MEDPAC | Medicare Payment Advisory Commission

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August 25, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8010
Baltimore, MD 21244–8010

Attention: CMS-1782-P

Dear Ms. Brooks-LaSure:

The Medicare Payment Advisory Commission (MedPAC) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; 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" in the *Federal Register*, vol. 88, no. 125, pp. 42430–42544 (June 30, 2023). This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2024, update the payment rate for services provided to individuals with acute kidney injury (AKI) when those services are furnished in ESRD facilities, address the ESRD Quality Incentive Program, and address the ESRD Treatment Choices Model. We appreciate your staff's ongoing efforts to administer and improve payment systems for ESRD, particularly considering the competing demands on the agency.

Our comments address the following provisions in the proposed rule:

- Update for the ESRD PPS base rate for calendar year (CY) 2024
- Wage index adjustment
- Outlier policy
- Payment for certain new renal dialysis drugs and biological products (referred to as ESRD drugs herein) after the transitional drug add-on payment adjustment (TDAPA) period ends
- Measurement of patient-level utilization: "Time on machine"
- Low-volume payment adjustment (LVPA) and development of a new payment adjustment based on geographic isolation

Update for the ESRD PPS base rate for CY 2024

Per statutory requirements, CMS proposes to update the ESRD PPS base rate for CY 2024 by 1.7 percent. This update is based on the ESRD Bundled (ESRDB) market basket increase factor (of 2.0 percent) reduced by a multifactor productivity adjustment (of 0.3 percent). The proposed CY 2024 ESRD PPS base rate is $269.99, which is an increase of $4.42 to the current base rate of $265.57.[1]

Comment

We support this proposal. In our March 2023 report to the Congress, the Commission's analysis of indicators of payment adequacy for the sector suggests that Medicare's payments to freestanding ESRD facilities in 2021 were adequate.[2] The Medicare fee-for-service (FFS) margin for freestanding ESRD facilities was 2.3 percent in CY 2021, and we project it will drop to –0.4 percent in CY 2023. Based on this assessment, the Commission recommended that, for 2024, the Congress should update the CY 2023 ESRD PPS base rate by the amount determined under current law.

Wage index adjustment

Since the inception of the ESRD PPS, CMS has used hospital wage data to develop the ESRD PPS wage index. For fiscal year 2024, CMS proposes to continue to use the unadjusted inpatient prospective payment systems (IPPS) wage index (referred to as the "pre-floor, pre-reclassification hospital inpatient wage index") to adjust ESRD payments.

Comment

The Commission has long been concerned with flaws in the wage indexes Medicare uses to adjust provider payments to reflect geographic differences in labor costs.[3] To improve the accuracy and equity of Medicare's wage index systems for IPPS hospitals and other providers (such as, but not limited to ESRD facilities), Medicare needs wage indexes that are less manipulable, accurately and precisely reflect geographic differences in market-wide labor costs, and limit how much wage index values can differ among providers that are competing with each other for patients and employees.

In the Commission's June 2023 report to the Congress, we recommended that the Congress repeal the existing Medicare wage index statutes, including current exceptions, and require the Secretary to phase in new Medicare wage index systems for hospitals and other types of providers that:

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[1] The update to the ESRD PPS base rate also reflects the application of the proposed wage index and transitional pediatric ESRD add-on payment adjustment budget-neutrality adjustment factors.
[2] Medicare Payment Advisory Commission. 2023. *Report to the Congress: Medicare payment policy*. Washington, DC: MedPAC.
[3] Medicare Payment Advisory Commission. 2007. *Report to the Congress: Promoting greater efficiency in Medicare.* Washington, DC: MedPAC

- use all-employer, occupation-level wage data with different occupation weights for the wage index of each provider type;
- reflect local area level differences in wages between and within metropolitan statistical areas and statewide rural areas; and
- smooth wage index differences across adjacent local areas.[4]

Given the Secretary's authority under Section 1881 of the Social Security Act to determine the appropriate wage index to adjust the portion of the ESRD base rate attributable to labor costs, we urge the Secretary to adopt the Commission's recommended approach to the wage index for this sector.

