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CENTER FOR MEDICARE

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TO: All Part D Plan Sponsors

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SUBJECT: Clarification of Exclusion from Part D Payment for Drugs and Biological Products Included in the End-Stage Renal Disease Prospective Payment System

Past guidance from the Centers for Medicare & Medicaid Services (CMS) for Medicare Part D sponsors regarding drugs and biological products included in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) has been contained in multiple Call Letters and memoranda issued from April 5, 2010 to December 20, 2024. This guidance is listed in Appendix A. Recently, CMS has received requests for clarification of our guidance, particularly the payment determination questions contained in the February 17, 2011 Health Plan Management System (HPMS) memorandum about excluding Part D payment for drugs and biological products that are included in the ESRD PPS for Medicare beneficiaries with ESRD on renal dialysis.

In this memorandum, after providing background on ESRD and the ESRD PPS, we take the opportunity to consolidate the earlier guidance and incorporate the requested clarification. Thus, this memorandum supersedes the past guidance listed in Appendix A.

Background on ESRD and the ESRD PPS

ESRD is a medical condition that occurs when there is permanent kidney failure and kidneys can no longer filter waste from the body's bloodstream adequately. Patients with ESRD require dialysis or a kidney transplant to stay alive. As of the end of calendar year (CY) 2023, there were 537,631 patients receiving chronic, life-saving dialysis in the U.S. at approximately 8,000 ESRD facilities.

Since January 1, 2011, Medicare makes a single payment for renal dialysis services under the ESRD PPS, as provided in section 1881(b)(14) of the Social Security Act. The CY 2011 ESRD PPS final rule (75 FR 49030), which appeared in the Federal Register on August 12, 2010, implemented this payment system and required the inclusion in the ESRD PPS bundled payment of all drugs and biological products used in the treatment of ESRD, effective January 1, 2011.

The drug designation process was an integral part of the CY 2011 ESRD PPS final rule. Table C in the Appendix of the CY 2011 ESRD PPS final rule listed drugs included in the ESRD PPS base rate; however, in the preamble, CMS noted that drugs used as substitutes for any of these drugs, or used to

accomplish the same effect, would also be included in the ESRD PPS bundled payment and, therefore, be ineligible for separate payment. As a result, to avoid inadvertently overlooking drugs that may be substitutes, and to enable CMS to consider new drugs developed or changes in standards of practice, for ESRD PPS payment, the CY 2011 ESRD PPS final rule identified categories of drugs or biological products that either are "always" or "may be" ESRD-related (i.e., used in the treatment of ESRD). We explained that any drug or biological product furnished for the purpose of access management, anemia management, vascular access site infection or peritonitis, cellular management, and bone and mineral metabolism will be considered renal dialysis services under the ESRD PPS (75 FR 49051). Originally, anti-infectives were considered to always be ESRD-related; however, this changed in the CY 2015 ESRD PPS final rule (79 FR 66149) in which CMS clarified that anti-infectives are no longer considered to always be ESRD-related but may be ESRD-related.

Prompted by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA), in the CY 2016 ESRD PPS final rule, CMS established requirements in 42 C.F.R. § 413.234 to reflect the drug designation process for incorporating new renal dialysis drugs and biological products into the ESRD PPS. We introduced the term "ESRD PPS functional category," which is defined at 42 C.F.R. § 413.234(a) as a distinct grouping of drugs or biological products, as determined by CMS, whose end action effect is the treatment or management of a condition or conditions associated with ESRD. We explained that the ESRD PPS functional categories describe the longstanding list of ESRD-related drug categories, and we narrowed the descriptions of the categories. We stated that these changes were consistent with how we believe the categories should be defined and help to ensure that the drugs and biological products that fall into them are those that are essential for the delivery of maintenance dialysis (80 FR 69018). We clarified the ESRD PPS functional categories as including access management, anemia management, bone and mineral metabolism, antiemetic, antipruritic, anxiolytic, cellular management, excess fluid management, fluid and electrolyte management including volume expanders, and pain management. Additionally, we defined anti-infectives as those that are used to treat vascular access-related and peritonitis infections and may include antibacterial and antifungal drugs (80 FR 69018).

