for Exclusion
Cardiac management	Drugs that manage blood pressure and cardiac conditions.
Cartilage	Used to replace synovial fluid in a joint space.
Coagulants	Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency.
Cytoprotective agents	Used after chemotherapy treatment.
Endocrine/metabolic management	Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia, and hyperglycemia.
Erectile dysfunction management	Androgens were used prior to the development of ESAs for anemia management and currently are not recommended practice. Also used for hypogonadism and erectile dysfunction.
Gastrointestinal management	Used to treat gastrointestinal conditions such as ulcers and gallbladder disease.
Immune system management	Anti-rejection drugs covered under a separate benefit category.
Migraine management	Used to treat migraine headaches and symptoms.
Musculoskeletal management	Used to treat muscular disorders such as prevent muscle spasms, relax muscles, improve muscle tone as in myasthenia gravis, relax muscles for intubation and induce uterine contractions.
Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs	Not a function performed by an ESRD facility.
Pulmonary system management	Used for respiratory/lung conditions such as opening airways and newborn apnea.
Radiopharmaceutical procedures	Includes contrasts and procedure preparation.
Unclassified drugs	Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified.
Vaccines	Covered under a separate benefit category.

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).

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 §60.D of this chapter.

Certain laboratory services 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 below includes the renal dialysis laboratory tests that are routinely performed for the treatment of ESRD. Payment for the laboratory tests identified on this list is included in the ESRD PPS. The laboratory tests listed in the table are used to enforce consolidated billing edits to ensure that payment is not made for renal dialysis laboratory tests outside of the ESRD PPS. 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. Additional renal dialysis laboratory tests may be added through administrative issuances in the future.

LABS SUBJECT TO ESRD CONSOLIDATED BILLING

CPT/ HCPCS	Short Description
80047	Basic Metabolic Panel (Calcium, ionized)
80048	Basic Metabolic Panel (Calcium, total)
80051	Electrolyte Panel
80053	Comprehensive Metabolic Panel
80061*	Lipid Panel*
80069	Renal Function Panel
80076	Hepatic Function Panel
82040	Assay of serum albumin
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82310	Assay of calcium
82330	Assay of calcium, Ionized
82374	Assay, blood carbon dioxide
82379	Assay of carnitine
82435	Assay of blood chloride
82565	Assay of creatinine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin

82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83735	Assay of magnesium
83970	Assay of parathormone
84075	Assay alkaline phosphatase
84100	Assay of phosphorus
84132	Assay of serum potassium
84134	Assay of prealbumin
84155	Assay of protein, serum
84157	Assay of protein by other source
84295	Assay of serum sodium
84466	Assay of transferrin
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85014	Hematocrit
85018	Hemoglobin
85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.
85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
85041	Automated rbc count
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040	Blood culture for bacteria
87070	Culture, bacteria, other
87071	Culture bacteri aerobic othr
87073	Culture bacteria anaerobic
87075	Cultr bacteria, except blood
87076	Culture anaerobe ident, each
87077	Culture aerobic identify
87081	Culture screen only

87340	Hepatitis b surface ag, eia
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

* Effective January 1, 2016, the lipid panel is no longer considered to be a renal dialysis service. However, if the panel is furnished for the treatment of ESRD it is the responsibility of the ESRD facility and should be reported on the facility's claim.

A. Automated Multi-Channel Chemistry (AMCC) Tests

During the ESRD PPS transition period (see §70 of this chapter) ESRD facilities were required to report the renal dialysis AMCC tests with the appropriate modifiers (CD, CE, or CF) on their claims for purposes of applying the 50/50 rule under the composite rate portion of the blended payment. Refer to §70.B of this chapter for additional information regarding the composite rate portion of the blended payment during the transition.

The 50/50 rule is necessary for those ESRD facilities that chose to go through the transition period. If the 50/50 rule allows for separate payment, then the laboratory tests are priced using the clinical laboratory fee schedule. Information regarding the 50/50 rule can be found in §20.2.E of this chapter and in Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.

NOTE: An ESRD facility billing a renal dialysis AMCC test must use the CF modifier when the AMCC is not in the composite rate but is a renal dialysis service. AMCC tests that are furnished to individuals for reasons other than for the treatment of ESRD should be billed with the AY modifier to Medicare directly by the entity furnishing the service with the AY modifier.

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

1. Independent Laboratory

A patient's physician or practitioner may order a laboratory test that is included on the list of items and services subject to 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 Medicare 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.

2. Hospital-Based Laboratory

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.

C. Laboratory Services Performed in Emergency Rooms or Emergency Departments

In an emergency room or emergency department, the ordering physician or practitioner may not know at the time the laboratory test is being ordered, if it is being ordered as a renal dialysis service. Consequently, emergency rooms or emergency departments are not required to append an AY modifier to these laboratory tests when submitting claims with dates of service on or after January 1, 2012.

When a renal dialysis laboratory service is furnished to an ESRD patient in an emergency room or emergency department on a different date of service, hospitals can append an ET modifier to the laboratory tests furnished to ESRD patients to indicate that the laboratory test was furnished in conjunction with the emergency visit. Appending the ET modifier indicates that the laboratory service being furnished on a day other than the emergency visit is related to the emergency visit and at the time the ordering physician was unable to determine if the test was ordered for reasons of treating the patient's ESRD.

Allowing laboratory testing to bypass consolidated billing edits in the emergency room or department does not mean that ESRD facilities should send patients to other settings for routine laboratory testing for the purpose of not assuming financial responsibility of renal dialysis items and services. For additional information regarding laboratory services furnished in a variety of settings, see Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §30.3 and §40.6.

D. Hepatitis B Laboratory Services for Transient Patients

Laboratory testing for hepatitis B is a renal dialysis service. Effective January 1, 2011, hepatitis B testing is included in the ESRD PPS and therefore cannot be billed separately to Medicare.

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.

E. Laboratory Services Included Under Composite Rate

Prior to the implementation of the ESRD PPS, the costs of certain ESRD laboratory services 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 have been billed separately to the Medicare program.

All laboratory services that were included under the composite rate are included under the ESRD PPS unless otherwise specified. Payments for these laboratory tests are included in the ESRD PPS and are 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. Laboratory tests included in the composite payment rate are identified below.

1. Routinely Covered Tests Paid Under Composite Rate

The tests listed below are usually performed for dialysis patients and were routinely covered at the frequency specified in the absence of indications to the contrary, (i.e., no documentation of medical necessity was required other than knowledge of the patient's status as an ESRD beneficiary). When any of these tests were performed at a frequency greater than that specified, the additional tests were separately billable and were covered only if they were medically justified by accompanying documentation. A diagnosis of ESRD alone was not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must have been present, along with ICD diagnosis coding, on the claim for payment.

a. Hemodialysis, IPD, CCPD, and Hemofiltration

- Per Treatment - All hematocrit, hemoglobin, and clotting time tests furnished incident to dialysis treatments;
- Weekly - Prothrombin time for patients on anticoagulant therapy and Serum Creatinine;
- Weekly or Thirteen Per Quarter - BUN;
- Monthly - Serum Calcium, Serum Potassium, Serum Chloride, CBC, Serum Bicarbonate, Serum Phosphorous, Total Protein, Serum Albumin, Alkaline Phosphatase, aspartate amino transferase (AST) (SGOT) and LDH; and
- Automated Multi-Channel Chemistry (AMCC) - If an automated battery of tests, such as the SMA-12, is performed and contains most of the tests listed in one of the weekly or monthly categories, it is not necessary to **separately** identify any tests in the battery that are not listed. Further information concerning automated tests and the "50 percent rule" can be found below and in Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.1.

b. CAPD

- Monthly – BUN, Creatinine, Sodium, Potassium, CO₂, Calcium, Magnesium, Phosphate, Total Protein, Albumin, Alkaline Phosphatase, LDH, AST, SGOT, HCT, Hbg, and Dialysate Protein.

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

2. Separately Billable Tests Under the Composite Rate

The following list identifies certain separately billable laboratory tests that were covered routinely and without documentation of medical necessity other than knowledge of the patient's status as an ESRD beneficiary, when furnished at specified frequencies. If they were performed at a frequency greater than that specified, they were covered only if accompanied by medical documentation. A diagnosis of ESRD alone was not sufficient documentation. The medical necessity of the test(s), the nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s) must have been furnished on claims using the ICD diagnosis coding system.

- Separately Billable Tests for Hemodialysis, IPD, CCPD, and Hemofiltration

Serum Aluminum - one every 3 months
Serum Ferritin - one every 3 months

- Separately Billable Tests for CAPD

WBC, RBC, and Platelet count – One every 3 months
Residual renal function and 24 hour urine volume – One every 6 months

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

3. Automated Multi-Channel Chemistry (AMCC) Tests Under the Composite Rate

Clinical diagnostic laboratory tests that comprise the AMCC (listed in Appendix A and B) could be considered to be composite rate and non-composite rate laboratory services. Composite rate payment was paid by the A/B MAC (A). To determine if separate payment was allowed for non-composite rate tests for a particular date of service, 50 percent or more of the covered tests must be non-composite rate tests. This policy also applies to the composite rate portion of the blended payment during the transition. Beginning January 1, 2014, the 50 percent rule will no longer apply and no separate payment will be made under the composite rate portion of the blended payment.

Medicare applied the following to AMCC tests for ESRD beneficiaries:

- Payment was the lowest rate for services performed by the same provider, for the same beneficiary, for the same date of service.
- The A/B MAC identified, for a particular date of service, the AMCC tests ordered that were included in the composite rate and those that were not included. The composite rate tests were defined for Hemodialysis, IPD, CCPD, and Hemofiltration (see Appendix A) and for CAPD (see Appendix B).
- If 50 percent or more of the covered tests were included under the composite rate payment, then all submitted tests were included within the composite payment. In this case, no separate payment in addition to the composite rate was made for any of the separately billable tests.
- If less than 50 percent of the covered tests were composite rate tests, all AMCC tests submitted for that Date of Service (DOS) were separately payable.
- A non-composite rate test was defined as any test separately payable outside of the composite rate or beyond the normal frequency covered under the composite rate that was reasonable and necessary.

Three pricing modifiers identify the different payment situations for ESRD AMCC tests. The physician who ordered the tests was responsible for identifying the appropriate modifier when ordering the tests.

- CD - AMCC test had been ordered by an ESRD facility or Medicare capitation payment (MCP) physician that was part of the composite rate and was not separately billable
- CE - AMCC test had been ordered by an ESRD facility or MCP physician that was a composite rate test but was beyond the normal frequency covered under the rate and was separately reimbursable based on medical necessity
- CF - AMCC test had been ordered by an ESRD facility or MCP physician that was not part of the composite rate and was separately billable

The ESRD clinical diagnostic laboratory tests identified with modifiers “CD”, “CE” or “CF” may not have been billed as organ or disease panels. Effective October 1, 2003, all ESRD clinical diagnostic laboratory tests must be billed individually. See Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.1, for additional billing and payment instructions as well as examples of the 50/50 rule.

For ESRD dialysis patients, CPT code 82330 Calcium; ionized shall be included in the calculation for the 50/50 rule (Pub. 100-04, Medicare Claims Processing Manual, chapter 16, §40.6.1). When CPT code 82330 is billed as a substitute for CPT code 82310,

Calcium; total, it shall be billed with modifier CD or CE. When CPT code 82330 is billed in addition to CPT 82310, it shall be billed with CF modifier.

20.3 - Drugs and Biologicals

(Rev. 224, Issued: 06-03-16, Effective: 01-01-16, Implementation: 09-06-16)

All drugs and biologicals used for the treatment of ESRD are included in the ESRD PPS and are not separately paid as of January 1, 2011. The drugs and biologicals include but are not limited to:

- Drugs and biologicals included under the composite rate as of December 31, 2010 (discussed below);
- Former separately billable Part B injectable drugs;
- Oral or other forms of injectable drugs used for the treatment of ESRD formerly billed under Part D; and
- Oral or other forms of drugs and biologicals without an injectable form. (Implementation delayed until January 1, 2025.)

See §60.D of this chapter for details on drug eligibility under the outlier payment policy.

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 shall append the claim with the AY modifier to receive separate payment. For more information regarding the AY modifier refer to Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1.

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 used for the ESRD PPS consolidated billing may be viewed at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. Information regarding consolidated billing requirements for drugs and biologicals can be found in §10.F. of this chapter and in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1.

This list is used to enforce consolidated billing edits which ensure that payment is not made for renal dialysis drugs and biologicals outside of the ESRD PPS. **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.

NOTE: 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 is furnished for reasons other than for the treatment of ESRD. The ESRD facility must indicate the appropriate ICD diagnosis code for which the vancomycin is indicated.

NOTE: 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 is furnished for reasons other than for the treatment of ESRD. The ESRD facility must indicate the appropriate ICD diagnosis code for which the daptomycin is indicated.

See Pub.100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1 for additional information.

A. 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, as discussed in section 20.3.1.

Drugs and biologicals always considered to be renal dialysis services are those used for access management, anemia management, bone and mineral metabolism management, and cellular management. ESRD facilities are responsible for furnishing these drugs directly or under arrangement. This includes any drug or biological that is furnished in the ESRD facility or taken by the patient outside of the ESRD facility.

Erythropoiesis stimulating agents (ESAs), such as epoetin alfa (EPOGEN®) and darbepoetin alfa (ARANESP®) when furnished to Medicare ESRD patients are always considered to be renal dialysis services and included in the ESRD PPS. Monthly dosages of these ESAs are subject to Medicare’s ESA claims monitoring policy. See Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.4.1 for more information on the ESA monitoring policy.

NOTE: ESA dose edits are applied prior to pricing so that ESAs are not overvalued in determining eligibility for outlier payments.

