

# **ESRD PPS Operational Guidance: XPHOZAH™ (tenapanor) Inclusion in the Medicare ESRD PPS Bundled Payment**

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## **Purpose of This Document**

This document provides operational guidance for End-Stage Renal Disease (ESRD) facilities submitting claims to Medicare Administrative Contractors (MACs) for renal dialysis services provided to Medicare beneficiaries.

## **What You Need to Know**

- XPHOZAH™ (tenapanor) is included in the ESRD Prospective Payment System (PPS) bundled payment effective January 1, 2025.
- This inclusion is based on Medicare statutory requirements at section 1881(b)(14) of the Social Security Act and is not dependent on drug manufacturer election or participation.
- ESRD facilities are responsible for furnishing renal dialysis service drugs either directly or under arrangements.
- Drug manufacturer distribution or reimbursement strategies do not override Medicare ESRD PPS requirements.

This article is informational only and does **not** announce new policy or change existing policy.

## **Background**

CMS finalized a requirement under 42 C.F.R. § 413.174(f)(6) that oral-only renal dialysis drugs are included in the ESRD PPS effective January 1, 2025. CMS identified XPHOZAH™ (tenapanor) as a renal dialysis service under the ESRD PPS because it is used to treat or manage a condition associated with ESRD. CMS also determined that this drug qualified as an oral-only drug as defined at § 413.234(a). CMS has stated that, effective January 1, 2025, XPHOZAH™ is included in the ESRD PPS using the drug designation process at 42 C.F.R. § 413.234. See <https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf>.

## **ESRD Facility Responsibility**

Under the ESRD PPS, ESRD facilities are responsible for furnishing renal dialysis services, including renal dialysis drugs, either:

- Directly, or
- Under arrangements, consistent with CMS payment and operational requirements.

For drugs designated as renal dialysis services, CMS policy assumes ESRD facility accountability for ensuring access to beneficiaries. Because these drugs are not separately payable to other Medicare providers or suppliers for ESRD patients, ESRD facilities must provide them in a manner that ensures beneficiaries have access when medically necessary as part of the dialysis treatment. ESRD facility arrangements with outside suppliers, such as pharmacies, must support this obligation and may not shift responsibility to the beneficiary.

## **Guidance Regarding Manufacturer Communications**

ESRD facilities may have received communications indicating that:

- XPHOZAH™ is not distributed or paid for by dialysis organizations; and

- The drug should be accessed through a specialty pharmacy outside the ESRD facility setting.

Manufacturer messaging does not supersede CMS ESRD PPS policy. When a drug is designated as a renal dialysis service under the ESRD PPS, ESRD facilities remain responsible for furnishing it to ESRD beneficiaries directly or under arrangements, regardless of manufacturer distribution preferences. The ESRD PPS payment is meant to encompass all renal dialysis services, including these drugs when medically necessary.

### **Operational Expectations**

Consistent with ESRD PPS requirements, CMS expects ESRD facilities to:

- Treat XPHOZAH™ as a renal dialysis service drug included in the ESRD PPS bundled payment effective January 1, 2025.
- Establish appropriate procurement, contracting, or “under arrangements” pathways to ensure beneficiary access.
- Avoid directing patients or prescribers to external pharmacy pathways that shift responsibility outside the ESRD facility when the drug is furnished for ESRD or Acute Kidney Injury (AKI) patients.
- Ensure that care decisions and beneficiary access are not delayed due to manufacturer reimbursement positioning.

### **Program Integrity and Access Considerations**

CMS expects ESRD facilities to operationalize bundled renal dialysis services in a manner that supports timely and equitable access for Medicare beneficiaries with ESRD and AKI..

Failure to align ESRD facility operations with ESRD PPS policy may result in:

- Patient care delays,
- Inconsistent access across ESRD facilities, and
- Payment and program integrity concerns, including cost-shifting and billing confusion.
- Denial of Medicare payments due to non-compliance with ESRD Facility Conditions for Coverage at 42 CFR part 494.90.<sup>1</sup>

### **Action Required**

ESRD facilities should:

- Review internal pharmacy and contracting pathways to assess beneficiary access for renal dialysis drugs.
- Identify and resolve operational barriers (for example, sourcing, contracting, or formulary processes).
- Direct policy questions to CMS ESRD payment contacts or their MAC rather than relying solely on manufacturer reimbursement guidance.

### **Additional Information**

This document provides information regarding existing ESRD PPS policy. It does not establish new requirements and does not modify current regulations. For questions, contact your MAC or the ESRD PAYMENT Mailbox.

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<sup>1</sup> To qualify for payment under [42 CFR part 413.210\(a\)](#), ESRD facilities must meet the conditions for coverage at [42 CFR part 494](#).