Outlier policy

The outlier policy in the ESRD PPS partially reimburses dialysis facilities for the costs of adult and pediatric beneficiaries who incur very high costs for items and services that were separately billable prior to the implementation of the ESRD PPS.[5] The policy aims to distribute 1 percent of total payments to the highest-cost months of treatment by reimbursing 80 percent of costs above a specified threshold. Each year, CMS estimates the outlier threshold based on two values: (1) the average spending on separately billable services (referred to as the Medicare Allowable Payment (MAP) amount) and (2) the amount of spending above the MAP that is necessary to meet the 1 percent of total spending target for the outlier policy (referred to as the Fixed Dollar Loss (FDL) amount). The outlier threshold is the sum of the MAP and the FDL dollar amounts. CMS funds the outlier policy by withholding 1 percent of total expected spending.[6] If the outlier threshold is too high, less than 1 percent of total expected spending will be paid through the outlier policy and total ESRD PPS payments will be lower than intended; likewise, if the outlier threshold is set too low, total ESRD PPS payments will be higher than intended..

In the CY 2023 ESRD rulemaking, CMS refined the methods for calculating outlier payments. CMS now calculates the adult FDL amount using claims data from the three most recent available data years, relative to the rule year.[7, 8] CMS made this change to address the concern

[4] Medicare Payment Advisory Commission. 2023. Report to the Congress: *Medicare and the health care delivery system*. Washington, DC: MedPAC.
[5] The remainder of the ESRD PPS bundle is made up of items and services that were included in the composite rate, Medicare's payment method for dialysis services prior to 2011. Items and services that were formerly separately billable are generally drugs, labs, and related services.
[6] When implementing the ESRD PPS in CY 2011, CMS funded the outlier pool by reducing the per treatment base rate by 1 percent to account for the proportion of the estimated total payments that are outlier payments.
[7] Prior to CY 2023, a single year of ESRD PPS claims (from two calendar years prior to the payment year) was used to calculate the MAP and FDL amounts.
[8] The outlier services MAP amounts and FDL amounts are different for adult and pediatric dialysis beneficiaries due to differences in the use of separately billable services by age group. In its 2022 rulemaking, CMS did not propose to calculate the pediatric FDL amount using the refined method it finalized to calculate the FDL amount for adults, as the pediatric population is too small to reliably use this method. Thus, CMS uses the latest year of available claims to calculate the FDL amount for pediatric beneficiaries.

that since 2011, when the ESRD PPS was established, the agency has set the outlier threshold too high. The Commission supported CMS's proposal to set the FDL amounts using a trend based on ESRD PPS claims data from the three most recent available data years.[9] The refined method likely contributed to more accurately achieving the 1 percent outlier target. In CY 2022 (the most recent year of data available), outlier payments represented approximately 0.9 percent of total Medicare payments rather than 1.0 percent. By contrast, between CY 2019 and CY 2021, CMS paid out between 0.4 percent and 0.6 percent of the outlier pool in each year.

Comment

We reiterate our comment on the CY 2023 proposed rule: CMS should make further refinements to the outlier policy, specifically its approach for applying the pricing data that the agency uses to project FDL amounts, particularly for drugs. Currently, CMS uses a blended four-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the rule year.[10] The average sales price (ASP) data that CMS uses to determine facilities' actual outlier payments might be a more accurate data source on drug prices than the ESRDB market basket pharmaceutical price proxies.

For example, the Commission's analysis shows that, during the most recent four-year period that data are available, the ASPs of nearly all the commonly used erythropoietin-stimulating agents (ESAs), iron products, and vitamin D analogs declined (Table 1). By contrast, the price indexes that CMS will use to measure the change in the prices of ESAs, iron agents, and all other drugs (including vitamin D analogs) increased by 16 percent, 8 percent, and 8 percent, respectively, between January 2019 and January 2023.

We continue to believe that using price indexes to inflate MAP and FDL amounts for drugs overestimates the outlier-eligible amounts for drugs compared with a method that is based on actual drug price trends using ASP data. CMS should account for both utilization and price trends to prevent continued overestimates of MAP and FDL amounts and underpayments for outlier services. To achieve the 1 percent outlier target, CMS should use a drug price inflation factor based on ASP values.

