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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-02 Medicare Benefit Policy | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 224 | Date: June 3, 2016 |
| | Change Request 9541 |

SUBJECT: Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) for Calendar Year (CY) 2016

I. SUMMARY OF CHANGES: The purpose of this change request is to update the End-Stage Renal Disease (ESRD) chapter in the Medicare Benefit Policy Manual to reflect the provisions in the CY 2016 ESRD Prospective Payment System (PPS) final rule.

EFFECTIVE DATE: January 1, 2016

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

IMPLEMENTATION DATE: September 6, 2016

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| R | 11/Table of Contents |
| R | 11/10/Definitions Relating to ESRD |
| R | 11/20.2/Laboratory Services |
| R | 11/20.3/Drugs and Biologicals |
| N | 11/20.3.1/Drug Designation Process |
| R | 11/60/ESRD PPS Case-Mix Adjustments |

III. FUNDING:

For Medicare Administrative Contractors (MACs):

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

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

| | | | |
|-------------|------------------|--------------------|----------------------|
| Pub. 100-02 | Transmittal: 224 | Date: June 3, 2016 | Change Request: 9541 |
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SUBJECT: Update to Pub. 100-02, Chapter 11 End-Stage Renal Disease (ESRD) for Calendar Year (CY) 2016

EFFECTIVE DATE: January 1, 2016

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IMPLEMENTATION DATE: September 6, 2016

I. GENERAL INFORMATION

A. Background: The ESRD PPS provides a single payment to ESRD facilities, that is, hospital-based and freestanding facilities, that cover all the resources used in providing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, training, and support services.

The ESRD PPS base rate is adjusted for patient-level case mix and facility-level characteristics. In accordance with section 632(c) of the American Taxpayers Relief Act of 2012 (ATRA), CMS analyzed the case-mix payment adjustments using more recent data. CMS revised the adjustments by changing the adjustment payment amounts and removing two comorbidity payment adjustments (bacterial pneumonia and monoclonal gammopathy). CMS also revised the low-volume payment adjustment and implemented a payment adjustment for rural ESRD facilities.

In accordance with section 217(c) of The Protecting Access to Medicare Act of 2014 (PAMA), CMS finalized a drug designation process for: (1) determining when a product would no longer be considered an oral-only drug; and (2) including new injectable and intravenous products into the bundled payment under the ESRD PPS.

B. Policy: There are no new coverage policies, payment policies, or codes introduced in this transmittal. Specific policy changes and related business requirements were announced in Change Request 9367.

II. BUSINESS REQUIREMENTS TABLE

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

| Number | Requirement | Responsibility | | | | | | | | |
|--------|---|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | | D M E M A C | Shared- System Maintainers | | | | Other |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | |
| 9541.1 | Contractors shall make providers aware of the revisions made to Pub. 100-02, Medicare Benefit Policy Manual, chapter 11, sections 10, 20.2, 20.3, 20.3.1, and 60. | X | X | | | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|--------|---|----------------|---|-------------|-------------|------------------|
| | | A/B MAC | | | D M E | C E D I |
| | | A | B | H H H | M A C | |
| 9541.2 | MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly. | X | X | | | |

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| | N/A |

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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

ATTACHMENTS: 0

Medicare Benefit Policy Manual

Chapter 11 - End Stage Renal Disease (ESRD)

Table of Contents
(Rev. 224, Issued: 06-03-16)

Transmittals for Chapter 11

20.3.1 - Drug Designation Process

10 - Definitions Relating to ESRD

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

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 cycler. Generally, there are three nocturnal exchanges occurring at intervals of 2 1/2 to 3 hours. Upon awakening, the patient disconnects from the cycler 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 account^{ed} 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.

20.2 - 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

| <i>Drug Category</i> | <i>Rationale for Exclusion</i> |
|-----------------------------|---|
| <i>Anticoagulant</i> | <i>Drugs labeled for non-renal dialysis conditions and not for vascular access.</i> |
| <i>Antidiuretic</i> | <i>Used to prevent fluid loss.</i> |
| <i>Antiepileptic</i> | <i>Used to prevent seizures.</i> |

| Drug Category | Rationale for Exclusion |
|---|--|
| <i>Anti-inflammatory</i> | <i>May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.</i> |
| <i>Antipsychotic</i> | <i>Used to treat psychosis.</i> |
| <i>Antiviral</i> | <i>Used to treat viral conditions such as shingles.</i> |
| <i>Cancer management</i> | <i>Includes oral, parenteral and infusions. Cancer drugs are covered under a separate benefit category.</i> |
| <i>Cardiac management</i> | <i>Drugs that manage blood pressure and cardiac conditions.</i> |
| <i>Cartilage</i> | <i>Used to replace synovial fluid in a joint space.</i> |
| <i>Coagulants</i> | <i>Drugs that cause blood to clot after anti-coagulant overdose or factor VII deficiency.</i> |
| <i>Cytoprotective agents</i> | <i>Used after chemotherapy treatment.</i> |
| <i>Endocrine/metabolic management</i> | <i>Used for endocrine/metabolic disorders such as thyroid or endocrine deficiency, hypoglycemia, and hyperglycemia.</i> |
| <i>Erectile dysfunction management</i> | <i>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.</i> |
| <i>Gastrointestinal management</i> | <i>Used to treat gastrointestinal conditions such as ulcers and gallbladder disease.</i> |
| <i>Immune system management</i> | <i>Anti-rejection drugs covered under a separate benefit category.</i> |
| <i>Migraine management</i> | <i>Used to treat migraine headaches and symptoms.</i> |
| <i>Musculoskeletal management</i> | <i>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.</i> |
| <i>Pharmacy handling for oral anti-cancer, anti-emetics and immunosuppressant drugs</i> | <i>Not a function performed by an ESRD facility.</i> |
| <i>Pulmonary system management</i> | <i>Used for respiratory/lung conditions such as opening airways and newborn apnea.</i> |
| <i>Radiopharmaceutical procedures</i> | <i>Includes contrasts and procedure preparation.</i> |
| <i>Unclassified drugs</i> | <i>Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified.</i> |
| <i>Vaccines</i> | <i>Covered under a separate benefit category.</i> |

