Including Oral-Only Drugs in the ESRD PPS Bundled Payment

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Under 42 C.F.R. § 413.174(f)(6), effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided. Although we included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014, and later updated it based on legislation to the current date of 2025. In the CY 2016 ESRD PPS final rule, CMS updated regulations at 42 C.F.R. § 413.174(f)(6) to incorporate ESRD drugs and biological products with only an oral form into the ESRD PPS bundled payment beginning January 1, 2025.

CMS will use the same process that it used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025, which was further discussed in MLN Matters Number: MM10065. We are not following this process for any other oral drugs or biological products. For renal dialysis drugs or biological products that are not phosphate binders, manufacturers would need to apply for Healthcare Common Procedure Coding System (HCPCS) codes and the Transitional Drug Add-on Payment Adjustment (TDAPA) for such drugs to be considered for TDAPA payment. Under our current policy (80 FR 69027; 87 FR 67180), if no injectable equivalent (or other form of administration) of phosphate binders is approved by the Food and Drug Administration prior to January 1, 2025, then we will pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will then undertake rulemaking to modify the ESRD PPS base rate to account for the cost and utilization of phosphate binders in the ESRD PPS bundled payment. Any new oral renal dialysis drug or biological product which is not a phosphate binder would have to follow the existing TDAPA application process described at 42 C.F.R. § 413.234. New renal dialysis drugs and biological products that do not follow the TDAPA application process under 42 C.F.R. § 413.234 would be incorporated into the ESRD PPS with no TDAPA.

Payment:

- ESRD facilities will receive payment of the TDAPA for phosphate binders listed in this guidance and those that apply for HCPCS codes on or before October 1, 2024, automatically for at least two years, followed by a modification to the ESRD PPS base rate, if appropriate.
- Pricing for phosphate binders under the TDAPA will be based on pricing methodologies available under section 1847A of the Social Security Act. A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP). If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Under these established methodologies, CMS will make payment under the TDAPA for at least two years (subject to the receipt of ASP data as provided by 42 C.F.R. § 413.234(c)) for each phosphate binder listed in this guidance and those that apply for HCPCS codes on or before October 1, 2024, based on 100 percent of ASP or WAC or the payment amount based on the drug manufacturer's invoice as available beginning January 1, 2025. CMS is soliciting comment in the CY 2025 ESRD PPS proposed rule about the extent to which 100 percent of ASP is appropriate for the TDAPA payment amount for phosphate binders and may finalize a

change to this amount after considering comments on this topic.

- ESRD facilities will not receive separate payment for the unused portion of a prescription for ESRD drugs and biological products with only an oral form after the base rate has been modified as appropriate for phosphate binders. CMS encourages ESRD facilities to develop education and strategies for managing the prescription of the appropriate number of doses during the titration period to reduce discarded drugs.
- On October 17, 2023, a new oral phosphate lowering agent received FDA marketing approval. According to the FDA label information for this drug, XPHOZAH™ (tenapanor) is indicated to reduce serum phosphorus in adults with chronic kidney disease who are on dialysis. CMS has identified XPHOZAH™ to be a renal dialysis service because it is used to treat or manage a condition associated with ESRD. Specifically, it is used as an add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. CMS has also determined that XPHOZAH™ meets the current regulatory definition of an oral-only drug as defined at § 413.234(a), and therefore, in accordance with § 413.174(f)(6), is not paid for under the ESRD PPS until January 1, 2025. Consistent with policies adopted in the CY 2016 and CY 2023 ESRD PPS final rules (see 80 FR 69025 and 87 FR 67183), XPHOZAH™ will be included in the ESRD PPS effective January 1, 2025, using the drug designation process under § 413.234. We are not using the process that we established for calcimimetics and phosphate binders for any other oral drugs or biological products. For any other renal dialysis drugs or biological products, including XPHOZAH™, manufacturers would need to apply for a HCPCS code and the TDAPA to be considered for TDAPA payment.
- The JW and JZ modifiers apply only to renal dialysis drugs and biological products from a single-dose container or single-use package. We do not expect that phosphate binders will be supplied in single-dose containers or single-use packages; thus, we do not expect phosphate binders to be subject to the ESRD PPS JW and JZ modifier reporting policies under 42 C.F.R. § 413.198(b)(5)(ii) & (iii).
- Renal dialysis drugs or biological products that are not paid for using the TDAPA would be considered for outlier payment, if the drug or biological product meets the definition of an ESRD outlier service at 42 C.F.R. § 413.237(a)(1) and all criteria for the outlier payment adjustment are met. Drugs or biological products without a HCPCS code that are ESRD outlier services can be billed using the National Drug Code (NDC) of the drug provided.

Coding:

CMS has a long-standing convention to assign dose descriptors in the smallest amount that could be billed in multiple units to accommodate a variety of doses and support streamlined billing. This long-standing policy makes coding more robust and facilitates accurate payment and reporting of the exact dose administered. Following this long-standing convention, in preparation for timely TDAPA payment beginning January 1, 2025, CMS has established the following HCPCS codes for use in billing generic phosphate binders under the ESRD PPS. We note that the effective date for these codes will be January 1, 2025 and they will be listed on the HCPCS Level II code file beginning with the October 2024 quarterly update. The HCPCS codes we are establishing are as follows:

- J0601, "Sevelamer carbonate (Renvela or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis)"
- J0602, "Sevelamer carbonate (Renvela or therapeutically equivalent), oral, powder, 20 mg (for ESRD on dialysis)"

- J0603, “Sevelamer hydrochloride (Renagel or therapeutically equivalent), oral, 20 mg (for ESRD on dialysis)”
- J0605, “Sucroferric oxyhydroxide, oral, 5 mg (for ESRD on dialysis)”
- J0607, “Lanthanum carbonate, oral, 5 mg (for ESRD on dialysis)”
- J0608, “Lanthanum carbonate, oral, powder, 5 mg, not therapeutically equivalent to J0607 (for ESRD on dialysis)”
- J0609, “Ferric citrate, oral, 3 mg ferric iron, (for ESRD on dialysis)”
- J0615, “Calcium acetate, oral, 23 mg (for ESRD on dialysis)”

For any other oral renal dialysis drug or biological product that is not assigned a HCPCS code, ESRD facilities would report the NDC of the drug on the claim form.

Important Timeframes:

- Pharmaceutical manufacturers should supply Average Sales Price (ASP) information as quickly as possible, but no later than October 30, 2024, for pricing information to be available for TDAPA payment beginning January 1, 2025. All the required information and required links are available at the Average Sales Price (ASP) Reporting webpage. Additional information can be found at ASP Education & Outreach | CMS along with educational videos. ASP regulations are available at: ASP Regulations & Policy | CMS.
- The regulations regarding ASP reporting and how to calculate the ASP can be found in sections 1847A and 1927(b) of the Social Security Act and codified in regulation text at 42 C.F.R. part 414, subpart J. Section 401 in the Consolidated Appropriations Act, 2021 requires all drug manufacturers to report average sales price (ASP) for drugs and biological products covered under Medicare Part B. It also adds a new requirement that drug manufacturers without a rebate agreement must report ASP.
- Pharmaceutical manufacturers may apply to CMS for HCPCS codes for their proprietary phosphate binders by October 1, 2024, for inclusion in the TDAPA calculation beginning January 1, 2025, if such proprietary phosphate binders are not adequately represented by the HCPCS codes listed above in this guidance document.

All questions related to ESRD PPS payment policy can be directed to CMS ESRD PAYMENT.