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August 14, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Blvd  
Baltimore, MD 21244–1850

**Re: CMS–1782–P: End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model**

Dear Administrator Brooks-LaSure:

The American Kidney Fund appreciates the opportunity to provide comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule referenced above.

The American Kidney Fund (AKF) fights kidney disease on all fronts as the nation's leading kidney nonprofit. AKF works on behalf of the 37 million Americans living with kidney disease, and the millions more at risk, with an unmatched scope of programs that support people wherever they are in their fight against kidney disease—from prevention through transplant. Through programs of prevention, early detection, financial support, disease management, clinical research, innovation and advocacy, no kidney organization impacts more lives than AKF. AKF is one of the nation's top-rated nonprofits, investing 97 cents of every donated dollar in programs, and holds the highest 4-Star rating from Charity Navigator and the Platinum Seal of Transparency from GuideStar.

In this letter, we focus our comments on the proposed CY 2024 market basket update and the proposed new add-on payment adjustment for certain new renal dialysis drugs and biological products after the transitional drug add-on payment adjustment (TDAPA) period ends.

AKF is also a member of Kidney Care Partners (KCP), an alliance of members of the kidney care community. In addition to our comments below, we support the comments that KCP has submitted.

**Proposed CY 2024 Market Basket Update**

AKF is deeply concerned that the proposed CY 2024 market basket update of 1.7 percent (after accounting for the productivity adjustment) does not accurately reflect the increase in health care inflation and the increased cost of labor that ESRD facilities face. Medicare beneficiaries with ESRD already confront significant health disparities, and the continued misalignment between the market basket and actual inflation only exacerbates those health disparities for the ESRD population. Appropriate payment to providers is critical to ensure facilities can hire and retain the clinical staff that is necessary to provide quality care. We urge CMS to adopt a forecast error adjustment for CY 2024 that is similar to the one used in the Skilled Nursing Facility (SNF) PPS and that was first introduced in 2004.

As described in KCP’s comment letter, we recommend that CMS adopt a forecast adjustment that would make a cumulative market basket forecast adjustment reflecting the under-forecast since the 2019 rebasing of the ESRD PPS, or alternatively, since the beginning of the ESRD PPS. If CMS were to adopt an adjustment that encompasses 2019 through 2022 (the most recent year when actual market basket inflation data are available), the total adjustment based on the difference between the market basket forecast and the actual market basket increase would be an increase of a little more than 4.0 percent (see figure 1). We ask that CMS calculate the cumulative forecast error and compare it to the threshold as a total percentage rather than applying the threshold on a year-to-year basis for the initial adjustment (as CMS did with the initial application of the SNF adjustment).

**Figure 1: 2019-2022 Retrospective Application of Forecast Error Adjustment**

MB Base Year	2016				Unadjusted Total Forecast Miss (percentage points)
	2019	2020	2021	2022	
<b>ESRD PPS Final Rule</b>					
<b>Unadjusted Final MB Update</b>	2.1	2	1.9	2.4	
<b>Actual MB Inflation (per IGI Global methodology)</b>	2.3	1.9	3.1	5.1	
<b>Final MB Update Compared to Actual (forecast error)</b>	-0.2	0.1	-1.2	-2.7	-4.0

For subsequent years, we recommend that CMS continue the use of the forecast error adjustment and apply a threshold to these annual rate adjustments of +/-0.5 percentage points, which is the same threshold percentage CMS finalized for the SNF forecast error adjustment. We also recommend that an ESRD forecast adjustment be applied uniformly, such that it is applied

not only when the forecasted percent change is lower than the actual percent change, but also when the forecasted percent change is higher than the actual percent change.

Medicare beneficiaries on dialysis are experiencing the impact of inadequate payment due to market basket updates that do not accurately reflect rising costs for labor, supplies and equipment. Facilities that rely primarily on Medicare rates are struggling to hire and retain qualified health care professionals such as nurses, dialysis technicians and dieticians, as they compete with other health care and non-health care employers who can offer higher wages and pass on those increased costs to consumers. Due to staff shortages, there are fewer personnel than needed at facilities and patients are experiencing reduced access. Patients medically ready to be discharged from hospitals have had to remain in the hospital for additional days until spots become available at dialysis facilities. Some patients have had their facility closed or shifts eliminated due to difficulties finding enough qualified staff to ensure patient safety.