Functional Categories Included in the ESRD PPS Base Rate, Always Considered to be Renal Dialysis Services, and Not Separately Payable

Category	Rationale for Association
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.

Anemia Management	Drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes ESAs as well as iron.
Bone and Mineral Metabolism	Drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.
Cellular Management	Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

Drugs and biologicals included in the ESRD PPS base rate that may be used for both the treatment of ESRD and for reasons other than the treatment of ESRD are those used as antiemetics, anti-infectives, antipruritics, anxiolytics, excess fluid management, fluid and electrolyte management including volume expanders, and pain management. ESRD facilities are responsible for furnishing these drugs directly or under arrangement when they are prescribed for the treatment of ESRD. This includes any drug or biological that is furnished in the ESRD facility or taken by the patient outside of the ESRD facility.

ESRD facilities are responsible for furnishing antibiotics for access site infections directly or under arrangement. When antibiotics are used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis, the antibiotics are included in the ESRD PPS and may not be paid separately. This includes antibiotics that may be added to a patient's dialysate solution for the purposes of vascular access-related and peritonitis infections.

Any other drugs (other than those categories described above and below) when used for the treatment of ESRD are also included in the ESRD PPS. For example,

- Patient A experiences nausea or pain during a hemodialysis dialysis treatment and requires medications. Any medication furnished during the dialysis treatment or after the treatment is considered a renal dialysis service and may not be billed separately.
- Patient B experiences anxiety with dialysis treatments and is prescribed anti-anxiety medication during and between the dialysis treatments. Any medications furnished in preparation for the dialysis treatment, during the dialysis treatment or after the dialysis treatment, is considered a renal dialysis service and may not be billed separately.
- Any drug or biological added to patient dialysate solutions.

Functional Categories Included in the ESRD Base Rate but May be Used for Dialysis and Non-Dialysis Purposes

Category	Rationale for Association
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Antiemetic	Used to prevent or treat nausea and vomiting related to dialysis. Excludes antiemetics used for purposes unrelated to dialysis, such as those used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Used to treat vascular access-related and peritonitis infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs in this classification have multiple clinical indications. Use within an ESRD functional category includes treatment for itching related to dialysis.
Anxiolytic	Drugs in this classification have multiple actions. Use within an ESRD functional category includes treatment of restless leg syndrome related to dialysis.
Excess Fluid Management	Drug/fluids used to treat fluid excess/overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs used to treat vascular access site pain and to treat pain medication overdose, when the overdose is related to medication provided to treat vascular access site pain.

B. Injectable Drugs and Biologicals

All injectable drugs or biologicals used for the treatment of ESRD are included in the ESRD PPS and are not separately paid. This includes renal dialysis drugs and biologicals that prior to the implementation of the ESRD PPS were separately billable under Part B. During the transition period, ESRD facilities receiving a blended payment were permitted to receive a separate payment for these drugs and biologicals under the composite rate portion of the blend during the transition. Since January 1, 2014, all facilities are paid 100 percent under the ESRD PPS and no separate payment is permitted for drugs and biologicals used for the treatment of ESRD. For more information on the transition, see §70 of this chapter.

Injectable drugs and biologicals furnished to Medicare ESRD patients that are not used for the treatment of ESRD may continue to be paid separately, when reported on the claim with an AY modifier. See §20.4.C of this chapter for more information on the AY modifier.

NOTE: ESRD patients should not be sent to other settings for the purpose of receiving separate payment for renal dialysis injectable drugs and biologicals or for the purpose of not assuming financial responsibility for renal dialysis items and services.

ESRD facilities must report the appropriate Healthcare Common Procedure Coding System (HCPCS) codes used for the administration and furnishing of renal dialysis drugs

and biologicals. This includes drugs and biologicals that are furnished in the beneficiary's home. 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 required for a drug to be given.

See Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1 for billing procedures. These supplies are eligible for payment as outlier services in accordance with §60.D of this chapter.

C. Oral or Other Forms of Injectable Drugs and Biologicals

The ESRD PPS includes certain drugs and biologicals that were previously paid under Part D. Oral or other forms of injectable renal dialysis drugs and biologicals, for example, Vitamin D analogs, Levocarnitine, antibiotics or any other oral or other form of injectable drug or biological furnished as renal dialysis services are also included in the ESRD PPS and may not be separately paid.

The ESRD facility should report any drug or biological furnished on the ESRD claim with the line item date of service and the quantity of the drug or biological furnished at the time of the visit. For claims processing instructions see Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.2.

For oral or other forms of renal dialysis drugs that are filled at the pharmacy for home use, ESRD facilities should report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period.

Example: A prescription for oral vitamin D was ordered for one pill to be taken 3 times daily for a period of 45 days. The patient began taking the medication on April 15, 2011. On the April claim, the ESRD facility would report the appropriate National Drug Code (NDC) code for the drug with the quantity 45 (15 days x 3 pills per day). The remaining pills which would be taken in May would appear on the May claim for a quantity of 90 (30 days x 3 pills per day). Prescriptions for a 3 month supply of the drug would never be reported on a single claim. Only the amount expected to be taken during the month would be reported on that month's claim.

Oral and other forms of injectable renal dialysis drugs are eligible for consideration as outlier services. See the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services.html for a list of these drugs. CMS prices these drugs using national average drug prices based on the Medicare Prescription Drug Plan Finder. Payment also includes a mean dispensing fee that is applied to each

NDC included on the monthly claim, in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.2.

Payments for oral or other forms of renal dialysis injectable drugs or biologicals are included in the ESRD PPS and are only made to the ESRD facility. ESRD facilities should report all oral or other forms of renal dialysis injectable drugs and biologicals furnished to their patients on the claim.

D. Oral-Only Renal Dialysis Service Drugs and Biologicals

Oral-only forms of renal dialysis drugs and biologicals that have no other form of administration will be included in the ESRD PPS as a Part B renal dialysis service.

NOTE: Implementation of renal dialysis oral-only drugs has been delayed until January 1, 2025.

E. 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 Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.2.1.1 for more information.

F. 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. All payment policies in effect for drugs and biologicals prior to the implementation of the ESRD PPS remained after implementation unless otherwise noted.

Drugs that were 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 is comprised of 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. For more information regarding the outlier policy see §60.D of this chapter.

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. Refer to 42 CFR §413.237 (a)(1)(i) for more information.

G. 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 A/B MAC's (A) medical staff. If the A/B MAC (A) determined 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 Pub. 100-04, chapter 8, §60.3.
- Immunizations may be separately billed when furnished by an ESRD facility to a Medicare ESRD Beneficiary. For further detail, see Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §60.6.

H. Drug Overfill Policy

Medicare does not pay for additional medications in drug containers provided at no cost to the ESRD facility. ESRD facilities may not receive additional payment under the ESRD PPS when they furnish drug overfill medications to Medicare beneficiaries. Drug overfill amounts are not eligible for outlier payments. In addition, ESRD facilities may not receive separate payment under the composite rate portion of the blended payment under the transition.

20.3.1 – Drug Designation Process

(Rev. 224, Issued: 06-03-16, Effective: 01-01-16, Implementation: 09-06-16)

A. Definition of a New Injectable or Intravenous Product

A new injectable or intravenous product is an injectable or intravenous product that is approved by the Food and Drug Administration (FDA) under section 505 of the Federal Food, Drug, and Cosmetic Act or section 351 of the Public Health Service Act, commercially available, assigned a Healthcare Common Procedure Coding System (HCPCS) code, and designated by CMS as a renal dialysis service.

B. Determination

To make the determination as to whether a product is a new injectable or intravenous drug or biological, whether the new injectable or intravenous drug or biological is a renal dialysis service, and whether the new injectable or intravenous drug or biological fits into an existing functional category CMS will:

- I.* Review the new product's FDA labeling data and information;

2. Review the new product's information presented for obtaining a HCPCS code; and
3. Conduct an internal medical review following the announcement of the new product's FDA and HCPCS decision.

If a new injectable or intravenous drug is used to treat or manage a condition for which there is an ESRD PPS functional category, the new drug would be considered included in the ESRD PPS bundled payment and no separate payment is available. If the new injectable or intravenous drug is used to treat or manage a condition for which there is not an ESRD PPS functional category, the following steps occur:

1. The new injectable or intravenous drug or biological would be paid for using a transitional drug add-on payment adjustment;
2. At the next rulemaking opportunity, CMS would add a new functional category applicable to the new injectable or intravenous drug or biological being used in the treatment of ESRD;
3. The new injectable or intravenous product would be added to the ESRD PPS bundled payment following payment of the transitional drug add-on payment adjustment.

C. Transitional Drug Add-On Payment Adjustment

If the new injectable or intravenous drug or biological is used to treat or manage a condition for which there is not an ESRD PPS functional category, CMS will pay for the drug or biological using a transitional drug add-on payment adjustment. The transitional drug add-on payment is based on payment methodologies under section 1847A and would continue for a period of 2 years.

During the time that injectable or intravenous drugs and biologicals are paid the transitional drug add-on payment adjustment, the drug or biological is not considered an outlier service.

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

An oral-only renal dialysis service drug or biological is 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 is no longer considered oral-only when a non-oral version of the oral-only drug or biological is approved by the FDA.

20.4 - Equipment and Supplies

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

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 as of January 1, 2011. The equipment and supplies include but are not limited to

- Equipment and supplies included under the composite rate (see §20.1 of this chapter) as of December 31, 2010,
- Equipment and supplies that were billed by ESRD facilities and paid separately by Medicare, and
- Equipment and supplies furnished to home patients that were under Method II prior to January 1, 2011, and billed by Durable Medical Equipment (DME) suppliers and paid separately by Medicare.

ESRD facilities and monthly capitation payment practitioners 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 or under the blended payment during the ESRD PPS transition.

ESRD facilities may not receive payment for renal dialysis equipment and supplies from ESRD beneficiaries.

A. 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 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. Medicare does not cover maintenance contracts on equipment, since Medicare pays only for costs that are actually incurred. The delivery and installation charge should be itemized, either on the face of the bill or an attached invoice.

b. Other Requirements for Coverage of Home Dialysis Equipment

Effective for renal dialysis services provided on or after January 1, 2011, 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).

Home dialysis equipment must also meet the requirements outlined in Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, §110.

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 (this does not include automatic blood pressure monitoring devices such as those mentioned in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 3), are included in the ESRD PPS, regardless of whether provided separately or as part of a start-up kit.

B. 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 found in §20.4.C of this chapter.

C. Equipment and Supplies Used for Reasons Other Than for the Treatment of ESRD

1. ESRD Facilities

Occasionally ESRD facilities furnish items and services that are not used for the treatment of ESRD. When this occurs, 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. 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.

For additional information regarding billing procedures for ESRD facilities that are transitioning into the ESRD PPS and that are furnishing drugs and biologicals for reasons other than for the treatment of ESRD, see Pub. 100-04, chapter 8, §60.2.1.

2. Other Providers

There are renal dialysis equipment and supplies that may also be used in other provider settings for reasons other than for the treatment of ESRD. These equipment and supplies can be found in the document titled “Items and Services Subject to Consolidated Billing

for the ESRD PPS” located at the ESRD Payment website:
http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html. To allow DME suppliers to receive payment for furnishing these services to other provider types, the DME suppliers can bill the DME MAC for the supplies included on this list with the AY modifier to indicate that the equipment is used for reasons other than for the treatment of ESRD.

There are renal dialysis equipment and supplies that are not used in other provider settings. These equipment and supplies are also listed in the document titled “Items and Services Subject to Consolidated Billing for the ESRD PPS.” These supplies and equipment are not otherwise covered by Medicare; therefore DME suppliers are not able to bill any of the supplies on this list using the AY modifier.

30 - Home Dialysis

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

For home dialysis services furnished prior to January 1, 2011, a beneficiary selected one of two methods to secure home dialysis items and services. Method I was when the ESRD facility with which the patient is associated assumes total responsibility for furnishing all home dialysis items or services. The second was Method II, which was when the beneficiary dealt directly with a single dialysis supplier to secure home dialysis items and services. Beginning January 1, 2011, Method II is no longer an option for home dialysis under Medicare. Therefore, all home dialysis patients are under Method I. For more information on Method II, see §10.E of this chapter.

30.1 - Home Dialysis Items and Services

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

Effective January 1, 2011, payment for renal dialysis services furnished for home dialysis are covered under the ESRD PPS and are not separately paid. ESRD facilities shall not bill Medicare beneficiaries directly when they furnish renal dialysis items and services included under the ESRD PPS. 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.

All renal dialysis items and services described in this section were included under the composite rate and are included under the ESRD PPS. Therefore these items and services must be furnished by the ESRD facility, either directly or under arrangement. 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 §20.4.A of this chapter);
- Home dialysis support services (see below), 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.

For additional information regarding conditions for coverage for home dialysis services, refer to 42 CFR §494.

A. 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. ESRD support services must be furnished periodically. These services will usually be furnished during a periodic follow-up visit, but they may be furnished at separate times. They may be furnished in the ESRD facility or in the home.

NOTE: For additional information on renal dialysis services furnished on or after January 1, 2011, and paid under the ESRD PPS, refer to §20 of this chapter.

B. 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.

C. 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.

If an entity wishes to bill Medicare for a non-covered renal dialysis service they provide to Medicare beneficiaries, they must first enroll with the appropriate Medicare contractor (assuming that Medicare recognizes such type of provider/supplier for billing purposes).

Providers/suppliers must enroll in the jurisdiction(s) where they intend to provide services and follow the jurisdiction rules specified in Pub. 100-04, chapter 1, §10.