In the CY 2023 ESRD PPS final rule (87 FR 67188), CMS further revised the descriptions of these ESRD PPS functional categories and presented them in a revised table. Tables 1 and 2 in this memorandum represent the functional categories of drugs and biological products that are "always" or "may be" renal dialysis services. When these categories were designated, the term "always drugs" was considered to mean that the drug was provided in a functional category to a beneficiary with ESRD receiving dialysis, and we believed these drugs would only apply to renal dialysis services when furnished to a beneficiary with ESRD when used as specified in Table 1 of this memorandum. Similarly, drugs that "may be" ESRD-related were also included in a functional category definition; however, we stated there could be medical circumstances when these drugs could be furnished to beneficiaries with ESRD receiving dialysis for reasons other than renal dialysis services.

Oral-only ESRD drugs were excluded from the ESRD PPS until Jan. 1, 2025, and thus were paid separately under Part D (42 C.F.R. §§ 413.174(f)(6)), 413.234(a)). In the CY 2025 ESRD PPS final rule (89 FR 89136), CMS discussed the incorporation of oral-only drugs into the ESRD PPS effective January 1, 2025. As set forth in § 413.174(f)(5)-(6), effective January 1, 2025, all drugs and biological products furnished for the treatment of ESRD are paid for under the ESRD PPS regardless of route. That is, any drug or biological product from the tables below that is provided to a Medicare beneficiary who has ESRD and is receiving dialysis is included in the ESRD PPS bundled payment when used as

specified in the table. This general policy applies to ***all*** renal dialysis drugs and biological products regardless of whether these are furnished directly by an ESRD facility. Under § 413.210(b), Medicare payment is ***only*** made to an ESRD facility for renal dialysis drugs and biological products, which are furnished directly or under arrangements. Medicare payment is not made to providers or suppliers other than an ESRD facility for renal dialysis drugs and biological products.

As discussed above, the ESRD PPS functional categories are defined to ensure that the drugs and biological products that fit the descriptions are essential for the delivery of maintenance dialysis. In the CY 2023 ESRD PPS final rule, we clarified that the provision of renal dialysis services is central to the ESRD PPS, and all renal dialysis drugs and biological products are ''secondary to dialysis'' (87 FR 67189). In certain circumstances, when a drug or biological product is furnished and billed by an ESRD facility for reasons other than the treatment of ESRD, it is not considered a renal dialysis service and may be billed using the Part B claims modifier AY, which allows separate payment to the ESRD facility for non-renal dialysis drugs and biological products.[1] As discussed in the following section, Part D plans should apply similar logic to determine whether a claim for a drug or biological product is included in one of the below ESRD PPS functional categories as payable under Part D when furnished to a beneficiary with ESRD who is receiving dialysis.

Claims Payment Guidance for Part D Sponsors

The purpose of this guidance is to assist Part D sponsors in excluding any submitted claims for renal dialysis drugs and biological products from Part D payment. Part D sponsors include Medicare Advantage-Prescription Drug (MA-PD) plans that must assign ESRD-related drugs and biological products to Part B coverage. In order to correctly assign the costs of drugs and biological products to Part C (which incorporates Part B) or to Part D, MA-PD plans must identify whether plan covered drugs and biological products prescribed by a contracted or non-contracted provider for their ESRD enrollees are ESRD-related.

As noted above, Medicare payment for all renal dialysis drugs and biological products is already included in the Part B ESRD PPS bundled payment to the ESRD facilities. Thus, CMS requires ESRD facilities to appropriately furnish renal dialysis services, including renal dialysis drugs and biological products, within the bundled ESRD PPS directly or under arrangements. As a result, beneficiaries should not be inappropriately directed to pharmacies that are not part of, or contracted with, the ESRD facility.