Inadequate payment rates to facilities are impacting patient access to care and the patient experience. Adopting a forecast error adjustment, for which there is precedent in the SNF PPS, would help provide a more appropriate payment that accurately accounts for rising costs and safeguards patient access to quality care.

### **Proposed New Add-On Payment Adjustment for Certain New Renal Dialysis Drugs and Biological Products After the TDAPA Period Ends**

AKF is pleased to see CMS propose, beginning in January 1, 2024, an add-on payment adjustment for new renal dialysis drugs and biological products in existing ESRD PPS functional categories after the end of the TDAPA period. AKF has advocated in previous rulemaking cycles that to ensure the long-term adoption of innovative treatments in existing functional categories for ESRD beneficiaries, CMS needs to ensure adequate payment after the TDAPA period ends.

Compared to other conditions such as cardiovascular disease and cancer, there has not been the same level of innovation for people with ESRD and receiving dialysis, despite the dramatic increase in kidney disease over the last two decades. Between 2000 and 2019 (the last pre-pandemic year) the incident count of ESRD increased from 94,466 to 134,862, an increase of 42.8%.<sup>1</sup> The number of individuals with prevalent ESRD increased by 107% during that same period, reaching a peak of 808,330 in 2019.<sup>2</sup> The alarming increase in ESRD has disproportionately impacted people from communities of color, particularly Black individuals, as the adjusted prevalence among Black individuals in 2019 (6437 per million population) was nearly double that of Hispanic individuals (3474 pmp), nearly triple that of Asian individuals (2361 pmp), and more than quadruple that of White individuals (1504 pmp).<sup>3</sup> Given that Medicare beneficiaries on dialysis are disproportionately from communities of color, have disabilities, and

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<sup>1</sup> 2022 USRDS Annual data report. National Institute of Diabetes and Digestive and Kidney Diseases. <https://usrds-adr.niddk.nih.gov/2022>. Published 2022.

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

have lower incomes compared to all Medicare FFS beneficiaries, ensuring access to innovative treatments is a critical step to advance health equity.

We commend CMS for agreeing with concerns in the kidney community that “a sudden decrease in payments after the end of the TDAPA for these products could result in a decrease in access for these new renal dialysis drugs and biological products.” We also agree with CMS’ goals for proposing a post-TDAPA add-on payment adjustment, which include ensuring payment after the TDAPA is not a barrier to beneficiaries’ access to new renal dialysis drugs and biological products; supporting ESRD facilities in their long-term planning with respect to these products; and incentivizing ESRD facilities to be efficient in the use of resources.

AKF strongly supports a post-TDAPA add-on payment adjustment in principle, and we support certain aspects of CMS’ proposal. Namely, we support CMS’ proposal to apply the post-TDAPA payment adjustment at the end of TDAPA; to apply it in a non-budget neutral manner; to use the most recent average sales price (ASP) and utilization data in calculating the add-on payment adjustment; and to update the amount annually using the ESRD PPS market basket update or the growth in the market basket price proxy for the pharmaceutical cost category.

However, we have significant concerns with major components of CMS’ proposal that we believe need to be addressed for the post-TDAPA add-on payment adjustment to achieve CMS’ stated goals. In the following section, we provide recommendations for each element of CMS’ proposal in which we have serious concerns and provide a rationale for how the recommended changes would better ensure beneficiary access to innovative and needed treatments.

**CMS proposal:** apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments. CMS proposes to use the most recent available 12 months of claims data to calculate the total expenditure of the new renal dialysis drug or biological product being paid for using TDAPA under the ESRD PPS. Total expenditure would be calculated by multiplying the latest available full calendar quarter of ASP data for the new product by the quantity of units billed. Then it would divide the total expenditure of the new product by the total number of ESRD PPS payments furnished during the same 12-month period. The resulting quotient would be the post-TDAPA add-on payment adjustment that would be applied to each ESRD PPS payment before accounting for case-mix standardization.