Once the ESRD facility is enrolled with the appropriate Medicare contractor(s), they should work with the contractor(s) to determine the appropriate code to bill for the service, if any. Finally, entities enrolled in Medicare as Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) suppliers may not bill the DME MACs for professional or quasi-professional services, including but not limited to nurse caregiver staff-assistance services. Instead, if a DMEPOS supplier is permitted under State law to furnish such services under its licensure and wishes to bill Medicare for such services, it must enroll with the appropriate Medicare contractor under such professional or quasi-professional service category as Medicare may recognize for Medicare billing purposes, if any.

For additional information, contact your appropriate Medicare contractor.

30.2 - Home Dialysis Training

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

Self-dialysis and home dialysis training 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. Dialysis training services are reimbursed in accordance with Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

Home dialysis training services and supplies may include but are not limited to personnel services; dialysis supplies, parenteral items used in dialysis, written training manuals and materials, and renal dialysis laboratory tests. For more information on the requirements for ESRD facilities, see 42 CFR Part 494.

An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training and 15 sessions for CCPD and CAPD. For information on how home dialysis training treatments are paid, see §60.C of this chapter.

NOTE: ESRD facilities that are certified for home dialysis training and support services are expected to provide training throughout the home dialysis experience. Information regarding home dialysis training certification may be found at the following link: <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>.

A. Hemodialysis Training

The average training time for hemodialysis patients is based upon 5-hour sessions given 3 times per week. In some dialysis programs, the dialysis partner is trained to perform the dialysis treatment in its entirety. The patient plays a secondary role. In other programs, the patient performs most of the treatment and is only aided by a helper.

B. Intermittent Peritoneal Dialysis Training (IPD)

The IPD patients can be trained in approximately 4 weeks. IPD is usually accomplished in sessions of 10-12 hours. It is sometimes accomplished in fewer sessions of longer duration. In the IPD program, the patient's partner is usually trained to carry out the dialytic care. The patient plays a secondary or minimal role, as most are unable to perform self-care dialysis. IPD patients are usually unable to perform self-care dialysis because of other debilitating conditions.

C. Continuous Ambulatory Peritoneal Dialysis (CAPD) Training

The CAPD training is furnished in sessions that can last up to 8 hours (one session per day) 5 - 6 days per week. Typically, 6 - 8 CAPD exchanges can be performed per day for the purpose of teaching the patient the CAPD technique; however, no specific number of exchanges is required. Normally patients are trained within 2 weeks (5 - 6 training sessions per week); however, up to 15 sessions (i.e., 15 training days) may be covered routinely. Additional CAPD training sessions are covered only when documented for medical necessity. Extra training sessions raise questions about either the adequacy of CAPD for the patient or the patient's capacity to learn or perform the CAPD technique. The patient's physician should address these questions in the explanation of the need for extra training sessions. The A/B MAC (A) will make a determination whether or not to permit training sessions in excess of 15.

Once the patient is trained, CAPD is primarily a home service because the patient performs CAPD 24 hours a day. Therefore, renal dialysis services that are specifically CAPD services are training services and include associated services that are furnished in the ESRD facility during training. Persons who are primarily treated by CAPD may also require in-facility dialysis, either intermittent peritoneal or hemodialysis, occasionally.

Prior to the implementation of the ESRD PPS, there were specific frequency coverage requirements of the routine laboratory services furnished for CAPD. The CAPD laboratory tests that were included under the composite rate are those monthly tests listed in (§20.2.E.1.b of this chapter) and they are covered during training. The coverage frequency screens for these laboratory tests did not apply during training, as these tests were commonly given during each training session. All of these tests were included in the training screen, regardless of how frequently they were given, and may have been billed separately. Under the composite rate, separately billable laboratory tests must have been documented for medical necessity. However, under the ESRD PPS all renal dialysis laboratory services are included in the bundle regardless of the frequency they are furnished.

Supplemental Dialysis during CAPD Training

It may be necessary to supplement the patient's dialysis during CAPD training with intermittent peritoneal dialysis because the patient has not yet mastered the CAPD technique. Generally, no more than three supplemental intermittent peritoneal dialysis sessions are required during the course of CAPD training, and these may be covered routinely. If more than three sessions are billed during training, the claims must be documented for medical necessity. Under certain circumstances, the form of supplemental dialysis may be hemodialysis.

D. Continuous Cycling Peritoneal Dialysis (CCPD) Training

Continuous cycling peritoneal dialysis training is furnished in sessions of 8 hours per day 5 days per week. Typically, five exchanges can be performed per day to teach the patient the technique; however, no specific number of exchanges is required. Most patients are trained within 2 weeks; however, up to 15 sessions may be covered routinely. The A/B MAC (A) will determine whether or not training sessions over 15 are medically necessary.

E. Retraining

Payment is 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. The ESRD facility may not bill for retraining services when they install home dialysis equipment or furnish monitoring services. For example, an ESRD facility nurse may not bill for retraining sessions to update treatment records, order new supplies, or add additional medicine for the treatment of infection.

NOTE: When retraining and educational services are furnished to a patient or caregiver already knowledgeable in some other form of self-dialysis or if training is being done for a change of equipment, fewer sessions are necessary because of the transferability of certain basic skills.

Criteria for retraining are explained in greater detail in Pub. 100-04, Medicare Claims Processing Manual, chapter 8, §50.8.

40 - Other Services

(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)

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

A. 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 beneficiary, entitled to Medicare under the ESRD program, is eligible for home health benefits as is any other Medicare beneficiary 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.

Medicare patients can receive care under both the ESRD benefit and the home health benefit. The key is whether or not the services are being furnished for the treatment of the patient's ESRD. 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. See 42 CFR 409.49(e).

B. Coverage under the Hospice Benefit

If the patient's terminal condition is not related to ESRD, the patient may receive covered services under both the ESRD benefit and the hospice benefit. Hospice agencies can provide hospice services to patients who wish to continue dialysis treatment.

C. Skilled Nursing Facility (SNF) Patients Needing Dialysis Services

Section 4432(b) of the Balanced Budget Act (BBA) requires consolidated billing for SNFs. 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. For more information regarding ESRD patients also receiving services in a SNF, see Pub. 100-02, chapter 8, §10.2 and Pub. 100-04, chapter 6, §20.2.1.

D. Nursing Homes and/or Long Term Care Facility (LTC) Patients Needing Dialysis Services

Medicare ESRD beneficiaries who permanently reside in a nursing home or LTC facilities and who meet the home dialysis requirements set forth under 42 CFR §494.100 are considered home dialysis patients. All home dialysis items and services will be paid under the ESRD PPS and no separate payment will be made to the facility.

E. Physician's Services for ESRD Beneficiaries

Physician services are excluded from the ESRD PPS. Payment for physician's services is subject to the guidelines in Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15,

§30. Medicare pays physician's services furnished in connection with dialysis sessions for outpatients who are on maintenance dialysis in an ESRD facility or at home by the monthly capitation payment method or the initial method. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 8, for payment instructions. For physician responsibilities, refer to 42 CFR §414.310.

F. The Sudden Onset of Acute Symptoms During Renal Dialysis Services

Renal dialysis services furnished in other settings, such as declotting of shunts, suture removal, or furnishing renal dialysis drugs may be paid separately only if the services could not have been furnished in the ESRD facility.

Emergency renal dialysis services furnished in a hospital emergency room are separately paid when medical justification is submitted on the claim and when the absence of immediate medical attention 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.

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

H. 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. If an ESRD facility or a renal physician decides to monitor the patient's access site with a non-invasive vascular study and does not have the

equipment to perform the procedure, the ESRD facility or physician may arrange for the service to be furnished by another source. The alternative source, such as an independent diagnostic testing facility must look to the ESRD facility for payment.

Procedures associated with monitoring access may include activities such as, but not limited to, taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are included under the ESRD PPS. Non-invasive vascular studies such as duplex and Doppler flow scans are not covered as separately billable services if used to monitor a patient's vascular access site.

Doppler flow studies may be considered appropriate in the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining the clinical course of the treatment for the patient. Routine monitoring by noninvasive Doppler flow studies is included under the ESRD PPS.

Examples supporting the medical necessity for Doppler flow studies include:

- Elevated dynamic venous pressure >200mm HG when measured during dialysis with the blood pump set on a 200cc/min.,
- Access recirculation of 12 percent or greater,
- An otherwise unexplained urea reduction ratio <60 percent, and
- An access with a palpable "water hammer" pulse on examination, (which implies venous outflow obstruction).

Unless the documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both. An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates:

- Reduced flow (blood flow rate less than 800cc/min or
- A decreased flow of 25 percent or greater from previous study) and
- The physician requires an arteriogram to define the problem.

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

The professional component of the procedure is included in the MCP. The professional component is denied if billed by the MCP physician. Medically necessary services that are included or bundled into the MCP (e.g., test interpretations) are separately payable when furnished by physicians other than the MCP physician. The MCP physician is

identified by the performing provider number that billed MCP services identified by the HCPCS code 90995.

I. Nutritional Services

ESRD facilities are required, in accordance with 42 CFR §494.80(a)(6) and §494.90(a)(2), 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.

**50 - ESRD Prospective Payment System (PPS) Base Rate
(Rev. 200, Issued: 12-02-14, Effective: 01-01-15, Implementation: 01-05-15)**

Updates to the provisions under the ESRD PPS are discussed through rulemaking on a yearly basis. The updates are implemented through Recurring Update Notifications.

A. Per Treatment Unit of Payment

Under the ESRD PPS payment is made on a per treatment basis. The ESRD PPS base rate is the per treatment unit of payment that 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. Payment for additional treatments may be considered when there is medical justification for more than 3 weekly treatments. For more information regarding home dialysis, see §30 of this chapter. 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.

Frequency of Dialysis Sessions by Dialysis Modality and Treatment Setting*

	In-Facility	Home
Hemodialysis	3 per week	Maximum of 3 per week regardless of frequency
Hemofiltration	3 per week	3 per week
Ultrafiltration	3 per week	Maximum of 3 per week, regardless of frequency
Peritoneal Dialysis (e.g., CAPD and CCPD)	HD-equivalent sessions	HD-equivalent sessions
Intermittent Peritoneal Dialysis (IPD)	3 per week	HD-equivalent sessions

* Regardless of dialysis modality or treatment setting, payments for additional treatments may be made when they are medically justified. The A/B MAC (A) reviews the medical

justification and is responsible for making the decision on the appropriateness of the extra treatment.

1. Hemodialysis: Payment Based on Standard of Three Treatments per Week

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 A/B MAC (A) and must be based upon an individual patient's need. The A/B MAC (A) reviews the medical justification for each additional treatment and is responsible for making the decision on the appropriateness of the extra treatment(s) and payments for these additional treatments.

2. Hemofiltration

Hemofiltration is an alternative to peritoneal dialysis and hemodialysis. Hemofiltration may be routinely performed either in an ESRD facility or at home in 3 weekly sessions. See §10.A.3 of this chapter.

3. Ultrafiltration

When ultrafiltration is performed the same day as the dialysis treatment; there is no separate payment. When ultrafiltration is performed on a day other than the day of a dialysis treatment, the ESRD facility must document in the medical record why the ultrafiltration could not have been performed at the time of the dialysis treatment. For the ESRD facility to be paid for the ultrafiltration, the ESRD facility must report the appropriate diagnosis code and the A/B MAC (A) must verify the medical justification to determine appropriate payment. If the A/B MAC (A) considers the medical justification appropriate, the ESRD facility will receive the ESRD PPS base rate. For more information regarding ultrafiltration, see Pub. 100-04, Chapter 8, §50.7.

4. Peritoneal Dialysis: Payment Based on Hemodialysis Equivalent Sessions

For home patients undergoing peritoneal dialysis (PD), the number of days of PD regardless of the number of dialysate exchanges performed each day, is converted to HD-equivalent sessions. This is accomplished by dividing the number of days of PD by 7, and multiplying the result by 3.

Example: Joe is a home CCPD patient who undergoes PD for 24 days. The number of HD-equivalent sessions is $24/7 \times 3$ or 10.28571. The number of HD-equivalent sessions or treatments for which case-mix adjusted prospective payments are applicable, is 10.28571.

Although CAPD and CCPD patients are home dialysis patients, occasionally it may be necessary to perform dialysis in-facility. The number of HD-equivalent sessions for PD performed in-facility is limited to 3 weekly, regardless of the number of days PD is

furnished in-facility. However, each day of in-facility PD is treated as one HD-equivalent session, up to a maximum of 3 per week.

Example: Mary is a home CCPD patient. After 21 days on CCPD in a month, Mary's cyclor required repair. Mary received CCPD in-center for 4 consecutive days before returning to home CCPD. The number of HD-equivalent sessions for which payments under the ESRD PPS may be made is 12, determined as follows:

Home CCPD HD-equivalent sessions	$21/7 \times 3 = 9$
In-center PD HD-equivalent sessions (limited to 3)	3
Total HD-equivalent sessions	12

Mary's ESRD facility would receive the case-mix adjusted ESRD PPS base rate for 12 treatments in the month.

5. Intermittent Peritoneal Dialysis (IPD)

Maintenance Intermittent Peritoneal Dialysis (IPD) is usually accomplished in sessions of 10 to 12 hours in duration. Sometimes it is accomplished in fewer weekly sessions of longer duration. The payment applicable for maintenance IPD, as well as the ESRD facility's actual payment for maintenance IPD, depends on the treatment setting (in-facility or at home). Payment for in-facility IPD follows the same payment rules as hemodialysis, i.e., 3 sessions per week (see Pub. 100-04, chapter 8, §50.5 and §50.6.2). Payment for home IPD is based on a weekly equivalence of 3 sessions per week (see Pub. 100-04, chapter 8, §80.3, §80.3.1, and §80.4). If additional dialysis beyond the usual weekly maintenance dialysis is required because of special circumstances, the ESRD facility's claim for these extra services must be accompanied by a medical justification for payment to be made.