ESRD Information to Part D Sponsors

Since the ESRD PPS bundled payment is for "renal dialysis services," the first question that a Part D sponsor should answer in determining whether a drug or biological product furnished to a beneficiary with ESRD is covered under Part D is whether the beneficiary is receiving "renal dialysis services." To this end, CMS implemented system changes in November 2010 to permit reporting ESRD dialysis start and end dates on the enrollment transaction reply report (TRR) and as necessary thereafter to report changes in the ESRD information. Part D sponsors should use this ESRD information to determine whether and when a beneficiary with ESRD is receiving/received renal dialysis services. It is not sufficient to confirm the ESRD indicator alone, but a dialysis start date and end date (if applicable because renal dialysis services have ended) is also necessary. In addition, CMS requires that, regardless

[1] See Pub. 104 Chapter 8, Section 60.2.1.1

of whether a dialysis treatment was received on the date the drug or biological product was prescribed or dispensed, the drug or biological product is paid for under the ESRD PPS if furnished for the treatment of ESRD.

In a September 28, 2015 memorandum, CMS stated that beneficiaries with ESRD have the right to choose any Medicare-approved ESRD facility and change to another facility at any time. We further noted that provider information is therefore not communicated to MARx and cannot be reported on the TRR or be accessible to plan sponsors via the MARx User Interface, but that sponsors may use information supplied by the pharmacy, prescriber, beneficiary, or beneficiary representative to identify the beneficiary's ESRD facility.

Drugs always considered ESRD-related

Table 1 provides the current list of ESRD PPS functional categories that are <u>always</u> considered renal dialysis drugs or biological products when used as specified in the table and furnished for the treatment of ESRD to a beneficiary with ESRD receiving dialysis.

Table 1 "Always Drugs"

ESRD PPS Functional Category	**Description and Examples**
Access Management	Drugs/biological products 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/biological products used to stimulate red blood cell production and/or treat or prevent anemia. Examples of drugs/biological products in this category includes ESAs and iron.
Bone and Mineral Metabolism	Drugs/biological products used to prevent/treat bone disease secondary to dialysis. Examples of drugs/biological products in this category include phosphate binders and calcimimetics.
Cellular Management	Drugs/biological products used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

Part D plan sponsors may either place prior authorization (PA) requirements on the identified categories of "always drugs" in Table 1 or should have other mechanisms in place to ensure payment under Part D is made only when appropriate.

Part D plan sponsors should answer the question below to make the payment determination, for renal dialysis drugs and biological products:

- Is the drug or biological product prescribed to be used as specified in the table of ESRD PPS Functional Categories?
    - If yes, the drug or biological product is included in an ESRD PPS functional category and not covered under Part D.
    - If no, the drug or biological product is not included in an ESRD PPS functional category. Proceed with any further Part D claim processing.

If a drug or biological product in one of these categories is furnished to a beneficiary with ESRD receiving renal dialysis services but is furnished for a use other than what is specified in the table, it is not included in the ESRD PPS and should not be rejected for payment under Part D for this reason. Sponsors should use caution in relying on beneficiary statements about bundled payments and whether a drug or biological product is for an ESRD-related condition or not.

Drugs that may be ESRD-related

Table 2 provides the current list of ESRD PPS functional categories of drugs and biological products that may be used for ESRD-related purposes.

Table 2 Drugs that "may be" ESRD-related

ESRD PPS Functional Category	**Description and Examples**
Antiemetic	Drugs/biological products used to prevent or treat nausea and vomiting secondary to dialysis. Excludes antiemetics used in conjunction with chemotherapy as these are covered under a separate benefit category.
Anti-infectives	Drugs/biological products used to treat infections. May include antibacterial and antifungal drugs.
Antipruritic	Drugs/biological products in this category are included for their action to treat itching secondary to dialysis but may have multiple clinical indications.
Anxiolytic	Drugs/biological products in this category are included for the treatment of restless leg syndrome secondary to dialysis but may have multiple clinical indications.
Excess Fluid Management	Drugs/biological products/fluids used to treat fluid excess or fluid overload.
Fluid and Electrolyte Management Including Volume Expanders	Intravenous drugs/biological products/fluids used to treat fluid and electrolyte needs.
Pain Management	Drugs/biological products used to treat graft site pain and to treat pain medication overdose.