**AKF recommendation:** apply the post-TDAPA add-on payment adjustment only to claims for patients who receive the new renal dialysis drug or biological product. CMS should calculate total expenditure of the new product using the most recent ASP and utilization data, as it proposes, but it should then divide total expenditure of the new product by the number of treatments with claims for the new product, instead of the total number of ESRD PPS payments. CMS should then apply that resulting post-TDAPA add-on payment adjustment only to claims for patients who received the new product.

**Rationale for AKF recommendation:** a more targeted approach in which the post-TDAPA add-on payment adjustment follows the patient better aligns payment and costs for the new product and would be a more effective way to ensure patient access to innovative treatments. This is especially true for new renal dialysis drug and biological products that a smaller portion of the ESRD population medically requires.

CMS reasons that in proposing to apply the post-TDAPA add-on payment adjustment to all ESRD PPS payments, it would create incentives for ESRD facilities to efficiently allocate resources, promote competition among products within the ESRD PPS functional categories, and help support access to new renal dialysis drugs and biological products to the widest scope of beneficiaries.

However, applying the post-TDAPA add-on payment adjustment to all ESRD PPS payments would have the opposite effect. This approach dilutes the add-on payment adjustment across all ESRD PPS payments, inefficiently distributes it to patients who are not receiving the new drug and provides insufficient funding for the patients who do require the drug. Applying the post-TDAPA add-on payment adjustment to all ESRD PPS payments disincentivizes the use of new drugs and biologicals to the patients who require them. As the case study of Korsuva demonstrates (and described further in this letter), CMS' proposal would result in an additional 9 cents to all ESRD PPS payments, which is woefully insufficient to cover the cost of that drug and ensure patient access to the treatment.

In the end, CMS' proposed approach would result in a slight increase to the base rate for all beneficiaries, but nothing to show for it. Funding for new renal dialysis drugs or biological products after the TDAPA period would be inadequate and barriers to patient access and innovation would persist. Competition among products within the ESRD PPS functional categories would not materialize because innovation in renal dialysis drugs and biological products would be stifled, as CMS' proposed approach would not provide a viable and sufficient funding mechanism after the TDAPA period. Essentially, CMS' proposed approach defies the concepts of proper incentives and competition to drive improved access to innovative products. However, CMS has implemented payment adjusters in other prospective payment systems that properly align incentives to safeguard patient access to innovative treatments, such as in the hospital outpatient prospective payment system, which we discuss further below.

Applying the post-TDAPA add-on payment adjustment only to claims for patients who receive the new product is a sounder approach that appropriately align payment and costs and will result in more efficient use of resources, fosters competition among products in the ESRD PPS functional categories, and ensures patients who require the new products have access to them.

**CMS proposal:** apply a 65 percent risk sharing factor to the post-TDAPA add-on payment adjustment, in lieu of reconciling estimated expenditures for a new renal dialysis drug or biological product with the declines in expenditures for related drugs.

**AKF recommendation:** apply an offset to the post-TDAPA add-on payment adjustment amount that accounts for products in the TDAPA product's functional category that are directly impacted by the new product. As we recommended in our comment to the Request for Information (RFI) in the CY 2023 PPS proposed rule, CMS should calculate an offset to the post-TDAPA add-on payment adjustment that reconciles the average expenditure per treatment for the renal dialysis drug or biological product that was paid for using the TDAPA with the reduction in expenditures for other formerly separately billable renal dialysis drugs or biological products that were caused by the inclusion of the new product.

CMS should use the primary indication on the FDA label to determine the clinical association between the new product and other formerly separately billable renal dialysis products. This approach should then be combined with empirical evidence using dialysis claims data that shows a significant difference in the utilization of the formerly separately billable renal dialysis product during the TDAPA period for the new product that is directly attributable to the adoption of the new product.

**Rationale for AKF recommendation:** Calculating and applying an offset to the post-TDAPA add-on payment adjustment amount that accounts for the impact of the TDAPA product on existing products within the same functional category (i.e., with a similar FDA-approved indication) would be a principled approach to ensuring that the post-TDAPA payment is sufficient, but not duplicative of the amount already included in the ESRD PPS bundle. CMS' proposed 65 percent risk sharing factor is a blunter approach that seems less transparent and contributes to an insufficient add-on payment adjustment that will impact patient access to new renal dialysis drugs and biological products. AKF's recommendation in calculating an offset is a more tailored approach that balances the need to improve patient access to innovative treatments while also being responsible stewards of the ESRD PPS bundle.

