

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services



**MLN Matters® Number: MM9541**

**Related Change Request (CR) #: CR 9541**

**Related CR Release Date: June 3, 2016**

**Effective Date: January 1, 2016**

**Related CR Transmittal #: R224BP**

**Implementation Date: September 6, 2016**

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

#### **Provider Types Affected**

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This MLN Matters® Article is intended for End-Stage Renal Disease (ESRD) facilities that submit claims to Medicare Administrative Contractors (MACs) for ESRD services provided to Medicare beneficiaries.

#### **What You Need to Know**

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Change Request (CR) 9541 updates Chapter 11 of the “Medicare Benefit Policy Manual” to reflect the provisions in the Calendar Year (CY) 2016 ESRD Prospective Payment System (PPS) final rule. There are no new coverage policies, payment policies, or codes introduced in CR9541. Specific policy changes and related business requirements were addressed in CR9367, as discussed in MLN Matters article [MM9367](#).

#### **Background**

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The End-Stage Renal Disease (ESRD) Prospective Payment System (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. This includes 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. For CY 2016, in accordance with the American Taxpayers Relief Act of 2012

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(ATRA; Section 632(c)), The Centers for Medicare & Medicaid Services (CMS) analyzed the case-mix payment adjustments using more recent data.

CMS revised the adjustments by changing the adjustment payment amounts based on an updated regression analysis using Calendar Years (CYs) 2012 and 2013 ESRD claims and cost report data. CMS also removed two comorbidity payment adjustments (bacterial pneumonia and monoclonal gammopathy). Because the updated regression analysis conducted enabled CMS to analyze and revise the case-mix payment adjustments, CMS also revised the low-volume payment adjustment and implemented a payment adjustment for rural ESRD facilities.

For CY 2016, in accordance with the Protecting Access to Medicare Act of 2014 (PAMA) (Section 217(c)), 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.

## Updates to the “Medicare Benefit Policy Manual”

The key clarifications/updates to the “Medicare Benefit Policy Manual” are as follows:

### **Section 20.2**

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**

<b>Drug Category</b>	<b>Rationale for Exclusion</b>
Anticoagulant	Drugs labeled for non-renal dialysis conditions and not for vascular access.
Antidiuretic	Used to prevent fluid loss.
Antiepileptic	Used to prevent seizures.
Anti-inflammatory	May be used to treat kidney disease (glomerulonephritis) and other inflammatory conditions.
Antipsychotic	Used to treat psychosis.

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

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Drug Category	Rationale for Exclusion
Radiopharmaceutical procedures	Includes contrasts and procedure preparation
Unclassified drugs	Should only be used for drugs that do not have a HCPCS code and therefore cannot be identified
Vaccines	Covered under a separate benefit category

Also, 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.

### Section 20.3

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., below in this article.

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 the "Medicare Claims Processing Manual," [Chapter 8, Section 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.

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.

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

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

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

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

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

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

### **Section 20.3.1 – Drug Designation Process**

#### **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

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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.

#### **Section 60**

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 in detail in the revised section 60, which also includes detailed examples. The revised Section 60 is included as part of CR9541 and the Web address for accessing the CR is in the Additional Information section of this article.

In addition, the revised Section 60 shows that beginning January 1, 2016, the ESRD PPS provides a 1.008 percent payment adjustment for ESRD facilities located in a rural Core Based Statistical Area.

### **Additional Information**

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The official instruction, CR9541, issued to your MAC regarding this change is available at <http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R224BP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html> under - How Does It Work.

Related MLN Matters Article MM9367 is available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM9367.pdf>.

Chapter 8, Section 60.4.1 of the “Medicare Claims Processing Manual” is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf>.

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