Drugs and biological products that fall within these functional categories are ESRD-related and included under the ESRD PPS when furnished to a beneficiary with ESRD and used as specified in the table. For example, vancomycin and daptomycin are considered included in the ESRD PPS bundled payment when furnished to a beneficiary with ESRD receiving dialysis services and used to treat access site infections. Indeed, if any other anti-infective (including oral or other forms used as a substitute for an injectable anti-infective) is used for vascular access infections or peritonitis, the drug or biological product would be a renal dialysis drug or biological product under the ESRD PPS and ineligible for separate payment.

If a drug or biological product is not furnished for the treatment of ESRD, then separate payment may be made under Part D. For example, if vancomycin or daptomycin is furnished to a beneficiary with

ESRD for uses other than to treat access site infections, the drug may be covered under Part D. In this regard we note that the drugs and biological products in these seven categories accounted for a very small percent (0.2 percent) of the payments for Medicare-allowable payments associated with ESRD PPS bundled drugs and biological products in CY 2024. Thus, when claims are submitted to Part D sponsors for drugs and biological products in these seven categories, CMS expects that these drugs and biological products are usually not being used for treatment of ESRD and may be coverable under Part D. Therefore, Part D sponsors are not expected to take special measures beyond their normal compliance and utilization review activities on these seven categories of drugs and biological products. However, if it is determined through routine utilization review or otherwise that a renal dialysis drug or biological product has been inappropriately billed to a Part D sponsor, the Part D sponsor and the ESRD facility should negotiate repayment. This includes drugs and biological products used in the treatment of ESRD that were paid under Part D prior to the sponsor receiving notification that a beneficiary with ESRD had begun a period of dialysis.

Sponsors should implement processes to handle payment resolution directly with ESRD facilities and beneficiaries without requiring the pharmacy to reverse and rebill the original claim in the retail setting. However, when the network pharmacy involved is also the ESRD facility pharmacy, as is often the case with long-term care pharmacies, reverse and rebill may be the most appropriate approach. Drugs and biological products prescribed for beneficiaries who are receiving renal dialysis services may continue to be subject to plans' standard Part D formulary management practices, which may include quantity limitations, step therapy, and PA requirements that have been approved by CMS. Nothing in this guidance should be taken as a change in the definition of a covered Part D drug or Part D payment rules or drug utilization review requirements.

CMS believes that this approach is appropriate to ensure beneficiaries have point-of-sale access to drugs and biological products in these categories that have not been prescribed for ESRD-related purposes. This approach also ensures that Part D payment ultimately is not made for the drugs and biological products in these categories when furnished to beneficiaries for the treatment of ESRD.

If you have any questions about the ESRD PPS functional categories, please contact CMS ESRD Payment via email at ESRDPAYMENT@cms.hhs.gov. Questions concerning the Part D claims payment guidance should be directed to PartDPolicy@cms.hhs.gov.

Appendix A: Previous Part D ESRD PPS Guidance

Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 5, 2010, pp. 57-58

HPMS Memorandum, "Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment", January 13, 2011

HPMS Memorandum, "Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment", February 17, 2011

HPMS Memorandum, "Clarification of Exclusion of Part D Payment for Drugs Included in the End-Stage Renal Disease Prospective Payment", May 5, 2011

HPMS E-Mail, "Reminder of Retrospective Notice Requirements for End-Stage Renal Disease (ESRD)-related Prior Authorization Formulary Changes", June 13, 2011

Announcement of Calendar Year (CY) 2014 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 1, 2013, pp. 134- 138

HPMS E-Mail, "Two Reminders Regarding Payment for ESRD Beneficiaries under Part D", January 31, 2014

HPMS Memorandum, "Two Updates Pertaining to End-Stage Renal Disease (ESRD)-Related Drugs", May 12, 2015

Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements Section 20.2 and Appendix C (ESRD content), January 15, 2016

HPMS Memorandum, "Sensipar® (cinacalcet) Furnished for the Treatment of ESRD Moving from Part D to ESRD PPS, Effective January 1, 2018", August 18, 2017

HPMS Memorandum, "Inclusion of Oral-Only Drugs in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Bundled Payment beginning January 1, 2025", December 20, 2024