



Seeking Comment Opportunities in ESRD PPS CY 2023 Proposed Rule

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KCP Requests that CMS Seek Comments on Priority Issues in CY 2023 ESRD PPS Proposed Rule

- Recognizing the limitations in the ESRD PPS bundle for innovative products in functional categories
 - Addressing the practical problem that current market basket proxies are not capturing the exponential increase in labor costs
 - Addressing the 2025 timeline for inclusion of oral-only drugs in the ESRD PPS
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- KCP continues to support addressing the problems with the case-mix and the facility-level adjusters.
- We recognize CMS's ongoing work with the technical expert panel.
- KCP appreciate CMS's request for detailed comments in the CY 2022 rulemaking cycle.

Post-TDAPA Policy Critical to Address Inequities and Support Innovation for Individuals Receiving Dialysis

Individuals living with kidney disease have experienced fewer innovative treatment options than individuals living with other chronic diseases.

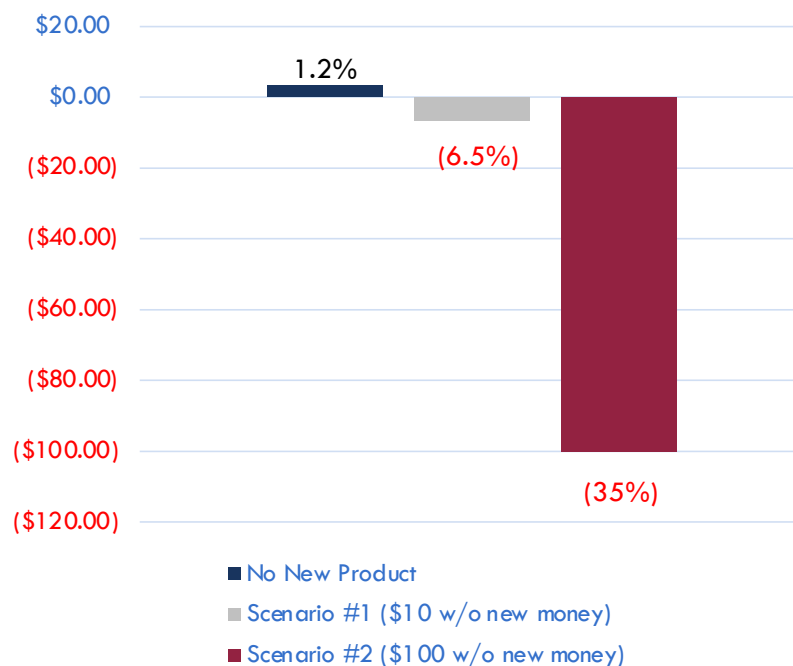
This lack of treatment innovation creates a health disparity that disproportionately affects people of color.

The Medicare program, which provides coverage for nearly 80% of individuals whose CKD has progressed to ESRD, should adopt policies that incentivize the adoption.

TDAPA is an important first step, but alone will not provide sufficient support for the long-term adoption of innovation or inspire innovators to develop new treatments for people who require dialysis.

The Moran Company Analysis Illustrates Significant Losses Regardless of Cost if New Drugs Added to Bundle without New Money

Adding New Products without New Money Is Not Sustainable
(based on MedPAC's 2022 projected facility margin)



The Outlier Pool Is Not a Solution



Source: The Moran Company analysis of CMS and MedPAC data (2022).

www.KidneyCarePartners.org

Principles for Innovative Drugs & Biologicals in the Medicare ESRD Program

- Medicare needs to signal in CY 2023 it recognizes that TDAPA alone may not be enough for some products, even in existing functional categories
- The adoption of an automatic “no new money” policy for functional category drugs creates a substantial barrier to innovation and ultimately to patient access to innovative products.
- With a new product receiving TDAPA in April 2022 and other potential products applying for TDAPA in 2022, there is an urgent need to address this problem.

One Policy Option about which CMS Could Seek Stakeholder Input

- TDAPA awarded
 - During TDAPA period, collect utilization data
- Before drug is added to the bundle,
 - Calculate amount in bundle for the competitive product
 - Calculate cost of the product (TDAPA utilization x most recent ASP data)
 - If the new product cost exceeds the amount in the base rate, then add the incremental difference
- Assess whether the drug is used by the “average” patient
 - If yes, increase the existing base rate by the incremental amount – using all treatments as the denominator
 - If no, create a separate pool/new “base rate/DRG” for patients who receive the product – using number of treatments for patients requiring that drug as the denominator
- Monitor utilization

KCP Asks CMS to Consider a Specific Labor Adjustment to Address the Unprecedented Increase in the Cost of Labor

- Recent BLS data show that the FTE has grown faster than the percentage FTE basis in the market-basket
- Shifting the labor-related share will not address this shift because of the budget neutrality requirement
- Current Q1 2022 forecast amount before the productivity reduction is 2.9%, which is significantly less than the 4.3% employment cost index for all hospital workers in Q4 2021
- CMS has the authority to implement an add-on: The authorizing statute states that the ESRD PPS “may include such other payment adjustments as the Secretary determines appropriate.”

Source: Cornell Institute for Compensation Studies “Employment Cost Index vs. CPI” (2022).

KCP Asks CMS to Address Potential for Oral-Only Phosphate Binders Being Added to the Bundle in 2025

- KCP members continue to have practical implementation concerns about adding oral-only products to the ESRD PPS
 - Phosphate binders are not administered in the facility
- Ideally, CMS would exercise its existing authority to exclude phosphate binders (the only oral-only products without an IV equivalent remaining outside of the PPS)
 - The statute does not mandate their inclusion in 2025, the language prohibits CMS including them prior to 2025
- If not, KCP asks CMS to seek comment on how to adopt a transitional add-on adjustment period to assess the utilization and cost of these products before adding them to the bundle with new money
 - A TDAPA period would parallel the policy the Congress established for oral-only drugs added to the bundled prior to 2025 because an IV equivalent became available

Conclusion: Seek Comments on Priority Issues in CY 2023 ESRD PPS Proposed Rule

- Signal willingness to assess new product and add incremental dollars to the ESRD PPS bundle for innovative products in functional categories when existing funding is not sufficient
- Provide options for an adjustment to address increase in labor costs
- Consider comments on excluding phosphate bundlers from the the ESRD PPS and/or seek comment about process to adjusting base rate if added