[9] Medicare Payment Advisory Commission. 2022. MedPAC comment letter regarding the Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2023. August 19.
[10] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; 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. *Federal Register* 87, no. 214 (November 7): 67167.

Table 1. ASP values of commonly used drugs under the ESRD PPS bundle declined between 2019 and 2023

		2019 Q1	2023 Q1	
Functional category	**Drug**	**Payment per unit**		**Aggregate change**
Anemia management	Darbepoetin alfa	$3.83	$3.12	–19%
Anemia management	Epoetin alfa	$1.20	$0.82	–31%
Anemia management	Epoetin beta	$1.72	$1.44	–16%
Anemia management	Sodium Ferric Gluconate	$1.94	$2.09	8%
Anemia management	Iron Sucrose	$0.24	$0.22	–5%
Bone and mineral metabolism	Paricalcitol	$0.64	$0.63	–2%
Bone and mineral metabolism	Doxercalciferol	$0.47	$0.32	–31%
Bone and mineral metabolism	Calcitriol	$0.45	$0.69	51%

Note: ASP (average sales price), ESRD (end-stage renal disease), PPS (prospective payment system), Q (quarter). Values represent ASP + 6 percent. This table includes commonly used renal drugs with ASP data available in 2019 Q1 and 2023 Q1 obtained from CMS's ASP pricing files located at ASP Pricing Files | CMS.

Source: CMS's ASP quarterly pricing files and MedPAC analysis of CMS's 2021 100 percent institutional outpatient file.

Payment for certain new ESRD drugs after the transitional drug add-on payment adjustment (TDAPA) period ends

When CMS implemented the ESRD PPS in 2011, the agency argued for a broad interpretation of the items and services to be included in the payment bundle, and it established 11 functional categories for ESRD-related drugs included in the bundle. The functional categories were defined to include drugs that were, before 2011, formerly paid under the prior ESRD payment system's prospective payment—the composite rate—and ESRD-related drugs that were separately billable (e.g., ESAs, iron agents, and vitamin D agents).

In 2016, to comply with a Protecting Access to Medicare Act of 2014 mandate related to the inclusion of new ESRD-related injectable and intravenous drugs in the PPS payment bundle, CMS implemented a policy that pays a TDAPA for:

- *New ESRD-related injectable drugs not in one of the 11 functional drug categories included in the PPS payment bundle.* Such drugs are eligible for a TDAPA for at least two years, until sufficient rate-setting data are available. When the TDAPA period ends, CMS includes the drug in the PPS payment bundle (by adding a new functional category or modifying an existing one) and adjusts the PPS base rate, if appropriate, to reflect changes to the functional categories. To date, no new ESRD-related injectable drug has qualified under this TDAPA policy.
- *ESRD-related oral-only drugs (calcimimetics and phosphate binders) once the Food and Drug Administration (FDA) approves a functionally equivalent injectable product (or other non-oral forms).* The agency pays facilities for both the oral and non-oral products under a TDAPA until sufficient claims data (at least two years' worth) for rate-setting analysis are available; thereafter, these drugs are included in the PPS payment bundle. To date, calcimimetics were paid under this TDAPA policy between 2018 and 2020, and since 2021, have been included in the PPS payment bundle (with an increase to the base payment to account for the costs associated with their use).

In its 2019 and 2020 ESRD PPS final rules, CMS expanded the TDAPA policy to allow, in a non-budget-neutral manner, add-on payments for all new ESRD injectable products (with the exception of certain drugs, including generics)[11] that are in an existing ESRD-related functional category and approved by the FDA on or after January 1, 2020. In other words, the expanded TDAPA policy makes an add-on payment for any new and qualifying ESRD product for two years, even for a new drug with a functional equivalent already included in the PPS payment bundle. After two years, CMS includes the new drug in the PPS payment bundle but does not change the ESRD PPS base payment rate (because the functional categories are unchanged). According to CMS, the expanded TDAPA policy is intended "to promote innovation and bring more high-value drugs to market."[12] As of April 2022, one product (Korsuva) has qualified for an add-on payment under the expanded TDAPA policy.