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 <i>Association</i> |
|-----------------------------|--|
| 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**

| <i>Category</i> | <i>Rationale for Association</i> |
|------------------------|---|
| Antiemetic | Used to prevent or treat nausea and vomiting <i>related</i> to dialysis. Excludes antiemetics used <i>for purposes unrelated to dialysis, such as those used</i> in conjunction with chemotherapy as these are covered under a separate benefit category. |
| Anti-infectives | Used to treat <i>vascular access-related and peritonitis</i> infections. May include antibacterial and antifungal drugs. |
| Antipruritic | Drugs in this classification have multiple clinical indications. <i>Use within an ESRD functional category includes treatment for</i> itching <i>related</i> to dialysis. |
| Anxiolytic | Drugs in this classification have multiple actions. <i>Use within an ESRD functional category includes</i> treatment of restless leg syndrome <i>related</i> to dialysis. |
| Excess Fluid | Drug/fluids used to treat fluid excess/overload. |

| | |
|---|--|
| Management | |
| Fluid and Electrolyte Management Including Volume Expanders | Intravenous drugs/fluids used to treat fluid and electrolyte needs. |
| Pain Management | Drugs used to treat <i>vascular access</i> site pain and to treat pain medication overdose, <i>when the overdose is related to medication provided to treat vascular access site pain.</i> |

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:

- 1. 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.

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.

Adult Patient-Level Characteristics

Adjustment Value

| | <i>CY 2011-2015</i> | <i>Beginning CY 2016</i> |
|------------|---------------------|--------------------------|
| Age: 18-44 | 1.171 | <i>1.257</i> |
| Age: 45-59 | 1.013 | <i>1.068</i> |
| Age: 60-69 | 1.000 | <i>1.070</i> |
| Age: 70-79 | 1.011 | <i>1.000</i> |

| | | |
|--|-------|--------------|
| Age: 80+ | 1.016 | <i>1.109</i> |
| Body Surface Area | 1.020 | <i>1.032</i> |
| <i>Low Body Mass Index</i> (BMI <18.5) | 1.025 | <i>1.017</i> |
| Onset of Dialysis | 1.510 | <i>1.327</i> |
| Pericarditis | 1.114 | <i>1.040</i> |
| Bacterial pneumonia | 1.135 | --- |
| Gastro-intestinal tract bleeding | 1.183 | <i>1.082</i> |
| Hereditary hemolytic or sickle cell anemia | 1.072 | <i>1.192</i> |
| Myelodysplastic syndrome | 1.099 | <i>1.095</i> |
| 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 $BSA = 0.007184 * \text{height}_{\text{cm}}^{.725} * \text{weight}_{\text{kg}}^{.425}$.

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

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

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:

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

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:

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

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* x *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/m². 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/m² which is a clinical measure of being underweight and an indicator of malnutrition.

The formula for the calculation of the BSA is $BSA = w^{0.425} * h^{0.725} * 0.007184$ 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 $1.032^{(BSA-1.90)/0.1}$. 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_Comorbidity_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> | |
|--|-------------------------|------------------------------|
| | <i>CY 2011-2015</i> | <i>Beginning CY 2016</i> |
| Age: <13, Modality: PD | 1.033 | <i>1.063</i> |
| Age:<13, Modality: Hemo | 1.219 | <i>1.306</i> |
| Age:13-17, Modality: PD | 1.067 | <i>1.102</i> |
| Age:13-17, Modality: Hemo | 1.277 | <i>1.327</i> |

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

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> | |
|------------------------------|-------------------------|--------------------------|
| | <i>CY 2011-2015</i> | <i>Beginning CY 2016</i> |
| Age: 18-44 | 0.996 | <i>1.044</i> |
| Age: 45-59 | 0.992 | <i>1.000</i> |
| Age: 60-69 | 1.000 | <i>1.005</i> |
| Age: 70-79 | 0.963 | <i>1.000</i> |

| | | |
|--|-------|--------------|
| Age: 80+ | 0.915 | <i>0.961</i> |
| Body Surface Area | 1.014 | <i>1.000</i> |
| <i>Low Body Mass Index</i> (BMI <18.5) | 1.078 | <i>1.090</i> |
| Onset of Dialysis | 1.450 | <i>1.409</i> |
| Pericarditis | 1.354 | <i>1.209</i> |
| Bacterial pneumonia | 1.422 | --- |
| Gastro-intestinal tract bleeding | 1.571 | <i>1.426</i> |
| Hereditary hemolytic or sickle cell anemia | 1.225 | <i>1.999</i> |
| Myelodysplastic syndrome | 1.309 | <i>1.494</i> |
| Monoclonal gammopathy | 1.074 | --- |
| Low-volume facility adjustment | 0.975 | <i>0.955</i> |
| <i>Rural facility adjustment</i> | --- | <i>0.978</i> |

Pediatric Characteristics

Adjustment Value

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

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

$$\begin{aligned} \text{The fixed dollar loss amount} &= \$86.97. \text{ The predicted ESRD outlier} \\ \text{services MAP amount} &= \$72.82 \\ &= \$72.82 + \$86.97 = \$159.79 \end{aligned}$$

Step 4: Calculate outlier payment per treatment

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

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.