

# CAPITOL STREET

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November 1, 2024

## +2.8% Dialysis Final Pay (Up 50bps) For 2025

Phosphate Binders Receive 100% ASP +\$36 (vs. 106% ASP)

Relevant Companies



CSL Vifor

AMGEN



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## »» Our Take & Next Up

**CMS dialysis pay for 2025 is improved at +2.8% (up from 2.3% in proposal) for large dialysis organizations (DVA, FMS) with CMS moving ahead on incorporating oral drugs into the bundle and providing an add-on fee (100% average sale price (ASP) + \$36 for phosphate binders vs. 106% ASP proposed).** The agency accepted comments and final CY25 rates start Jan 1, 2025. CMS released the final 2025 end-stage renal disease (ESRD) (PPS) rates after the close of the US markets today [here](#). The agency accepted comments and final CY25 rates start Jan 1, 2025. In a win for home dialysis providers, AKI (acute kidney injury) patients will be able to access home dialysis. Phosphate binders get 100% ASP + \$36 (instead of 106% ASP, as proposed by CMS). We do not view legislation addressing a two year delay in oral inclusion as terribly likely in 2024, but we will watch for movement given the almost minuscule spending (<\$1B) for a two year punt. See *major policies & legislative updates below*.

## »» Key Points

**The overall ESRD payment update is +2.7%, a \$220 M increase, positive for large dialysis organizations (LDOs) — DVA, FMS.** Medicare expects to pay \$6.2 B to approximately 7,700 ESRD facilities for furnishing renal dialysis services. This includes pay update (MB, or +2.2%), updates to the outlier policy (+0.5%, versus 0.4% proposed) and to the wage index (0.0%). This amounts to an increase of approximately \$260 M in Medicare payments to ESRD facilities; \$220 M associated with the payment rate update, the updated post-TDAPA add-on payment adjustment amounts, and continuation of the approved TDAPA. This also includes approximately \$40 M for the additional TDAPA payment for operational costs in excess of 100% of ASP for phosphate binders, which is derived from 6% of per-patient phosphate binder spending based on utilization and cost data.

**Oral-only drugs will be included in the ESRD PPS bundled payment as per current law.** Starting in 2025, payment to an ESRD facility for oral-only renal dialysis service drugs and biological products is included in the ESRD PPS bundled payment. This includes phosphate binders (*see below, for separate payments*). CMS expects that incorporation of oral-only drugs and biological products into the PPS will increase access to these drugs, as CMS has seen previously that incorporating Part D drugs into the bundle has had a significant positive

effect on expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage, with significant positive health equity impacts.

**Phosphate binders will get 100% ASP + \$36.41 (dispensing costs, storage of phosphate binders) instead of 106% ASP (as proposed by CMS).** CMS believes that paying 106% of ASP could potentially incentivize ESRD facilities to prescribe higher-cost phosphate binders to receive additional payment. CMS will finalize a policy to pay the TDAPA for phosphate binders based on 100% of ASP, increased by a fixed amount of \$36.41 for incremental costs such as dispensing and storage of phosphate binders, which will be added to any monthly claim for which there is a TDAPA payment for phosphate binders.

**Recall industry is trying to push oral only inclusion start date out by two years, but *PATIENT Act* passage is unlikely in 2024 (and may be moot in 2025+).** On the legislative side, the *Kidney PATIENT (Patient Access to Technologically Innovative and Essential Nephrology Treatments) Act* is about budget neutral. The bill prohibits CMS from moving oral ESRD drugs into the bundle until 2027 (two-year delay), or until new intravenous therapies are FDA approved. The bill has bipartisan support but is low on the healthcare / extender totem pole for lame duck 2024 (Nov-Dec). The Act passed out of both the House Energy & Commerce (Chair McMorris Rodgers, R-WA) and Ways & Means Committee (Chair Smith, R-MO) in March 2024.

**Positively, expansion of home dialysis coverage for acute kidney injury (AKI) is finalized.** Under current Medicare regulations, CMS covers only in-center hemodialysis for beneficiaries with acute kidney injury (AKI) who are not hospitalized. The payment amount for home dialysis for AKI beneficiaries would be the same as the payment amount for in-center dialysis for AKI beneficiaries.

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