According to the CY 2023 rulemaking, since 2019, dialysis associations and pharmaceutical manufacturers have raised concerns about payment following the TDAPA period for new ESRD drugs that are in an existing ESRD functional category. Specifically, stakeholders assert that:

> *"…unless money is added to the ESRD PPS base rate for these drugs and biological products, similar to what occurred with calcimimetics, then it is unlikely that ESRD facilities would be able to sustain the expense of these drugs and biological products when*

[11] The following drugs are excluded from TDAPA eligibility: generic drugs approved under Section 5050(j) of the Federal Food, Drug, and Cosmetic Act and drugs for which the new drug application is classified by the FDA as Type 3, 5, 7 or 8; Type 3 in combination with Type 2 or Type 4 or Type 5 in combination with Type 2; or Type 9 when the "parent NDA" is a Type 3, 5, 7, or 8.

[12] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2018. Medicare program; 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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and fee schedule amounts, and technical amendments to correct existing regulations related to the CBP for certain DMEPOS. *Federal Register* 83, no. 139 (July 19): 34304.

> *the TDAPA period ends. Further… uncertainty about payment could affect ESRD facility adoption of these drugs and biological products during the TDAPA.*"[13]

During CY 2023 rulemaking, CMS issued a request for information about whether it would be appropriate to establish an add-on payment adjustment for ESRD drugs in existing ESRD functional categories after their TDAPA period ends. The agency discussed possible approaches including establishing an add-on payment that would be based on the product's cost alone, or an add-on payment that includes an offset based on the cost per treatment of all other formerly separately billable ESRD drugs.

In response to stakeholders' concerns that a sudden decrease in payment for certain new ESRD drugs after the TDAPA period ends could negatively affect Medicare beneficiaries' access to such products, CMS now proposes a three-year post-TDAPA payment for new ESRD drugs in an existing ESRD functional category after the end of the new drug's two-year TDAPA period. Thus, this proposal would provide increased payments for five years for new ESRD drugs in an existing functional category by paying a TDAPA for two years and a post-TDAPA for three years. By contrast, between 2011, when the ESRD PPS was implemented, and 2018, new drugs in an ESRD functional category were paid under the existing base rate and received no add-on payments whatsoever.

Under CMS's proposal, the post-TDAPA add-on payment adjustment would be applied to each ESRD PPS treatment, beginning eight calendar quarters after the first calendar quarter in which TDAPA payment is made for the new ESRD drug in an existing ESRD PPS functional category, and would end no later than the 12th calendar quarter after the last calendar quarter in which TDAPA payment is made. The per-treatment post-TDAPA payment would be calculated based on the utilization of the new drug and the total number of treatments furnished during the most recent available twelve months of claims data and the latest available full calendar quarter of ASP data. The post-TDAPA payment would be applied to each dialysis treatment regardless of whether the post-TDAPA drug is used, and the payment would be:

- Adjusted for patient characteristics using the ESRD PPS case-mix adjusters.
- Reduced by 65 percent, an offset intended to: (1) incentivize ESRD facilities to efficiently allocate resources by sharing a significant portion of the new drug's cost with ESRD facilities, and (2) reduce beneficiaries' cost-sharing burden for new ESRD drugs.
- Applied in a non-budget-neutral manner.
- Updated by the ESRDB market basket.