**CMS proposal:** apply the post-TDAPA add-on payment adjustment for three years after the end of the TDAPA.

**AKF recommendation:** apply the post-TDAPA add-on payment adjustment on a permanent basis.

**Rationale for AKF recommendation:** sunseting the post-TDAPA add-on payment adjustment after three years creates another financial cliff for ESRD facilities, similar to the end of the TDAPA period. We have heard from patients and physicians that Korsuva has not been prescribed to patients who may medically benefit and despite the product's effectiveness. This is due to concerns about long-term funding for the product and providers not wanting to be in a position of ending the prescription when the TDAPA ends. Utilization data seems to back up this concern, as only about 1% of patients on hemodialysis have been treated with Korsuva, even though available data describes the prevalence of pruritus at approximately 35% of hemodialysis patients.



Making the add-on payment adjustment permanent would provide long-term certainty and predictability for manufacturers and ESRD facilities, and create a payment structure that better protects patient access to innovative treatments that can improve their quality of life and clinical outcomes. There is also precedent for CMS to make the add-on payment adjustment permanent. For example, the hospital outpatient prospective payment system (HOPPS) has permanent payment adjusters and other mechanisms that recognize the needs of patients who may require different clinical treatments and resource use from the average patient. HOPPS has a complexity adjustment that is similar to our recommendation that the post-TDAPA add-on payment adjustment be applied to claims in which the patient received the new product. Therefore, there is a precedent for CMS to support higher adjustments to a base rate bundle on a permanent basis to ensure patient access to innovative treatments.

### **Analysis of CMS' proposed post-TDAPA add-on payment adjustment on facilities with patients prescribed Korsuva**

At AKF's request, The Moran Company conducted an analysis that examined how the three elements of CMS' proposed policy described above would impact facilities that used Korsuva, and how that would likely affect patient access to the treatment.

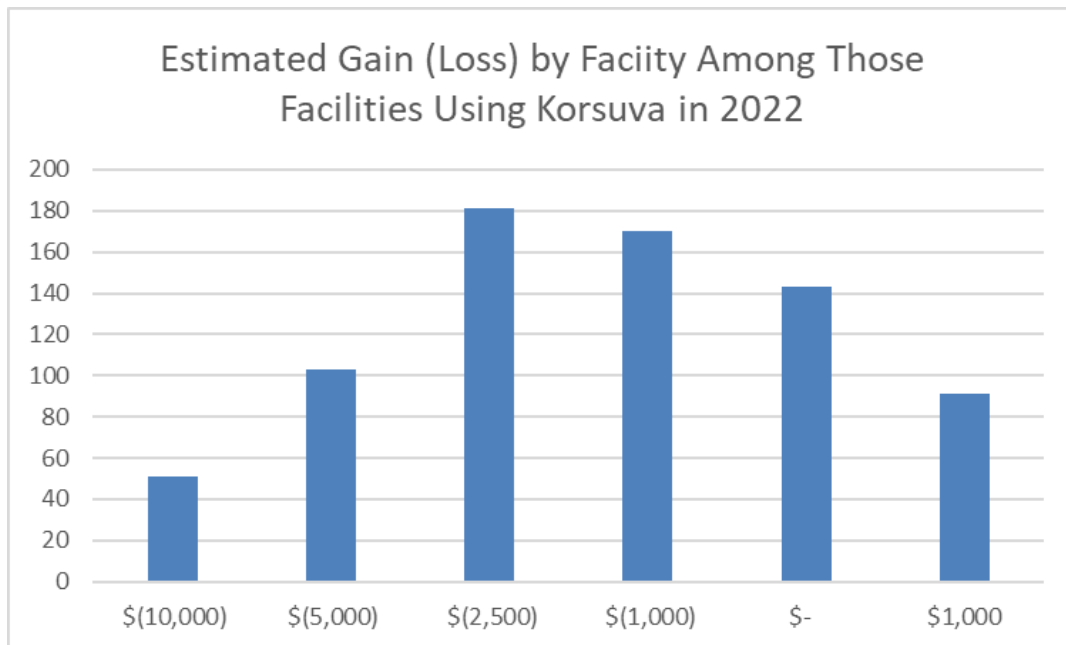
The Moran Company analyzed 2022 claims data from the Quarterly Standard Analytic Files for Q1-Q4. The analysis found that 738 facilities billed for Korsuva alongside at least one dialysis treatment. Many of these facilities billed only a small number of units of Korsuva during 2022. Overall, the analysis found that using the CMS methodology to calculate Korsuva billing across all treatments at these 738 facilities, these facilities were being reimbursed approximately \$0.80 per treatment. As noted in the proposed rule, CMS' post-TDAPA policy would result in an additional 9 cents to all ESRD PPS payments, regardless if a facility used Korsuva. Thus, the proposed post-TDAPA policy will underpay the current utilization rate at facilities that used the product by 89%. At the labeled dosage for an 80kg adult, facilities will lose over \$80 per treatment whenever they use Korsuva under this proposed policy. This demonstrates the inadequacy of the CMS policy, as CMS has chosen to average all the facilities which never used the product into the calculation.

