

Overview of Existing Medicare Policy Related to Drugs and Biological Products Under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS).

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Purpose of This Document

This document provides an educational overview of existing Medicare policy regarding payment for drugs and biological products under the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS). The goal is to consolidate and reiterate previously issued CMS guidance to support understanding of current policy.

This article is **educational only** and:

- does not introduce new Medicare payment, coverage, or contracting requirements;
- does not establish new operational expectations; and
- does not modify existing ESRD PPS policy.

Overview of Drug Payment Under the ESRD PPS

Under the ESRD PPS, Medicare makes a single bundled payment to ESRD facilities for renal dialysis services furnished to Medicare beneficiaries. The bundled payment generally includes:

- dialysis-related items and services;
- diagnostic laboratory tests furnished for ESRD treatment; and
- all renal dialysis drugs and biological products used in the treatment of ESRD.

These policies are established through statute, regulation, and longstanding CMS guidance.

Furnishing of Drugs and Biological Products Under Existing Policy

Consistent with current ESRD PPS policy, CMS does not prescribe a specific operational or distribution model for drugs and biological products included in the ESRD PPS bundled payment. ESRD facilities must furnish all covered renal dialysis items and services either directly or under arrangements.

Depending on clinical and operational circumstances, renal dialysis drugs and biological products may be furnished through a variety of arrangements that are consistent with Medicare requirements. These arrangements may involve different entities participating in the furnishing or distribution of drugs, such as:

- ESRD facilities,
- hospital-based arrangements,
- pharmacies, including independent pharmacies, or
- other suppliers operating in accordance with applicable Medicare rules.

CMS policy does not require or favor the use of any particular entity or model.

Existing CMS Guidance and MLN Resources

This article summarizes and consolidates information previously addressed in CMS guidance, including but not limited to:

- **MLN Matters® Article MM 14313** – *ESRD and Acute Kidney Injury Dialysis: CY 2026 Update: Outlines updates to the ESRD PPS and AKI dialysis payment for CY 2026, including base rate, outlier policies, and TDAPA amounts* (<https://www.cms.gov/files/document/mm14313-esrd-acute-kidney-injury-dialysis-cy-2026-update.pdf>)
- **MLN Matters Article MM 14089** – ESRD Prospective Payment System: July 2025 Update: Details the July 2025 updates to the ESRD PPS, including changes to the outlier services list and costs for certain drugs. (<https://www.cms.gov/files/document/mm14089-esrd-prospective-payment-system-july-2025-update.pdf>)

- **MLN Matters® Article MM13608** – *ESRD Prospective Payment System Update: Announces the TDAPA for HCPCS code J0911 (taurolidine and heparin sodium) and provides an updated list of outlier services.* (<https://www.cms.gov/files/document/mm13608-esrd-prospective-payment-system-quarterly-update.pdf>)
- **MLN Matters® Article MM13445** – ESRD and Acute Kidney Injury Dialysis Updates: Provides the CY 2024 rate updates for ESRD PPS, including information on TDAPA drugs like difelikefalin and daprodustat. (<https://www.cms.gov/files/document/mm13445-esrd-acute-kidney-injury-dialysis-cy-2024-updates.pdf>)
- **MLN Matters Article MM13275** – ESRD Prospective Payment System: October 2023 Update: Discusses the TDAPA for daprodustat (J0889) and updates the ICD-10-CM codes for comorbidity payment adjustments. (<https://www.cms.gov/files/document/mm13275-esrd-prospective-payment-system-october-2023-update.pdf>)
- **MLN Matters Article MM12978** – ESRD and Acute Kidney Injury Dialysis: CY 2023 Updates: Details updates to the ESRD PPS and payment for renal dialysis services for patients with AKI, including TDAPA and TPNIES information. (<https://www.cms.gov/files/document/mm12978-esrd-acute-kidney-injury-dialysis-cy-2023-updates.pdf>)
- **MLN Matters Article MM12583** – Quarterly Update to the End-Stage Renal Disease Prospective Payment System (ESRD PPS) : Describes the Transitional Drug Add-on Payment Adjustment (TDAPA) for the new renal dialysis drug, difelikefalin. (<https://www.cms.gov/files/document/mm12583-quarterly-update-end-stage-renal-disease-prospective-payment-system-esrd-pps.pdf>)
- **MLN Matters Article MM12011** – Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis: Explains the transition of calcimimetics from TDAPA to the ESRD PPS base rate and their eligibility for outlier payments. (<https://www.cms.gov/files/document/mm12011.pdf>)
- **MLN Matters Article MM10851** – Implementation of Healthcare Common Procedure Coding System (HCPCS) Code J3591 and Additional Changes for End Stage Renal Disease (ESRD) Claims: Announces the implementation of a new HCPCS code for unclassified drugs or biological products for ESRD. (https://www.cms.gov/sites/default/files/2021-03/MM10851_0.pdf)
- **MLN Matters Article MM3176** – Clarification of Billing for Separately Billable End Stage Renal Disease Drugs: Clarifies the billing procedures for separately billable ESRD injectable drugs and administration supply charges. (<https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3176.pdf>)
- **N/A** – Including Oral-Only Drugs in the ESRD PPS Bundled Payment: Explains the inclusion of oral-only drugs into the ESRD PPS bundled payment effective January 1, 2025. (<https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf>)
- Annual ESRD PPS Final Rules. (<https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-payment-regulations-and-notices>)
- Medicare manuals including sub-regulatory guidance related to renal dialysis services, including renal dialysis drugs and biological products.
 - Medicare Claims Processing Manual, Chapter 8. (<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf>)
 - Medicare Benefit Policy Manual, Chapter 11. (<https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf>)

Readers should refer to these existing resources for more detailed policy information.

Key Takeaway: The ESRD PPS provides a bundled payment framework that includes all renal dialysis drugs and biological products and allows ESRD facilities flexibility in how they furnish renal dialysis services, consistent with existing Medicare policy.

This document is intended solely to support understanding of current policy and does not reflect new or revised CMS expectations.