6. Uncompleted Dialysis Treatments under the ESRD PPS

If a dialysis treatment is started, (i.e., a patient is connected to the machine and a dialyzer and blood lines are used), 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. See Pub.100-04, chapter 4, section 200.2 for additional information.

B. Market Basket

For renal dialysis services furnished on or after January 1, 2011 and before January 1, 2012, CMS adjusts the composite rate portion of the basic case-mix adjusted composite payment system described in 42 CFR 413.220 by the ESRD bundled market basket percentage increase factor. For renal dialysis services furnished on or after January 1, 2012, CMS updates on an annual basis, the ESRD PPS base rate and the composite rate portion of the basic case-mix adjusted composite payment described in 42 CFR 413.220 by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor. Effective for renal dialysis services furnished on or after January 1, 2014, there is no longer a transition, therefore only the ESRD PPS base rate would be updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment factor.

60 - ESRD PPS Case-Mix Adjustments

(Rev. 224, Issued: 06-03-16, Effective: 01-01-16, Implementation: 09-06-16)

The ESRD PPS includes patient-level adjustments (also known as the case-mix adjustments), facility-level adjustments, and training adjustments, as well as an outlier payment. Under the ESRD PPS, the beneficiary co-insurance amount is 20 percent of the total ESRD PPS payment, after the deductible (see §60.E of this chapter).

A. 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 (see §60.A.6 of this chapter), 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.

1. Adult case-mix adjusters

This section presents a list of the ESRD PPS case-mix adjusters for adults and provides several examples using the adult case-mix adjusters implemented in CY 2011 and refined in CY 2016. Any revisions to the case-mix adjusters will be published in subsequent rulemaking.

<u>Adult Patient-Level Characteristics</u>	<u>Adjustment Value</u>	
	CY 2011-2015	Beginning CY 2016
Age: 18-44	1.171	1.257

Age: 45-59	1.013	1.068
Age: 60-69	1.000	1.070
Age: 70-79	1.011	1.000
Age: 80+	1.016	1.109
Body Surface Area	1.020	1.032
Low Body Mass Index (BMI <18.5)	1.025	1.017
Onset of Dialysis	1.510	1.327
Pericarditis	1.114	1.040
Bacterial pneumonia	1.135	---
Gastro-intestinal tract bleeding	1.183	1.082
Hereditary hemolytic or sickle cell anemia	1.072	1.192
Myelodysplastic syndrome	1.099	1.095
Monoclonal gammopathy	1.024	---

Calculating the ESRD PPS Adjusted Payment

The following example demonstrates the calculation of the ESRD PPS payment in an urban area with a wage index of 1.10. Before giving the particulars of the dialysis patient for the example, shown first is how to calculate the labor-adjusted base rate, which is the starting point for the computation of the case-mix adjusted base rate.

- Base rate: \$230.39
- Labor-related share of base rate: $\$230.39 * 0.50673 = \116.75
- Wage index adjusted labor-related share: $\$116.75 * 1.1000 = \128.42
- Non labor-related share of base rate: $\$230.39 * (1 - .50673) = \113.64
- Wage index adjusted base rate: $\$128.42 + \$113.64 = \$242.06$

Provided next is the continuation of the example with the inclusion of the patient characteristics portion of the payment.

A 45 year old male Medicare beneficiary is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. He receives dialysis in an ESRD facility on January 1, 2016.

Using the formula for BMI, note that the patient is not underweight, having a BMI of 26.89 kg/m², which is greater than the threshold value of 18.5 kg/m².

$$\begin{aligned}\text{BMI}_{\text{Patient}} &= \text{weight}_{\text{kg}} / \text{height (m}^2\text{)} \\ &= 95 / 1.8796^2 \\ &= 95 / 3.5329 \\ &= 26.89\end{aligned}$$

The formula for calculation of a patient's BSA is:

- 0.007184 multiplied by height in meters^{0.725} multiplied by weight in kg.^{0.425}
- or BSA = 0.007184 * height_{cm}^{.725} * weight_{kg}^{.425}.

The BSA for the patient in this example is calculated as:

$$\begin{aligned}\text{BSA}_{\text{Patient}} &= 0.007184 * 187.96^{.725} * 95^{.425} \\ &= 0.007184 * 44.5346 * 6.9268 \\ &= 2.2161\end{aligned}$$

Using the adult case-mix adjusters table shown above, the BSA multiplier of 1.032 is used. The patient's case-mix adjustment or payment multiplier (PM) based on his BSA of 2.2161 is computed as follows:

$$\begin{aligned}\text{PM}_{\text{BSA}} &= 1.032^{(2.2161-1.90)/0.1} \\ &= 1.032^{3.161} \\ &= 1.1047\end{aligned}$$

The example patient's PM would reflect the applicable case-mix adjustments from the adult case-mix adjusters table above for both age and BSA and may be expressed as:

$$\begin{aligned}\text{PM}_{\text{Patient}} &= \text{PM}_{\text{age}} * \text{PM}_{\text{BSA}} \\ &= 1.068 * 1.1047 \\ &= 1.1798\end{aligned}$$

The example patient's ESRD payment rate for treatments furnished in his ESRD facility would be:

$$\$242.06 * 1.1798 = \$285.58$$

NOTE: This example is computed without regard to other adjustments (e.g., outlier payments, training add-on, low-volume adjustment, etc.).

2. 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

beneficiary 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. The examples shown below draw on values from the table of the CY 2016 adult case-mix adjusters as well as the discussion of the wage adjusted ESRD PPS base rate found in the section above.

- Example 1: Mr. Taylor is 38 years of age and is classified in the 18-44 age group with an associated case-mix adjuster of 1.257. Applying the case-mix adjuster of 1.257 to the wage index adjusted base rate of \$242.06 yields the age adjusted base rate amount of \$304.27 ($\$242.06 \times 1.257 = \304.27).
- Example 2: Mrs. Williams was born on July 4, 1936. On June 15, 2016, she is 79 years old and is classified in the 70-79 age category with a case-mix adjustment of 1.000 (the reference group). However, beginning with dialysis treatments occurring on and after July 1, 2016, she will move into the 80+ age group with an associated case-mix multiplier of 1.109.
- Example 3: Mr. Davis was born on September 29, 1971. For dialysis treatments occurring in August 2016, he is 44 years old and would be classified in the 18-44 age group with an associated case-mix adjuster of 1.257. Beginning with dialysis treatments occurring on and after September 1, 2016, he is classified in the 45-59 age category with a case-mix adjuster of 1.068 because he is considered to have attained age 45 on September 1.

3. Body Size: 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.

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/m^2 . As an example, the designated low BMI adjustment factor of 1.017 (see §60.A.1 of this chapter) is only applied for those beneficiaries with a BMI value that is less than 18.5kg/m^2 which is a clinical measure of being underweight and an indicator of malnutrition.

The formula for the calculation of the BSA is $\text{BSA} = w^{0.425} * h^{0.725} * 0.007184$ 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 $1.032^{(\text{BSA}-1.90)/0.1}$. The reference BSA used to calculate the BSA is the national average among Medicare dialysis patients.

4. 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. For example, when a dialysis patient is not eligible for the Medicare ESRD benefit 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.

5. Comorbidity Categories

The two acute comorbidity categories are pericarditis and gastro-intestinal tract bleeding with hemorrhage. The two chronic comorbidity categories are myelodysplastic syndrome and hereditary hemolytic anemia (including sickle cell anemia). The related comorbidity

diagnosis codes can be found at the CMS ESRD Payment Web site located at http://www.cms.gov/ESRDPayment/40_Comorbidities_Conditions.asp#TopOfPage.

NOTE: Prior to the refinement of the ESRD PPS, effective January 1, 2016, the ESRD PPS included payment adjustments for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy.

The ESRD facility is responsible for obtaining documentation of the presence of an acute or chronic comorbidity. If an ESRD facility is unaware of the existence of a comorbidity because it does not impact the facility's costs, then the ESRD facility should not expect to receive a comorbidity adjustment. The comorbidity payment adjustment is only applied if the appropriate diagnosis code, specified under one of the categories above, is identified on the ESRD claim. Comorbidities other than the two acute and the two chronic conditions identified above do not qualify for a comorbidity adjustment. Even if an ESRD patient has or has had one of the four conditions that would qualify for a comorbidity payment adjustment, the condition must be currently active and have an effect on the cost of care for the ESRD facility to be eligible to receive the adjustment.

To qualify for the comorbidity adjustment there must be:

- Clear documentation in the beneficiary's medical record, and
- Adherence to diagnosis coding requirements.

Diagnosis codes are updated annually as stated in Pub. 100-04, chapter 23, section 10.2 and are published in the Federal Register in April/May of each year as part of the Proposed Changes to the Hospital Inpatient Prospective Payment Systems and are effective each October.

For transfer patients, it is expected that ESRD facilities will work together on the appropriate transfer of information to facilitate appropriate billing for dialysis services. The counting of treatments for an acute comorbidity adjustment is based on the patient and not on the ESRD facility. Therefore, counting does not restart when a beneficiary moves to a new ESRD facility, but rather continues for the remaining 4 months.

a. Duration of Acute Comorbidity Adjustment

Payment for an acute comorbidity adjustment begins in the month in which the diagnosis is established, and lasts for the next 3 consecutive patient months. A patient month is any month in which a dialysis treatment is furnished, and an acute comorbidity applies.

The acute diagnosis comorbidity adjustment is applied to each dialysis treatment for 4 patient months. If a second comorbidity is diagnosed during that period (either acute or chronic), then the adjustment is made using the higher adjustment factor. At no time is an adjustment applied for more than one comorbidity.

When there is a recurrence of an acute comorbidity within the 4 patient month period, there will not be an extension of the 4 patient month adjustment. A recurrence is defined as a new episode of a comorbidity that was previously experienced by an individual beneficiary. However, if the recurrence happens after the completion of the 4 month period, then a new comorbidity adjustment for 4 months would start.

- Example – A male patient has been receiving hemodialysis since January 2010. He had a 2-week hospitalization due to a fracture in mid-January 2016. During his stay in the hospital, he was diagnosed with gastro-intestinal tract bleeding with hemorrhage on January 20, 2016. He resumed his outpatient maintenance dialysis on January 29, 2016. The 4 patient months in which the patient’s ESRD facility would be eligible to have the comorbidity adjustment applied to each dialysis treatment are January through April 2016.

Acute Comorbidity Eligibility Criteria

In order to receive the comorbidity payment adjustment, validation of the existence of the comorbidity should be established and the comorbidity should have an effect on the cost of the dialysis treatment. The following guidelines are to be used:

- Pericarditis - At least two of the four following criteria must be met: atypical chest pain; pericardial friction rub; suggestive electrocardiogram changes (e.g., widespread ST segment elevation with reciprocal ST segment depressions and PR depressions) not previously reported; and new or worsening pericardial effusion.
- Gastro-intestinal tract bleeding with hemorrhage - At least one of the following objective criteria must be met: endoscopy, colonoscopy, radionuclide scanning, radionuclide imaging, and/or angiography. Absence of bleeding such as bleeding hemorrhoids without objective diagnosis of hemorrhaging would not meet the diagnosis criteria.

b. Duration of Chronic Comorbidity Adjustment

The chronic diagnosis comorbidity adjustment is applicable only when the comorbidity has an effect on the cost of dialysis care and when that chronic diagnosis comorbidity appears on the claim. The adjustment does not automatically continue each month. When an acute diagnosis comorbidity with a higher adjustment value is applicable at the same time a chronic comorbidity applies, then the higher adjustment will be applied for 4 patient months, and then revert to the lower chronic comorbidity payment adjustment factor.

c. Chronic Comorbidity Eligibility Criteria

In order to receive the comorbidity payment adjustment, validation of the existence of the comorbidity should be established and the comorbidity should have an effect on

the cost of the dialysis treatment. Testing patients for the presence of a chronic comorbidity in absence of medical necessity for the purpose of receiving a payment adjustment is not appropriate. The following guidelines are to be used:

- Myelodysplastic Syndrome – Evidence of dysplasia in >10% of cells with at least one cell lineage on bone marrow aspiration and biopsy.
- Hereditary hemolytic anemia (including sickle cell anemia) - One or more of the following must be present: an abnormal peripheral smear; evidence of increased serum lactate dehydrogenase with a decrease in haptoglobin; an abnormal absolute reticulocyte count response or an abnormal reticulocyte production index. For sickle cell anemia specifically, an abnormal electrophoresis test as a definitive test, but the hemolytic criteria could be used.

6. 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 (PD or HD).

The pediatric case-mix adjusters, applicable for CY 2011, are shown below. These values are presented for the purpose of demonstrating the computations shown in the examples in the following sections. Any revisions to the case-mix adjusters will be published in subsequent rulemaking.

Based on the two classification categories for age and modality, there are four pediatric classification groups.

<u>Pediatric Patient-Level Characteristics</u>	<u>Adjustment Value</u>	
	CY 2011-2015	Beginning CY 2016
Age: <13, Modality: PD	1.033	1.063
Age:<13, Modality: Hemo	1.219	1.306
Age:13-17, Modality: PD	1.067	1.102
Age:13-17, Modality: Hemo	1.277	1.327

ESRD facilities do not receive the low-volume adjustment, described in §60.B.1, or the rural adjustment, described in §60.B.3, for pediatric beneficiaries. However, they are eligible for training add-on and outlier payments (described in §60.C and §60.D, of this chapter respectively).