The analysis suggests that the 51 facilities which used the most Korsuva during 2022 would lose over \$10,000 in reimbursement under CMS' proposed post-TDAPA policy (see Table 1). The top 5 Korsuva adopting facilities in 2022 would lose a combined \$250,000 in reimbursement under this policy or \$9.42 per treatment. It seems unlikely these facilities would be able to sustain a \$9.42 loss per treatment to continue delivering the product. The only Korsuva-using facilities in 2022 which are projected to benefit from the post-TDAPA policy are the 91 facilities which delivered the least amount of Korsuva in 2022. Many of these 91 facilities billed for an amount of Korsuva less than a full year for a single patient according to the Korsuva label.

As proposed by CMS, the post-TDAPA policy does not meet its stated goals. It does not adequately compensate providers of products which are used by a small proportion of the community. The proposed policy cannot preserve access to care as it financially rewards facilities

which do not offer the product to their patients. For the facilities which do use the product, it dramatically underfunds relative to current TDAPA payments and the current list price of the drug. Removing the 35% reduction or extending the policy permanently will not resolve the structural policy problem of directing funds to facilities regardless of whether they use the product on an ongoing basis.

**Table 1. Distribution of Losses and Gains under proposed Post-TDAPA Korsuva policy**



**Post-TDAPA add-on payment adjustment and beneficiary cost-sharing**

In addition to our recommendations above, AKF would like to address CMS’ concerns regarding the impact a post-TDAPA add-on payment adjustment will have on beneficiary coinsurance obligations. In explaining its rationale for its proposed approach, CMS notes that applying the add-on payment adjustment to all ESRD PPS payments will result in a minimal increase in per-treatment coinsurance amounts for all beneficiaries. AKF appreciates CMS’ concern with mitigating Medicare beneficiary cost-sharing burdens, which is an important policy priority for AKF and the people we serve. We have long advocated at the state and federal level for legislation that would guarantee access to Medicare supplemental coverage for all ESRD beneficiaries as a means of reducing this burden.

However, we believe that CMS’ concern for the beneficiary cost-sharing burden as a reason for its proposed approach to a post-TDAPA add-on payment adjustment is misplaced. The more pressing need is to establish a viable and adequate payment structure that promotes innovation



and ensures patient access to new products that can improve their daily lives. As noted above, the pace of innovation and access to new treatments for people on dialysis has been stalled for far too long. The majority of Medicare FFS beneficiaries have access to supplemental coverage or Medicaid that helps cover their cost-sharing obligations. For patients without supplemental coverage, it should be their decision, in clinical consultation with their physician, as to whether they want to assume the coinsurance amount that would come with a new and innovative product. But an appropriate post-TDAPA add-on payment adjustment structure needs to be in place for patients to have access to new products and to be able to make that decision.

Thank you for your consideration of AKF's comments and recommendations.

Sincerely,



LaVarne A. Burton  
President and CEO