CMS contends that the post-TDAPA payment would "…provide consistency and predictability in a way that would support beneficiaries' continued access to new renal dialysis drugs and biological

[13] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; 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. *Federal Register* 87, no. 123 (June 28): 38464.

products, while appropriately reducing expenditures for such drugs after the TDAPA period ends both for the Medicare program and for individual beneficiaries…."[14]

Comment

We reiterate our comment made during CY 2023 ESRD rulemaking: The Commission is strongly opposed to an add-on payment adjustment after the TDAPA period ends for any ESRD drug in an existing ESRD functional category. In the Commission's view, an important goal of the ESRD PPS is to give nephrologists and ESRD facilities an incentive to provide ESRD-related items and services as efficiently as possible. This goal is best achieved by relying on the ESRD payment bundle to the greatest extent possible when determining payment amounts. Bundled payment encourages judicious consideration of the items and services provided to dialysis beneficiaries. Including all items and services with a similar function (i.e., functionally equivalent) in the bundle reduces incentives to overutilize drugs (to the extent clinically possible), fosters competition for ESRD-related items and services, and generates pressure on manufacturers to reduce prices among competing products. Though the Commission has found that the use of ESRD drugs that are covered under the PPS bundle (including ESAs, which are used in anemia management) has declined in aggregate,[15] CMS has concluded that the payment method has resulted in no sustained negative changes in beneficiaries' outcomes.[16, 17]

CMS does not provide evidence that beneficiary access was impeded to a needed therapy when a new ESRD drug was directly included in the PPS bundle. On the contrary, the Commission has shown that when Mircera (an ESA) became available in 2015, beneficiary access to the new drug was not impeded when the agency included it in the PPS bundle (in a budget-neutral manner). Between 2015 and 2020, use of Mircera significantly and steadily increased. In at least one situation, switching was an explicit goal: One of the large dialysis organizations (LDOs) announced its intent to have more than 70 percent of the company's ESA patients (110,000 patients) switched to Mircera (from epoetin alfa) by the end of the first quarter of 2016, and sources suggest that this LDO reduced its total ESA costs.[18] The price competition within the anemia functional category increased after Mircera was introduced into the bundle. Thus, policies (i.e., broader payment bundles) that create incentives for price competition among manufacturers of competing products encourage use, not impede access. Unless CMS has clear evidence that beneficiary access was impeded after ESRD drugs were directly included in the PPS bundle, we urge the agency not to proceed with the proposed post-TDAPA payment policy.

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[14] Centers for Medicare & Medicaid Services. 2023, op cit.
[15] Medicare Payment Advisory Commission. 2023, op cit. Between 2010 (the year prior to the ESRD PPS) and 2020 (the most current year data are available), ESRD drug use per treatment declined in aggregate by nearly 60 percent.
[16] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. *ESRD prospective payment system claims-based monitoring program.* Baltimore, MD: CMS.
[17] Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2022. Medicare program; 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. Proposed rule. *Federal Register* 88, no. 123 (June 28): 38464.
[18] Reuters. 2016. FMC aims for 110,000 U.S. patients to be on Mircera in first-quarter. February 24.
Seeking Alpha. 2016. Fresenius Medical Care AG & Co. KGaA (FMS) Rice Powell on Q4 2015 results—Earnings call transcript. February 24.

Beyond the concerns about undermining the incentives for provider efficiency created by broad payment bundles, we are also concerned about the effect of the post-TDAPA payment policy on the affordability of care for beneficiaries and taxpayers. Under CMS's proposal:

- The payments for new ESRD drugs would be duplicative of the payment that is already made as part of the ESRD bundle. The cost of providing all drugs in a given functional category is included in the base rate. Thus, Medicare and beneficiaries would pay ESRD facilities twice for a drug that is included in an existing functional category and that is paid under the post-TDAPA policy. Dialysis beneficiaries are responsible for 20 percent cost sharing for: (1) the ESRD PPS base rate and (2) the add-on payment adjustments for new ESRD drugs and equipment, including the current adjustments (TDAPA and TPNIES) and the proposed post-TDAPA adjustment. The duplicative payment is an inappropriate use of beneficiary and taxpayer funds.
- CMS would not apply a clinical superiority standard when implementing the post-TDAPA policy. Thus, beneficiaries and taxpayers would pay for a new drug without evidence that the new product is an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS.
- The payment for new ESRD drugs would only increase. CMS's proposal would update the payment rate using either the ESRDB market basket or price proxies for pharmaceuticals. By contrast, Table 1 shows the prices of key ESRD drugs in the bundle generally declined during this period.