The following example demonstrates the calculation of the payment rate for a pediatric patient who receives dialysis at an ESRD facility and is located in an urban area with a wage index of 1.10. The example also shows the application of the training add-on for eligible training treatments. Before giving the particulars of the pediatric dialysis patient, shown first is the calculation of the labor-adjusted base rate of \$242.06, which is the starting point for the computation of the case-mix adjusted base rate.

- Base rate: \$230.39
- Labor-related share of base rate: $\$230.39 * 0.50673 = \116.75
- Wage index adjusted labor-related share: $\$116.75 * 1.1000 = \128.42
- Non labor-related share of base rate: $\$230.39 * (1 - 0.50673) = \113.64
- Wage index adjusted base rate: $\$128.42 + \$113.64 = \$242.06$

Provided next is the characteristics of the pediatric patient and continue with the example.

- Andrew, a 12 year old male, has been on CCPD since June 2010. His mother, who assists him with his dialysis at home, is no longer able to assist with dialysis beginning May 10, 2016. His aunt, who lives nearby, has agreed to be the caregiver and assist him with his dialysis. The aunt required 17 training sessions at an ESRD facility in order to become knowledgeable and skilled sufficiently to perform this role. These training sessions began May 16 and ended June 10. The above pediatric classification table reveals that Andrew's pediatric dialysis classification group is cell 1, with an associated patient multiplier of 1.063. During the months of May and June 2016, the ESRD payment rate per HD-equivalent treatment would be:

$$\$242.06 * 1.063 = \$257.31$$

- However, the ESRD facility is entitled to receive payment for a maximum of 15 training treatments furnished in connection with a new caregiver. Because the amount of the training add-on is adjusted by the ESRD facility's wage index (1.10), the amount of the training add-on is calculated as follows:

Training rate: \$50.16

Wage index: 1.10

$$\text{Training payment: } \$50.16 * 1.10 = \$55.18$$

- For the maximum number of 15 training treatments for which the training adjustment may be provided in connection with a PD patient, the payment rate, including the training add-on, would be:

$$(\$242.06 * 1.063 + \$55.18) = \$312.49$$

NOTE: This example is computed without regard to other adjustments (e.g., outlier payments.)

B. 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.

1. 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. For CY 2011 the payment adjustment was 18.9 percent, and beginning January 1, 2016, the payment adjustment is 23.9 percent.

a. Low-Volume Criteria

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.
 - The term "payment year" is the period of time that is used for determining payment to ESRD facilities, which is a calendar year. The ESRD PPS is based on a calendar year which begins January 1 of each year.
 - The eligibility years are defined as the 3 years preceding the payment year and are based on cost reporting periods. Specifically, the cost reporting periods that end in the 3 years immediately preceding the payment year. The cost reporting periods must report costs for 12 consecutive months.
 - 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. For example, a patient on PD for 21 days would have $(21/7) \times 3$ or 9 HD-equivalent treatments. See §50.A.4 of this chapter for more information on hemodialysis equivalent treatments.

- The ESRD facility must not have opened, closed, or received a new provider number due to a change in ownership, (see Pub. 100-07, chapter 3, §3210), in the 3 years preceding the payment year. As stated above, this 3 year period is based on the ESRD facility's as-filed or final settled 12-consecutive month cost reports that end in the 3 years immediately preceding the ESRD PPS payment year. An ESRD facility is determined to be "opened" when the ESRD facility is a new establishment newly surveyed by the state and Medicare, is certified for Medicare participation, receives a provider number, and begins furnishing Medicare certified outpatient maintenance dialysis treatments. If there is a change in ownership that does not result in a change in provider number but does cause a change in the fiscal year reporting to that of the new provider, the A/B MAC (A) should combine the reporting periods for determining eligibility to the LVPA.

For example, prior to a change of ownership (CHOW), Facility A had a cost reporting period that spanned January 1 through December 31. Facility A had a CHOW mid-year that did not result in a new provider transaction access number (PTAN) but caused a break in the cost reporting period. The A/B MAC (A) would add Facility A's cost report that spanned January 1 through May 31 to its cost report that spanned June 1 through December 31 to verify the total treatment count. The other situation that could occur is when a CHOW results in a change of the original fiscal period. For example, prior to a CHOW, Facility B had a cost reporting period that spanned January 1 through December 31 and, based on its cost reports for 2012 and 2013, it met the LVPA eligibility criteria. Then, Facility B had a CHOW in the beginning of 2014 that did not result in a new PTAN, but changed its cost reporting period to that of its new owner, October 1, 2014, through September 30, 2015. This scenario would create a short and a long cost report that would not total 12 months that the A/B MAC (A) would need to review for verification. That is, Facility B would have a cost report that spanned January 1, 2014, through July 31, 2014 (7 months) and a cost report that spanned August 1, 2014, through September 30, 2015 (14 months). In this situation, the A/B MAC (A) should combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period.

- 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.

For example, ESRD facility A received its Medicare certification on February 1, 2011, allowing them to bill and receive payment for outpatient maintenance

dialysis that they furnish to Medicare beneficiaries. ESRD facility A will need to meet the low-volume criteria for 3 years. When the ESRD facility A submits its attestation to the A/B MAC (A), the A/B MAC (A) will need to consider ESRD facility A's ownership and the ownership of all of the ESRD facilities located within a 5 road mile radius or less when determining total treatments. A/B MACs (A) shall use the Provider Enrollment, Chain, and Ownership System (PECOS) (or the most recent available Medicare enrollment system) to locate the ESRD facility's ownership information. A/B MACs (A) shall refer to 42 CFR §421.404(a) when determining common ownership.

Prior to January 1, 2016, ESRD facilities that were Medicare certified prior to January 1, 2011, were grandfathered into the geographic proximity criterion.

NOTE: The low-volume adjustment does not apply to dialysis treatments provided to pediatric patients.

b. 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). The attestation must state that the ESRD facility qualifies as a low-volume facility in accordance with 42 CFR §413.232 as described above. Specifically, the attestation states that the ESRD facility was low-volume for the first 2 eligibility years and that they will be for the third eligibility year, that is, the cost reporting period ending in the year that immediately precedes the payment year. In most cases, the A/B MACs (A) will not have received the third eligibility year's cost report and will rely on the attestation in order to allow the application of the adjustment. November 1st of each year is the mandatory deadline for the submission of attestations for ESRD facilities that believe they are eligible to receive the low-volume payment adjustment. However, for new or resubmitted attestations applicable to payment years 2011 to 2015, to allow A/B MACs (A) and facilities adequate time to review policy clarifications related to the low volume adjustment, the attestation deadline was extended to December 31, 2014. For attestations applicable to payment year 2016, the attestation deadline is extended to December 31, 2015, to allow A/B MACs (A) and facilities adequate time to review policy changes finalized in the CY 2016 ESRD PPS final rule. A/B MACs (A) have a maximum of 60 days to verify attestations for implementation of the low-volume adjustment beginning January 1 of the following payment year.

A/B MACs (A) shall notify the ESRD facilities no later than September 1 of each year that they need to submit the low-volume attestation no later than November 1st of each year in order to receive the adjustment the following payment year. A/B MACs (A) may not accept attestations submitted after the mandatory deadline. If an ESRD facility is receiving the low-volume payment adjustment and will qualify for the adjustment in the subsequent payment year they must submit another attestation. If

the ESRD facility does not submit an attestation, the A/B MAC (A) should no longer apply the low-volume payment adjustment beginning January 1st of the next payment year and the ESRD facility cannot receive the low-volume payment adjustment until the following payment year.

An ESRD facility should notify its A/B MAC if it determines that it did not maintain low-volume status for its cost reporting period ending immediately preceding the payment year or if it finds that it will not remain low-volume for any subsequent cost reporting year. The A/B MAC (A) is responsible to reconcile incorrect payments made to ESRD facilities retroactively, if needed, to ensure overpayments have not been made. If an A/B MAC (A) determines that an ESRD facility has received the low-volume adjustment in error, the A/B MAC (A) is required to adjust all of the ESRD facility's affected claims to remove the adjustment within 6 months of finding the error.

The A/B MAC (A) shall:

- Recoup low-volume adjustment payments made to an ESRD facility that failed to meet the low-volume adjustment criteria defined in 42 CFR §413.232(b)(1). Recoupment shall occur when the A/B MAC (A) receives the as-filed cost report for the third eligibility year and finds that the ESRD facility did not meet the eligibility criteria. Recoupment shall also occur if any cost reports used for eligibility are subsequently found to have not met the low-volume criteria, for example, reopening or appeals. A/B MACs (A) shall reprocess claims paid during the payment year in which the ESRD facility incorrectly received the low-volume payment adjustment.
- Recoup low-volume adjustment payments made to an ESRD facility that failed to meet the low-volume adjustment criteria defined in 42 CFR §413.232(b)(2). A/B MACs (A) shall use PECOS (or most recent Medicare enrollment system) to locate the ESRD facility's ownership information at the time of verification to determine if the ESRD facility is in the process of a CHOW. A/B MACs (A) shall use the current owner provided in PECOS. If the ESRD facility was in the process of a CHOW, recoupment shall occur when the CHOW is effective and the new owner is assigned a new provider number. A/B MACs (A) shall reprocess claims paid during the payment year in which the ESRD facility incorrectly received the low-volume payment adjustment.

If an ESRD facility does not remain low-volume for each of the 3 years (described above in §60.B.1.a) immediately preceding the payment year, the ESRD facility cannot be eligible for the adjustment until it can demonstrate again that for 3 years it has met the low-volume criteria.

Example - Provider 21-25XX is an independent ESRD facility that has a June 30th cost report year end.

The ESRD facility concluded in October 2010 that it met the criteria of a low-volume facility. For its cost reporting periods, 7/1/2007 – 6/30/2008, 7/1/2008 – 6/30/2009, and 7/1/2009 – 6/30/2010, it did not open, close, or have a change of ownership and furnished less than 4,000 dialysis treatments in each of those cost reporting periods. In October 2010, the ESRD facility sent its A/B MAC (A) an attestation stating that it believes that it meets the low-volume criteria and would like to begin to receive the low-volume adjustment. The A/B MAC (A) receives the attestation on November 1st and then has 60 days (that is, until December 30th) to verify if the ESRD facility qualifies as a low-volume facility. On December 28th the A/B MAC (A) was able to verify that provider 21-25XX met the criteria and allowed for the adjustment to be applied to each dialysis treatment the ESRD facility furnished beginning January 1, 2011.

Determining Low-Volume Eligibility in Hospitals with Multiple Subunits and Satellites

A hospital may be affiliated with multiple hospital-based ESRD facilities. In addition, an individual hospital-based ESRD facility may have several locations that are subsumed under it, billing under the same ESRD facility provider number.

Verification of an ESRD facility's low-volume status is based on the A/B MAC's (A) review of the total treatment count on an ESRD facility's (or a hospital's) cost report. In the situation where a hospital has multiple locations of a hospital-based ESRD facility under its governing body, the aggregate cost and treatment data of all of the locations (not just the treatment count of one of the subunits or satellite entities) are reported on the hospital's cost report I series. In the case where a hospital has multiple locations and treatment counts are aggregated in the hospital's cost report, the A/B MAC (A) may consider other supporting documentation which may include individual facility treatment counts, rather than the hospital's cost report alone. The hospital must provide the documentation to support the total treatment count for all the facilities that make up the total treatment count on the cost report for the A/B MAC (A) to review, even if not all the facilities are applying for the low volume adjustment.

2. 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.

The wage index values and the budget neutrality adjustment factor are updated during rulemaking, are issued via annual Recurring Update Notifications, and are posted on the ESRD Payment Webpage.

3. Rural adjustment

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

C. 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. For more information regarding dialysis training, see §30.2 of this chapter. For more information regarding retraining, see §30.2.E of this chapter.

D. 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 which were or would have been considered separately billable prior to the implementation of the ESRD PPS. ESRD outlier services include:

- 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;
- Laboratory tests used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;
- Medical or surgical supplies 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
- Drugs and biologicals used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Part D. Implementation of renal dialysis service oral-only drugs has been delayed until January 1, 2025.

The list of renal dialysis services that are included as outlier services may be found at http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage.

NOTE: All renal dialysis service Part B drugs and biologicals reported with a HCPCS code that is on the ASP List are included for outlier payments (with the exception of composite rate drugs). The laboratory tests that comprise the AMCC panel do not qualify for an outlier, see §20.2.A for information regarding the 50/50 rule.

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.

For example, the average outlier services MAP amount per treatment for pediatric and adult dialysis patients for CY 2016 were \$39.20 and \$50.81, respectively. After multiplication by applicable patient and facility specific adjusters to yield a predicted outlier services MAP amount, a fixed amount is added (the “fixed dollar loss” amount) to determine the outlier threshold. The fixed dollar loss amounts for CY 2016 were \$62.19 for pediatric patients and \$86.97 for adult patients. The CY 2016 values of the average outlier services MAP amount and the fixed dollar loss amount are used below for the purpose of following the outlier payment computation. These values may be revised as a result of subsequent rulemaking.

In computing the MAP amount, the adjusters used are:

<u>Adult Characteristics</u>	<u>Adjustment Value</u>	
	CY 2011-2015	Beginning CY 2016
Age: 18-44	0.996	1.044
Age: 45-59	0.992	1.000
Age: 60-69	1.000	1.005
Age: 70-79	0.963	1.000
Age: 80+	0.915	0.961
Body Surface Area	1.014	1.000
Low Body Mass Index (BMI <18.5)	1.078	1.090

Onset of Dialysis	1.450	1.409
Pericarditis	1.354	1.209
Bacterial pneumonia	1.422	---
Gastro-intestinal tract bleeding	1.571	1.426
Hereditary hemolytic or sickle cell anemia	1.225	1.999
Myelodysplastic syndrome	1.309	1.494
Monoclonal gammopathy	1.074	---
Low-volume facility adjustment	0.975	0.955
Rural facility adjustment	---	0.978

Pediatric Characteristics

Adjustment Value

	CY 2011-2015	Beginning CY 2016
Age: <13, Modality: PD	0.319	0.410
Age: <13, Modality: Hemo	1.185	1.406
Age: 13-17, Modality: PD	0.476	0.569
Age: 13-17, Modality: Hemo	1.459	1.494

Both the adult and pediatric CY 2016 separately billable case-mix adjusters are presented for the purpose of following the outlier payment computations shown below and may be revised as a result of subsequent rulemaking.

