



Patient Access & Equity Priorities in ESRD PPS for CY 2024

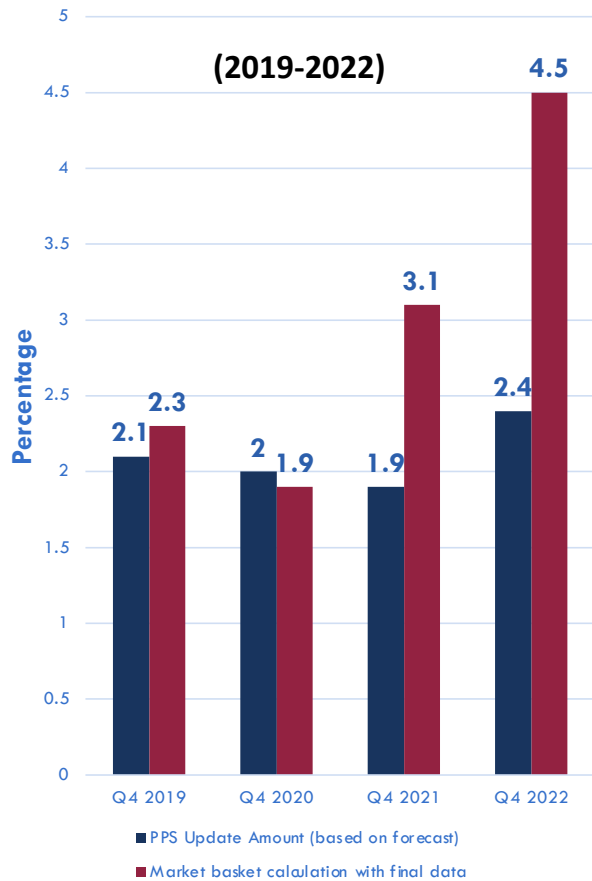
June 1, 2023



KCP Requests that the CY 2024 ESRD PPS Proposed Rule Address the Labor Crisis and Innovation

- Propose and adopt an annual adjustment to address missed forecasts
 - Forecast misses in 2021 and 2022 resulted in a significantly lower annual update percentage than actual data would have determined
 - Anticipate similar problem for 2023
- Propose and adopt a new money adjustment after the TDAPA period ends
 - Ensure that Medicare Advantage enrollees also have access to innovative products by paying TDAPA and TPNIES to facilities

Comparison of ESRD PPS Market Basket Update Percentage to Percentage Market Basket Should Have Been Using Q4 Data



ESRD PPS Annual Updates in CY 2021, 2022, and likely 2023 Do Not Reflect the Actual Rise in Costs

- The Moran Company analysis of CMS data shows that the projected increases for 2021 and 2022 were lower than actual increases for those years; concern that CY 2023 could result in a similar outcome
 - 2021 update was 1.9% - a 1.2% difference
 - 2022 update was 2.4% - a 2.1% difference (based on most recently available forecasts)
 - 2023 update will also likely under-estimate inflationary costs
- Based on the most recently available data, The Moran Company calculated that the differences between projected and actual increases in these two years creates a \$7.70 gap in funding available for dialysis treatments

Forecast Misses Limit Facilities' Ability to Address Workforce Crisis and Harms Patients

- Cost of labor increasing, but Medicare rates do not provide funds for facilities to adjust
 - Agency nurses command substantially higher rates than Medicare PPS supports
 - Many positions cannot be filled because of a lack of applicants; hospitals or other employers can offer higher salaries
- Patients already experiencing negative impact
 - Facilities having to reduce shifts
 - More than 400 facilities have closed since 2019
 - Patients required to remain hospitalized for longer periods because they cannot find a facility with sufficient staff to admit new patients
- USRDS indicates that 60% of ESRD patients are people of color; 80% of patients rely on Medicare as primary coverage
 - According to MedPAC, 53% of Medicare ESRD beneficiaries are non-white: “FFS dialysis beneficiaries are disproportionately young, male, and Black compared with all other Medicare FFS beneficiaries”
 - A decision not to address the workforce crisis will disproportionately impact people of color.

USRDS 2022 Annual Report; MedPAC
Report to the Congress (2023).

Adopting a Forecast Error Adjustment Is a Critical Step to Improve Access and Address Health Inequities

- KCP asks that the proposed rule propose adopting a forecast error adjustment policy like that applied in the SNF PPS
 - For SNF PPS, CMS calculates the difference between the forecasted and actual percentage change in the market basket index
 - If that difference is greater than 0.5%, then CMS adds the entire difference to the current year's market basket
- To address the current crisis, KCP asks that the proposal apply an adjustment in CY 2024
 - The CY 2024 rule should account for the forecast misses during 2021 and 2022 because CMS should have final data for these two calendar years
 - The adjustment would be determined for 2023 and future years in subsequent rulemakings
 - The adjustment could be an increase or a decrease, based on the difference calculated for each year

Payment Policies Drive Access to Innovative Products

- Physicians do make decisions based on payment policy – if there is no money allocated for a product, they cannot prescribe it
 - Especially problematic in the ESRD PPS, where MedPAC has found the Medicare margins to be extremely low or negative
 - MedPAC calculated the aggregate Medicare margin for CY 2023 to be **negative** 0.4%
- The lack of a post-TDAPA pathway recognizing new money for innovation has severely limited patient access to the product
 - Vast majority of patients who could benefit from Korsuva not able to access it
- The decision of many Medicare Advantage plans not to pay TDAPA has also limited access to the more than 40 percent of patients enrolled in these plans
 - If phosphate binders, which nearly all dialysis patients require, are included in the bundle and MA plans do not pay TDAPA, the impact on patients could be catastrophic
- Protecting access to innovation means Medicare adopting predictable payment policies that support innovation
 - Nearly 80% of individuals whose CKD has progressed to ESRD rely upon Medicare

KCP Appreciates RFI on Post-TDAPA Pathways and Recommends Methodology for Calculating the Add-on

- **Support an add-on approach**
- **Set at the per treatment cost for the “average” patient using the product**
 - Patient medical necessity should drive utilization
 - The TDAPA period should be for at least 3 years to allow for the use of 2 full years of data for calculation
- **Address implementation issues**
 - Available at the end of the TDAPA period, avoiding any gap period
 - Update amount annually to reflect inflationary changes
- **Support targeted offset**
 - Corresponding reduction in expenditures for drugs that are directly attributable to the addition of the product
 - Attribution of reduction determined based on a predictable, objective, transparent source – such as FDA approved indication that lists the same primary indication

KCP Seeks to Work with CMS To Address Short-Comings in the ESRD PPS to Protect Patient Access and Address Inequities

- Seek a forecast error adjustment to address increase in labor costs
- Important to propose post-TDAPA add-on adjustment as follow-up to the RFI in last year's rule
- CMS pays the TDAPA/TPNIES, as it does for pass-through products in other payment systems, then adjusts the MA rates to incorporate TDAPA