1. 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.

The following example shows how outlier payments are calculated under the ESRD PPS. For further information on the calculation of a patient's BSA, see §60.A.1. The pricing amounts for laboratory services qualifying as outlier services are based on the clinical

laboratory fee schedule. For injectable drugs and biologicals, pricing is based on the latest available quarterly average sales price plus 6 percent (ASP + 6) methodology. For formerly Part D drugs with an injectable version, pricing is based on national average drug prices based on the Medicare Prescription Drug Plan Finder. For medical/surgical supplies, pricing is based on prices established by the local A/B MAC (A). For further information regarding A/B MAC (A) pricing of medical/surgical supplies, see Pub. 100-04, chapter 8, §20.1.

2. Example of Outlier Payment

Ms. Brown is a 66 year old ESRD patient and is 167.64 cm. tall, weighs 105 kg., and has a recent diagnosis of GI bleeding. She does not qualify for a low BMI adjustment.

Ms. Brown's BSA is 2.1284.

The list of adjusters in §D reveals that the separately billable multiplier for BSA is 1.000.

Ms. Brown's case-mix adjustment based on her BSA of 2.1284 is 1.000.

Step 1: Determine the predicted, ESRD outlier services MAP amount using the product of all applicable case-mix adjusters.

The patient-level outlier services case-mix adjusters are identified in the list in §D:

$$\begin{aligned} &66 \text{ years old: } 1.005, \text{ BSA: } 1.000, \text{ and GI bleeding: } 1.426: \\ &= 1.005 * 1.000 * 1.426 \\ &= 1.4331 \end{aligned}$$

The adjusted, average, ESRD outlier services MAP amount
= \$50.81

The adjusted, average ESRD outlier services MAP amount * product of
the outlier services case-mix adjusters:
= \$50.81 * 1.4331 = \$72.82

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount based on utilization of all separately billable services on the monthly ESRD facility bill

Assume the imputed monthly ESRD outlier services amount = \$4,000 and that the corresponding total number of treatments in the month = 10

The imputed, average, per treatment, outlier services MAP amount
= \$4,000/10 = \$400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount

The fixed dollar loss amount = \$86.97. The predicted ESRD outlier services MAP amount = \$72.82
 $= \$72.82 + \$86.97 = \$159.79$

Step 4: Calculate outlier payment per treatment

Outlier payment = imputed average, per treatment, outlier services MAP amount minus (predicted ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:
 $= (\$400.00 - \$159.79) * .80 = \$240.21 * .80 = \192.17

The outlier payments for Ms. Browns' 10 treatments would be:
 $10 * \$192.17 = \$1,921.70$

E. Co-Insurance

Eighty percent of the total ESRD PPS payment amount for renal dialysis services furnished by ESRD facilities to ESRD beneficiaries is paid by Medicare. ESRD beneficiaries are responsible for the remaining 20 percent after the deductible. Therefore, the beneficiary co-insurance amount under the ESRD PPS is 20 percent of the total ESRD PPS payment, which includes the ESRD PPS base rate, all applicable adjustments, any applicable training add-on amounts, and any applicable outlier payments. For example, under the ESRD PPS the patient's co-insurance liability is based on the payment made to the ESRD facility and NOT on specific renal dialysis items and services. Therefore, any renal dialysis service drug or biological or laboratory service furnished to a beneficiary would NOT require a co-insurance amount because the renal dialysis service drug or biological or laboratory service is included in the payment made to the ESRD facility.

In the event a claim is reprocessed and the amount that was paid to the ESRD facility changes, the ESRD facility is responsible for reconciling with the ESRD patient any overpayment or underpayment of co-insurance or deductible amounts paid to the ESRD facility.

70 - ESRD PPS Transition Period

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

The ESRD PPS provides ESRD facilities a 4-year transition period under which the ESRD facilities receive a blend of payments comprised of the ESRD PPS and the basic case-mix adjusted composite payment system. For CY 2011 through 2013, CMS will continue to update the basic case-mix composite payment system for purposes of determining the composite rate portion of the blended payment amount, including adjusting payments for geographic differences in area wage levels. CMS continues to

apply the budget neutrality adjustment to the wage index values for the composite rate portion of the ESRD PPS during the transition.

- As of January 1, 2011, the blended amount consists of 25 percent based on the ESRD PPS payment and 75 percent of the basic case-mix adjusted composite payment system.
- For CY 2012, payment will be based on 50 percent of the payment rate under the ESRD PPS and 50 percent of the payment rate under the basic case-mix adjusted composite payment system.
- For CY 2013, payment will be based on 75 percent of the payment rate under the ESRD PPS and 25 percent of the payment rate under the basic case-mix adjusted composite payment system.
- For renal dialysis services furnished on or after January 1, 2014, payments to ESRD facilities will be based on 100 percent of the payment amount under the ESRD PPS. See §60 of this chapter for examples of how the ESRD PPS payment amount is calculated and see §50 of this chapter for more information to the ESRD PPS base rate.

Calendar Year	ESRD PPS Portion During Transition	Basic Case-Mix Adjusted Composite Payment System Portion During Transition
2011	25%	75%
2012	50%	50%
2013	75%	25%
2014 and beyond	100	0%

A. ESRD PPS Portion of the Blended Payment

The ESRD PPS portion of the blended payment is comprised of the ESRD PPS base rate (which is adjusted by any applicable patient-level and facility-level case-mix adjusters and a wage index), any applicable training add-ons, and any applicable outlier payments. See §10.F.1 of this chapter for more on the ESRD PPS.

For CY 2011, the ESRD PPS base rate was adjusted by an ESRD market basket. For CY 2012 and all subsequent years, the ESRD PPS base rate is updated by an ESRD market basket minus a productivity adjustment. See §50.B of this chapter for more on the market basket.

The following table summarizes the features of the ESRD PPS portion of the blended payment rates for two different scenarios (adult and pediatric) in CY 2011.

Feature	Adult Scenario	Pediatric Scenario
ESRD PPS base rate	Yes	Yes

Wage index adjustments	Yes, reflecting current wage data, including any applicable floor	Yes, reflecting current wage data, including any applicable floor
Patient-level case-mix adjustments	Yes, Adult	Yes, Pediatric
Low-volume adjustment	Yes, if applicable	No
Training add-on	Yes, if applicable	Yes, if applicable
Outlier payment	Yes, if applicable	Yes, if applicable

B. Composite Rate Portion of the Blended Payment

Under the composite rate, hemodialysis is paid for at 3 treatments per week and peritoneal dialysis is paid based on hemodialysis equivalent sessions (see §50.A.1 and §50.A.4, respectively, of this chapter). For per treatment unit of payment information for hemofiltration, ultrafiltration, and IPD, respectively, see §50.A.2, §50.A.3, and §50.A.5. Additional composite rate payments may be made when they are medically justified. The FI or A/B MAC reviews the medical justification and is responsible for making the decision on the appropriateness of the extra treatment. Additional information regarding home dialysis can be found in §30. ESRD facilities furnishing dialysis in-facility or in a patient's home are paid for up to 13 treatments during a 30 day month and 14 treatments during a 31 day month unless there is medical justification for additional treatments.

The composite rate portion of the blended payment rate is based on the payment amount under the basic case-mix adjusted composite payment system. It is comprised of the composite payment rate, which is adjusted by both the basic case-mix adjustments and a wage index.

The composite rate portion of the blended payment may include adjustments for:

- A drug add-on amount,
- Applicable home training add-ons for ESRD facilities going through the transition will continue to be paid the current training add-on rates of \$12 for CAPD and \$20 for CCPD and home hemodialysis for the portion of the blended payment that is based on the basic case-mix adjusted composite payment system. For more information on training and retraining, see §60.C.
- Payment amounts for renal dialysis services furnished to dialysis patients that were separately paid under Part B.
- Under the blended payment rate, the composite rate includes a \$0.49 per treatment amount to account for oral and other forms of injectable drugs that had previously been paid under Part D. Beginning in CY 2012, the composite payment rate is updated annually by applying a market basket minus a productivity adjustment factor.

As of January 1, 2011, CMS will not accept any new applications for composite rate exceptions. Those facilities with existing exceptions will continue with those exceptions, which do not include any case-mix adjustments. Any existing exceptions will terminate effective for ESRD treatments on or after January 1, 2014. In the event that an ESRD facility elects to receive full payment on or after January 1, 2011, any current exception will terminate. In the event that an ESRD facility receives payment under the transition period, any exceptions would be recognized for purposes of the basic case-mix adjusted composite payment system portion of the blended payment through the transition.

The following table presents the features of the composite rate portion of the blended payment rates for three different scenarios (adult, pediatric, and exception), using CY 2011 as the timeframe.

Feature	Adult Scenario	Pediatric Scenario	Exception Scenario
Rate Type	Composite payment rate	Composite payment rate	Exception rate (type and dollar amount unique to the ESRD facility)
Rate updated by an ESRD market basket	Yes	Yes	No
Drug add-on adjustment	Yes	Yes	No
Case-mix adjustment(s)	Age, BSA, and BMI	Single pediatric adjustment factor	No
Wage index adjustments	Yes, reflecting current wage data, including any applicable floor	Yes, reflecting current wage data, including any applicable floor	No
Adjustment for ESRD-related drugs and biologicals previously paid under Part D	Yes	Yes	No
Training add-ons	Yes, if applicable	Yes, if applicable	Yes, but only applies to ESRD facilities that have exceptions for reasons other than training
Payment amounts for renal dialysis services furnished to dialysis patients that had been	Yes	Yes	Yes

separately paid under Part B			
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C. Transition Budget Neutrality Factor

An adjustment to payments for renal dialysis services provided by ESRD facilities during the transition will be made so that the estimated total amount of payments under the ESRD PPS, including payments under the transition, equals the estimated total amount of payments that would otherwise occur under the ESRD PPS without such a transition. The transition budget neutrality adjustment factor is applied to the blended payment amount if the ESRD facility is going through the transition. If the ESRD facility is not going through the transition, then the transition budget neutrality adjustment factor is applied to the ESRD PPS payment. The adjustment factor is addressed in the ESRD PPS through rulemaking during the transition period. After the transition period, the transition budget neutrality adjustment factor no longer applies.

80 - Bad Debt

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Bad debt payments will continue to be made for the unpaid Medicare deductibles and co-insurance amounts for only those items and services associated with the composite rate. For payments made under the ESRD PPS for items and services included in the composite rate and for drugs and laboratory tests, only the bad debt amounts associated with the composite rate portion of the single ESRD payment rate will be used to determine an ESRD facility's allowable bad debt payments. A facility-specific composite cost percentage will be applied to the total bad debt amount associated with the ESRD PPS payment to compute the bad debt amount for only the composite rate services.

Bad debt payments for ESRD facilities will continue to be made in accordance with 42CFR413.89 and §413.178. However, effective January 1, 2013, the cap on bad debt reimbursement is no longer applied. General requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and co-insurance are found in chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15-1) and cost reporting worksheets and instructions in the PRM Part 2 (CMS Pub. 15-2).

90 – Medicare as a Secondary Payer (MSP)

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

The implementation of the ESRD PPS does not have an effect on the 30 month coordination period and MSP rules. See Pub. 100-05, Chapter 2, §20 for the MSP and coordination of benefit provisions that are applicable to ESRD beneficiaries.

100 - Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (AKI)

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

On June 29, 2015, the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114-27) was enacted. In the TPEA, Congress amended the Act to include coverage and provide for payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Social Security Act (the Act) by including coverage for renal dialysis services furnished on or after January 1, 2017 by a renal dialysis facility or provider of services currently paid under section 1881(b)(14) of the Act to an individual with AKI. In addition, section 808(b) of TPEA amended section 1834 of the Act by adding a new subsection (r). Subsection (r)(1) of section 1834 of the Act provides that in the case of renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or a provider of services paid under such section during a year (beginning with 2017) to an individual with AKI, the amount of payment under Part B for such services shall be the base rate for renal dialysis services determined for such year under such section, as adjusted by any applicable geographic adjustment applied under subparagraph (D)(iv)(II) of such section and may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

100.1 Definition of AKI

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

Section 1834(r)(2) of the Act defines “individual with acute kidney injury” to mean an individual who has acute loss of renal function and does not receive renal dialysis services for which payment is made under section 1881(b)(14) of the Act.

100.2 Payment Rate for AKI Dialysis

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

The payment rate for AKI Dialysis is the ESRD PPS per treatment base rate updated annually by the market basket, less the productivity adjustment and adjusted by any other adjustment factor applied to the ESRD PPS base rate.

100.3 Geographic Adjustment Factor

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

The payment rate for AKI dialysis is adjusted by the geographic adjustment factor that is applied to the ESRD PPS base rate for a particular facility, which is the same wage index applied under the ESRD PPS.

100.4 Other Adjustments to the AKI Payment Rate

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

There are currently no other adjustments applied to the AKI Payment Rate

A. ESRD Network Fee

The ESRD Network Fee reduction is not applicable to claims for beneficiaries with AKI.

B. ESRD Quality Incentive Program (QIP)

The ESRD QIP is not applicable for beneficiaries with AKI at this time.

C. Sequestration Adjustments

The 2 percent sequestration adjustment is applicable to claims for beneficiaries with AKI.

100.5 Renal Dialysis Services Included in the AKI Payment Rate

(Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

Drugs, biologicals, laboratory services, and supplies that are considered to be renal dialysis services under the ESRD PPS as defined in 42 CFR 413.171, are considered to be renal dialysis services for patients with AKI. As such, no separate payment would be made for renal dialysis drugs, biologicals, laboratory services, and supplies that are included in the ESRD PPS base rate when they are furnished by an ESRD facility to an individual with AKI.

Other items and services furnished to beneficiaries with AKI that are not considered to be renal dialysis services as defined in 42 CFR 413.171, but that are related to their dialysis treatment as a result of their AKI and that an ESRD facility might furnish to a beneficiary with AKI, would be separately payable. In particular, an ESRD facility could seek separate payment for 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. Items and services included on the consolidated billing list are not separately payable for patients with AKI.

All dialysis treatments, that is, hemodialysis and peritoneal dialysis, furnished to individuals with AKI in an ESRD facility will be paid the AKI payment rate. This includes any treatments that exceed the three times-weekly limitation applied to treatments furnished to ESRD beneficiaries. CMS expects that individuals with AKI will need renal dialysis services for a finite number of days since the intent of the dialysis for these patients is curative.

100.6 Applicability of Specific ESRD PPS Policies to AKI Dialysis

(Rev. 244, Issued: 07-20-18, Effective: 10-23-18, Implementation: 10-23-18)

A. Dialysis Modality

Beneficiaries with AKI can receive their dialysis via the most clinically appropriate in-facility modality.

B. Uncompleted Dialysis Treatment

Generally, CMS only pays for one treatment per day across all settings. However, similar to the policy applied under the ESRD PPS for treatments for patients with ESRD, in the interest of fairness and in accordance with Chapter 8, section 10.2 of the Medicare Claims Processing Manual, if a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, for example, a medical emergency when the patient must be rushed to an emergency room, both the ESRD facility and the hospital would be paid. This is considered to be a rare occurrence that must be fully documented to the A/B MAC's satisfaction.

C. Home and Self-Dialysis

Due to the nature of AKI, dialysis treatments at home or self-dialysis in the dialysis facility are not permitted. Specifically, these patients require supervision by qualified staff during their dialysis and close monitoring through laboratory tests to ensure that they are receiving the necessary care to improve their condition and get off of dialysis. Therefore, the home dialysis benefit does not extend to beneficiaries with AKI.

D. Vaccines and Their Administration

Section 1881(b)(14)(B) of the Act specifically excludes vaccines covered under section 1861(s)(10) of the Act from the ESRD PPS. However, ESRD facilities are identified as an entity that can bill Medicare for vaccines and their administration. Therefore, ESRD facilities may furnish vaccines to beneficiaries with AKI and bill Medicare in accordance with billing requirements in the Medicare Claims Processing Manual (Pub. 100-04, Chapter 18 Preventive and Screening Services, section 10.2). The staff time associated with vaccine administration is covered in the AKI dialysis payment rate.

E. Telehealth

Since telehealth dialysis services are limited to renal dialysis services for home dialysis patients telehealth related to renal dialysis services is not available for beneficiaries with AKI.

F. ESRD Conditions for Coverage (CfCs)

The ESRD CfCs at 42 CFR part 494 are health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients, including ESRD and AKI patients, receive safe and appropriate care.

G. Payment for Erythropoietin Stimulating Agents (ESAs) and the ESA Monitoring Policy for AKI Patients

ESAs are included in the bundled payment amount for treatments administered to patients with AKI. The Non-ESRD HCPCS codes should be used (J0881, *J0883*, J0885, J0888, *Q0138*) *and* reported using revenue code 0636.

The ESA monitoring policy has not yet been extended to AKI patients receiving treatment in an ESRD facility. Since this policy is not applicable to these treatments, the value codes used to report hemoglobin and hematocrit levels are not required when billing for ESAs.

100.7 Billing for Physicians' Services for Individuals with AKI (Rev. 240, Issued: 01-19-18, Effective: 01-01-17, Implementation: 02- 20-18)

Physicians are able to bill separately for services provided to individuals with AKI. CMS expects providers to follow correct coding guidelines and use the appropriate HCPCS or CPT codes for the items and services provided to the patient.

The following CPT codes are available for ESRD facilities and physician's offices to use when billing for physicians' services provided in either an ESRD facility (place of service 65) or a physician's office (place of service 11):

- 90935 - Hemodialysis procedure with single evaluation by a physician or other qualified health care professional;
- 90937 - Hemodialysis procedure requiring repeated evaluation(s) with or without substantial revision of dialysis prescription;
- 90945 - Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous replacement therapies), with single evaluation by a physician or other qualified health care professional;
- 90947 - Dialysis procedure other than hemodialysis (eg, peritoneal dialysis, hemofiltration, or other continuous renal replacement therapies) requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revision of dialysis prescription.

Please note: this is not an exhaustive list – as indicated above, CMS expects facilities and physician's offices to bill the appropriate codes.

110 - Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

120 - Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

130 - Reserved

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Appendix A

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Composite Rate Tests for Hemodialysis, IPD, CCPD, and Hemofiltration (Items in bold are non composite rate test)

Chemistry	CPT Code	Monthly	Weekly	13 x Quarter
Albumin	82040	X		
Alkaline Phosphates	84075	X		
ALT (SGPT)	84460			
AST (SGOT)	84450	X		
Bilirubin, total	82247			
Bilirubin, direct	82248			
Calcium	82310	X		
Calcium ionized (billed with modifier CD or CE)	82330	X		
Calcium ionized (billed with modifier CF)	82330	X		
Chloride	82435	X		
Cholesterol	82465			
CK, CPK	82550			
CO2 (bicarbonate)	82374	X		
Creatinine	82565		X	
GGT	82977			
Glucose	82947			
LDH	83615	X		
Phosphorus	84100	X		
Potassium	84132	X		
Protein, total	84155	X		
Sodium	84295			
Triglycerides	84478			
Urea nitrogen (BUN)	84520			X
Uric Acid	84550			

Appendix B

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Composite Rate Tests for CAPD (Items in bold are non composite rate test)

Chemistry	CPT Code	Monthly	Weekly	13 x Quarter
Albumin	82040	X		
Alkaline Phosphatase	84075	X		
ALT (SGPT)	84460			
AST (SGOT)	84450	X		
Bilirubin, total	82247			
Bilirubin, direct	82248			
Calcium	82310	X		
Calcium ionized (billed with modifier CD or CE)	82330	X		
Calcium ionized (billed with modifier CF)	82330	X		
Chloride	82435			
Cholesterol	82465			
CK, CPK	82550			
CO2 (bicarbonate)	82374	X		
Creatinine	82565	X		
GGT	82977			
Glucose	82947			
LDH	83615	X		
Phosphorus	84100	X		
Potassium	84132	X		
Protein, total	84155	X		
Sodium	84295	X		
Triglycerides	84478			
Urea nitrogen (BUN)	84520	X		
Uric Acid	84550			

Appendix C

(Rev. 171, Issued: 06-07-13, Effective: 01-01-11, Implementation: 09-09-13)

Brief History of ESRD Composite Payment Rates for Outpatient Maintenance Dialysis

Effective January 1, 2005, section 623 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) amended section 1881(b)(7) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. The MMA also required a drug add-on adjustment to the composite payment rate to account for the difference between pre-MMA payments for separately billable drugs and payments based on revised drug pricing for 2005 which used average acquisition costs. For CY 2005, CMS computed a drug add-on adjustment of 8.7 percent.

Effective January 1, 2006, section 5106 of the Deficit Reduction Act of 2005 amended section 1881(b)(12) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. In addition, because the drug add-on adjustment is determined as a percentage of the composite payment rate, CMS must adjust the drug add-on adjustment to account for the 1.6 percent increase to the composite payment rate in order to ensure that the total dollars allocated from the drug add-on adjustment remains constant. The growth update to the drug add-on adjustment of 1.4 percent was unchanged; therefore the total drug add-on adjustment to the composite payment rate for 2006 was 14.5 percent.

For dialysis services furnished on or after January 1, 2007 through March 31, 2007, the growth update to the drug add-on adjustment to the composite payment rate was 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for 2007 increased from 14.5 percent to 15.1 percent.

For dialysis services furnished on or after April 1, 2007, section 103 of the Tax Relief and Health Care Act of 2006 amended section 1881(b)(12) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. The effect of the 1.6 percent increase to the composite payment rate was a reduction in the drug add-on adjustment from 15.1 percent to 14.9 percent.

Effective January 1, 2008, there was no increase to the composite payment rate however; the drug add-on adjustment to the composite payment rate was increased by a growth update of 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for CY 2008 increased from 14.9 percent to 15.5 percent.

Effective January 1, 2009, section 153 of the Medicare Improvements for Patients and Providers Act of 2008 amended section 1881(b)(12) of the Social Security Act to require a 1 percent increase to the ESRD composite payment rate and that hospital-based ESRD facilities are paid the same composite payment rate as independent ESRD facilities. The effect of the 1 percent increase in the composite payment rate is a reduction in the drug add-on adjustment from 15.5 percent to 15.2 percent.

Effective January 1, 2010, CMS continued to apply the growth update to the drug add-on adjustment to the composite payment rate, which was 0.percent. As a result, the drug add-on adjustment to the composite payment rate for 2010 was reduced from 15.2 to 15.0 percent. Also, as required by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), CMS applied a 1.0 increase to the ESRD composite payment rate.

Section 153 of the MIPPA amended section 1881(b)(12) of the Social Security Act to require a 4-year transition (phase-in) from the current composite payment system to the ESRD Prospective Payment System (PPS). Effective January 1, 2011, CMS continued to apply the growth update to the drug add-on adjustment to the composite payment rate portion of the blended payment rate, which was 0.percent. As a result, the drug add-on adjustment to the composite payment rate portion of the blended payment for 2010 is reduced from 15.0 to 14.7 percent. For a detailed description of the transition period, see §70 of this chapter.

For further information on the drug add on amounts for CY 2012 and 2013, see the respective ESRD final rules.

Effective 2014, the drug add-on will no longer be applied.

Future updates will be issued via Recurring Update Notifications.

140 - Transplantation

(Rev. 1, 10-01-03)

A3-3178, PR 1-2770, RDF-230

Introduction

Renal transplantation is a principal form of treatment for patients with ESRD. Medicare has developed a method of reimbursement for the variety of medical services required to support a transplant program, including payment for Medicare's share of the costs of organ procurement.

In addition, Medicare has developed coverage and reimbursement criteria for necessary medical services provided to potential donors and recipients. In some situations, these services are provided before the effective date of Medicare entitlement for the potential transplant recipient.

Medicare pays for the covered services provided a Medicare patient who receives a living or cadaveric transplant. A certified transplant center's (CTC) or organ procurement organization's (OPO) expenses in providing kidneys are included in the transplant provider's living or cadaveric kidney acquisition cost center. To participate in the Medicare program, any CTC or OPO must be a member of the Organ Procurement and Transplantation Network (OPTN). The CTC is required to notify the OPO designated for

its service area of potential donors. (See the Medicare Provider Reimbursement Manual, Part 1, §§2771, for rules in developing a living and cadaveric acquisition charge.)

See the OPTN Web site at <http://www.optn.org/members/search.asp> or a search facility for various transplant centers, including kidney transplant centers.

140.1 - Identifying Candidates for Transplantation (Rev. 1, 10-01-03)

A3-3178.1, RDF-231

After a patient is diagnosed as having ESRD, the physician should determine if the patient is suitable for transplantation. If the patient is a suitable transplant candidate, a live donor transplant is considered first because of the high success rate in comparison to a cadaveric transplant. Whether one or multiple potential donors are available, the following sections provide a general description of the usual course of events in preparation for a live-donor transplant.

140.2 - Identifying Suitable Live Donors (Rev. 1, 10-01-03)

A3-3178.2, RDF-231

Those who are willing and medically able to donate a kidney are tested to determine whether they are of the same blood type as the recipient. After blood typing, the recipient and the donors are tissue typed. Only those candidates with blood and tissue types similar to the recipient are considered further.

After tissue typing, those medically suitable donors are evaluated on physical, psychological, and social factors. Potential donors who remain after the above testing may be hospitalized for about two days for further evaluation using procedures not appropriately performed on outpatients. These procedures may include intravenous urography and renal arteriography.

If the results of the above tests identify several suitable donors, the most suitable donor is selected, and arrangements are made for the transplant. At such time, the donor and recipient will enter the hospital to undergo the excision and transplantation, respectively.

When tests do not identify an acceptable living donor, the patient is considered for a cadaveric transplant and placed on hemo- or peritoneal dialysis, if this has not already proved necessary. If the ultimate goal is transplantation, the patient is registered with a kidney transplant registry.

140.3 - Pretransplant Outpatient Services (Rev. 1, 10-01-03)

A3-3178.3

All hospital outpatient services provided to live donors and recipients in anticipation of a transplant during the preentitlement period and after entitlement, but prior to admission to the hospital for transplantation, are covered. Such services would include kidney recipient registration fees, laboratory tests (including tissue typing of recipient and donors), and general medical evaluations of the recipient and the donor(s). Pretransplant physicians' services are also covered.

140.4 - Pretransplant Inpatient Services (Rev. 1, 10-01-03)

A3-3178.4

The following rules apply to kidney transplant inpatient medical evaluations when the kidney recipient has Medicare entitlement or is in the preentitlement period. The preentitlement period is that period prior to the patient's actual Medicare entitlement, during which services are furnished in anticipation of a transplant, after the patient has been diagnosed to have end stage renal disease. If the potential kidney recipient does not have entitlement, or is not in the preentitlement period, no services rendered to the kidney recipient or to the related living donor for kidney transplant the Medicare program will cover medical evaluations.

140.5 - Living Donor Evaluation, Patient Has Entitlement or is in Preentitlement Period (Rev. 1, 10-01-03)

A3-3178.5, RDF-233.1

When a living donor is admitted to a hospital (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, all hospital and physicians' services costs applicable to medical evaluation are considered kidney acquisition service costs. As such, the hospital statistics (charges, patient days, etc.) and the physicians' charges should be treated in accordance with all other kidney acquisition service statistics and the related costs are included in Medicare costs.

When the live donor subsequently enters the hospital for the actual excision, the hospital costs of services rendered to the donor will continue to be treated as kidney acquisition service costs under Part A. However, at that point physician services are no longer considered kidney acquisition services and are not reimbursable under Part A. Instead, during the donor's inpatient stay for the excision surgery and during any subsequent donor inpatient stays resulting from a direct complication of the organ donation, physician services are billed under Part B. They are billed in the normal manner but on the account of the recipient at 100 percent of the fee schedule. Note that services furnished to kidney donors are covered under the account of the recipient.

Services listed in the following sections are also covered. However, they are not billed as such but become a part of the kidney acquisition costs.

140.6 - Kidney Recipient Admitted for Transplant Evaluation
(Rev. 1, 10-01-03)

A3-3178.6, RDF-233, RDF-233.2

When a potential recipient is admitted to a hospital (before admission for the actual transplant) solely for a medical evaluation for an anticipated kidney transplant, all hospital and physicians' services costs applicable to the anticipated transplant are considered kidney acquisition service costs.

140.7 - Kidney Recipient Evaluated for Transplant During Inpatient Stay
(Rev. 1, 10-01-03)

A3-3178.7, RDF-233.3

When a recipient is admitted to a hospital for a medical reason other than in anticipation of a transplant, but during the stay, a medical evaluation for an anticipated kidney transplant is performed, all hospital and physicians' services costs applicable to the medical evaluation are considered kidney acquisition service costs. Accordingly, those services will be treated the same as the services above. However, all hospital and physicians' services applicable to the nontransplant related services (i.e., related to the medical services for which the patient was actually admitted) must not be included with kidney acquisition services costs; instead such services must be billed in the same manner as any other inpatient service on the account of the recipient. These latter services may be billed to the Medicare program only if the recipient has actual Medicare entitlement.

140.8 - Kidney Recipient Admitted for Transplantation and Evaluation
(Rev. 1, 10-01-03)

A3-3178.8, RDF-233.4

When the medical evaluation for a transplant is performed on the recipient or the living donor during the same inpatient stay in which the actual transplant occurs, all such services will be billed, and the costs will be accumulated in the normal manner. For example, all hospital services rendered to the donor will be considered kidney acquisition services. However, all physicians' services rendered to the living donor and all hospital and physicians' services rendered to the recipient will be billed in the same manner as any other inpatient services on the account of the recipient.

140.9 – Post-transplant Services Provided to Live Donor
(Rev. 148, Issued: 10-28-11; Effective: Policy Effective date: November 28, 2011;
Claims Processing Effective date: April 1, 2012; Implementation: April 2, 2012)

The donor of an organ for a Medicare transplant beneficiary is covered for an unlimited number of days of care in connection with the organ removal operation. Days of inpatient hospital care used by the donor in connection with the organ removal operation shall not be charged against either party's utilization record. However, the program's assumption of liability is limited to those donor expenses that are incurred directly in connection with the organ donation.

Coverage of organ donor services includes postoperative recovery services directly related to the organ donation. For routine follow-up care the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Claims for services rendered more than 3 months after donation surgery will be reviewed. However, follow-up examinations may be covered up to 6 months after the donation to monitor for possible complications. The requirement that additional payment cannot be made for services included in the donor's organ removal charge still applies.

Regarding donor follow-up:

Expenses incurred by the transplant center for routine donor follow-up care are included in the transplant center's organ acquisition cost center.

Follow-up services performed by the operating physician are included in the 90-day global payment for the surgery. Beyond the 90-day global payment period, follow-up services are billed using the recipient's health insurance claim number.

Follow-up services billed by a physician other than the operating physician for up to 3 months following donation surgery should be billed under the recipient's health insurance claim number.

Regarding donor complications:

Expenses incurred for complications that arise with respect to the donor are covered only if they are directly attributable to the donation surgery. Complications that arise after the date of the donor's discharge will be billed under the recipient's health insurance claim number. This is true of both facility cost and physician services. Billings for donor complications will be reviewed.

In all of these situations, the donor is not responsible for co-insurance or deductible.

140.10 - Coverage After Recipient Has Exhausted Part A (Rev. 1, 10-01-03)

A3-3178.11

If the recipient has exhausted Part A benefits while the donor still requires and receives inpatient hospital care, the program continues to pay for such donor care under Part A at 100 percent reimbursement.

140.11 - Cadaver Kidneys

(Rev. 1, 10-01-03)

A3-3178.12

Costs incurred by the provider in connection with the acquisition of a cadaver kidney are reimbursable by the program through the kidney acquisition cost center. Typical covered costs involved in excising the cadaver kidney include: surgeons' service, operating room, anesthetist, donor evaluation and support, preservation supplies (perfusion materials and equipment), preservation technician, telephone consultation charge, intensive care costs, pathology, central supply costs, organ transportation costs, and transportation costs for a technician. There is no provision in the law for coverage of charges by an agent transporting a kidney for transplant into an eligible beneficiary, if the agent bills the program or the patient directly. However, reimbursement may be made to hospitals and included in kidney acquisition costs.

140.12 - Services Involved

(Rev. 1, 10-01-03)

A3-3178.13, RDF-232

When there is no suitable living donor, a patient with renal failure may be considered for a cadaveric transplant. In such cases, the services provided to recipients of "live donor" kidneys (i.e., tissue typing and other related tests) are also provided to potential recipients of cadaver kidneys. However, because a kidney may not be available for a long period of time, additional services may be provided in the form of direct physician care for the patient's renal condition, and certain tests may be performed on a regular basis to allow the physician to have current information regarding the status of the patient and his or her suitability for transplant. In addition, the number of mixed lymphocyte cultures which are prepared whenever a kidney is procured that may suit the recipient depends on the number of kidneys which become available for transplant. The cost of registering a potential recipient with a kidney transplant registry is also covered, as well as the services furnished to maintain organ viability after excision, i.e., preservation, and transporting the kidney to the place of transplantation.

140.13 - Tissue Typing Services for Cadaver Kidney

(Rev. 1, 10-01-03)

A3-3178.14

Tissue typing services for cadaveric kidney recipients are treated in a similar manner to the way in which such services are covered and reimbursed in live donor cases. Tissue

typing of the cadaveric organ by the excising hospital becomes an organ acquisition cost that is included in the charges for organs, which are supplied by the hospital.

140.14 - Cadaver Excision Yielding Two Kidneys (Rev. 1, 10-01-03)

A3-3178.15

When two kidneys are obtained from a cadaver, and both kidneys are shipped to the same transplant hospital or organ procurement agency, the hospital should adjust its normal charges to reflect any increased perfusion, preservation, and shipping costs due to the additional kidney. On the other hand, when the kidneys are sent to separate organizations or transplant hospitals, the excising hospital should prorate its charges to the receiving organizations so that the total charges do not exceed the amount that would have been billed if one transplant hospital or agency had received both kidneys.

140.15 - Provider Costs Related to Cadaver Kidney Excisions (Rev. 1, 10-01-03)

A3-3178.16

Typical provider costs involved in excising a cadaver kidney whether or not it is eventually transplanted include:

- Intensive care costs;
- Surgeon's services - anesthetist services, operating room, preservation supplies (perfusion materials and equipment), preservation technician's services, donor evaluation and support, pathology, central exchange costs (transportation and packaging), and administration costs (overhead items).

140.16 - Noncovered Transplant Related Items and Services (Rev. 1, 10-01-03)

A3-3178.17

The following list represents some of the transplant related items and services which are not covered and for which no program payment can be made:

- Travel, room, and board expenses incurred by a live donor;
- Travel, room, and board expenses (to any transplant center) incurred by the recipient;
- Reimbursement for the kidney itself when the live donor or the cadaver donor's next of kin sells the kidney;

- Transportation of the potential cadaveric donor to the transplant hospital (only transportation of the organ is reimbursable as part of the organ procurement charge); or
- Pronouncement of death and burial expenses for the cadaveric donor.

140.17 - Other Covered Services (Rev. 1, 10-01-03)

A3-3178.18

A. Tissue Typing

Tissue typing of the recipient, as well as tissue typing and tests to determine the suitability of a living donor or a cadaveric kidney, are covered as medical expenses, necessary for the treatment of an eligible recipient. The costs of these services are covered under the hospital insurance or medical insurance programs (Part B coverage after recipient has exhausted Part A), and are reflected in the kidney acquisition costs.

B. Preservation Laboratories

The services performed by preservation laboratories are medically necessary for the treatment of a beneficiary's illness. A participating hospital is reimbursed for the reasonable cost of such services which its own laboratory performs or which the hospital purchases from a freestanding preservation laboratory or organ procurement agency.

C. Registration Fees

A participating hospital which expects to perform a kidney transplant will be reimbursed for the reasonable cost incurred in listing the patient and the patient's blood characteristics with a professionally recognized organization that maintains a registry of potential transplant candidates, and which provides a regular listing of such patients to hospitals engaged in kidney procurement.

140.18 - Hospitals that Excise but Do Not Transplant Kidneys (Rev. 1, 10-01-03)

A3-3178.19, PR 1-2772

The excising hospital plays an important part in the national organ procurement effort. Most of these hospitals are community hospitals and neither excise kidneys on a regular basis nor perform transplants. A hospital that excises but does not transplant kidneys must be certified to participate in the Medicare program. Where the hospital is not participating in the Medicare program, organs may be accepted from it only if they cannot be obtained from any other source.

A hospital that excises but does not transplant kidneys may perform excisions on cadavers or on live donors; however, regardless of the vital status of the donor, most of the hospital services utilized in the excision are the same.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R244BP</u>	07/20/2018	Internet Only Manual (IOM) Update to Publication 100-02, Chapter 11 - End Stage Renal Disease (ESRD), Section 100	10/23/2018	10809
<u>R240BP</u>	01/19/2018	Internet Only Manual (IOM) Update to Pub. 100-02, Chapter 11 - End Stage Renal Disease (ESRD), Section 100	02/20/2018	10366
<u>R224BP</u>	06/03/2016	Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) for Calendar Year (CY) 2016	09/06/2016	9541
<u>R219BP</u>	01/13/2016	Calendar Year (CY) 2016 Eligibility Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Low-Volume Payment Adjustment (LVPA)	01/22/2016	9478
<u>R218BP</u>	01/08/2016	Calendar Year (CY) 2016 Eligibility Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Low-Volume Payment Adjustment (LVPA) – Rescinded and replaced by Transmittal 219	01/22/2016	9478
<u>R200BP</u>	12/02/2014	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015	01/05/2015	8978
<u>R199BP</u>	11/14/2014	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2015 – Rescinded and replaced by Transmittal 200	01/05/2015	8978
<u>R197BP</u>	10/24/2014	Clarification of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Low Volume Adjustment	01/05/2015	8898
<u>R195BP</u>	10/10/2014	Clarification of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Low Volume Adjustment – Rescinded and replaced by Transmittal 197	01/12/2015	8898

<u>R177BP</u>	12/13/2013	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2014	01/06/2014	8472
<u>R174BP</u>	11/29/2013	Implementation of Changes in the End-Stage Renal Disease Prospective Payment System (ESRD PPS) for Calendar Year (CY) 2014 – Rescinded and replaced by Transmittal 177	01/06/2014	8472
<u>R171BP</u>	06/07/2013	Implementation of the End Stage Renal Disease (ESRD) Prospective Payment System (PPS)	09/09/2013	8261
<u>R148BP</u>	01/28/2011	Billing for Donor Post-Kidney Transplant Complication Services	04/02/2012	7523
<u>R136BP</u>	01/28/2011	Clarification of Existing Policy Regarding Items and Services Included Under End Stage Renal Disease (ESRD) Composite Payment Rate	02/25/2011	7312
<u>R98BP</u>	12/12/2008	Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year 2009	01/05/2009	6216
<u>R83BP</u>	02/15/2008	Clinical Lab: New Automated Test for the AMCC Panel Payment Algorithm	07/07/2008	5874
<u>R67BP</u>	03/09/2007	2007 Update to the End Stage Renal Disease Composite Payment Rates	04/02/2007	5535
<u>R61BP</u>	11/24/2006	Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2007	01/02/2007	5407
<u>R50BP</u>	06/02/2006	Immunosuppressive Therapy For Kidney Transplant	07/03/2006	4143
<u>R44BP</u>	02/10/2006	Update to the ESRD Composite Payment Rate	02/13/2006	4291

<u>R35BP</u>	06/03/2005	Automated Multi-Channel Chemistry (AMCC) for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Non-CAPD Patients	07/05/2005	3802
<u>R27BP</u>	11/23/2004	New ESRD Composite Payment Rates Effective January 1, 2005	01/03/2005	3554
<u>R08BP</u>	03/05/2004	Policy Changes to Reflect Billing for Darbepoetin Alfa and Epoetin	04/05/2004	2984
<u>R07BP</u>	02/20/2004	Restoring Composite Rate Exceptions for Pediatric Facilities Under the ESRD Composite Rate System	04/01/2004	3119
<u>R01BP</u>	10/01/2003	Introduction to the Benefit Policy Manual	N/A	N/A

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