When CMS first proposed expanding the TDAPA policy to allow add-on payments for all new ESRD products that are in an existing ESRD-related functional category, the Commission raised concerns—specifically, that such an expansion would undermine the structure of the ESRD PPS (by unbundling services).[19, 20] We also noted that payments under the TDAPA for new ESRD drugs in an existing functional category are duplicative of the payment that is already made as part of the ESRD bundle. Consequently, in our June 2020 report to the Congress, we recommended the elimination of the expanded TDAPA policy for new ESRD drugs in an existing ESRD functional category.[21] Eliminating the add-on payment policies for these drugs would maintain the integrity of the ESRD PPS bundle, better ensure that providers are judicious in the items and services furnished to beneficiaries, and create pressure for drug manufacturers to constrain the growth of prices for new and existing ESRD drugs.

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[19] Medicare Payment Advisory Commission. 2019. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2020. September 20. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/09202019_esrd_cy2020_medpac_comment_v2_sec.pdf.

[20] Medicare Payment Advisory Commission. 2018. MedPAC comment letter regarding Medicare end-stage renal disease prospective payment system and quality incentive program proposed rules for 2019. August 31. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/comment-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.

[21] Medicare Payment Advisory Commission. 2020. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC: MedPAC.

Some stakeholders have asserted that it is not appropriate to assume that the base rate is sufficient to support new drugs that represent a clinical improvement. However, in the Commission's view, the competitive forces within the PPS payment bundle are undermined by paying a TDAPA for new drugs in an existing ESRD functional category or paying an add-on payment for these ESRD drugs after their TDAPA period ends. Both policies fail to create pressure on drug manufacturers to constrain prices for new and existing ESRD drugs and fail to maximize the incentive for nephrologists and ESRD facilities to provide ESRD-related items and services as efficiently as possible. Bundled payment encourages thoughtful consideration of the items and services provided to patients. Including all ESRD drugs in an existing functional category (and thus with a similar function) in the bundle fosters competition for these products and generates pressure to constrain prices.

The Commission recognizes that as new products are added to the bundle and diffused into medical practice, there may be a need for rebasing to keep Medicare payments aligned with providers' costs. For example, the Congress mandated that the Secretary rebase the ESRD PPS base payment rate in 2014 to account for the decline in the use of ESRD drugs covered under the bundle. The Commission's annual payment adequacy analysis can help inform policymakers about the alignment of Medicare's payments to providers' costs. Our payment adequacy analysis also tracks dialysis drug use and changes in patients' outcomes over time.

By proposing a three-year post-TDAPA payment, CMS may be at odds with the agency's justification for implementing the original two-year TDAPA policy. We urge the agency to address why its justification for establishing a two-year TDAPA for new ESRD drugs within a functional category and then folding the new drugs into the PPS payment bundle no longer applies. During CY 2019 rulemaking when establishing the TDAPA policy, the agency stated that:

> "We believe that 2 years is a sufficient timeframe for facilities to set up system modifications, and adjust business practices so that there is seamless access to these new drugs within the ESRD PPS base rate… We believe that this 2-year timeframe is similar in that facilities are making changes to their systems and care plan to incorporate the new renal dialysis drugs and biologicals into their standards of care and this could be supported by a transition period. Also, the TDAPA for 2 years would address the stakeholders concerns regarding additional payment to account for higher cost of more innovative drugs that perhaps may not be adequately captured by the dollars allocated in the ESRD PPS base rate… Meaning, once the timeframe is complete, drugs would then qualify as outlier services, if applicable, and the facility would no longer receive the TDAPA for any one particular drug. Instead, in the outlier policy space, there is a level playing field where drugs could gain market share by offering the best practicable combination of price and quality. We believe that the proposed timeframe is long enough to be meaningful but not too long as to improperly incentivize high-cost items without more value, for example, substitutions of those drugs that already exist in the functional category."[22]

Finally, we urge CMS to provide additional explanation that establishing a three-year post-TDAPA period is necessary to study the ESRDB drug price proxies:

[22] Centers for Medicare & Medicaid Services. 2018, op cit.

> "…we are proposing a 3-year payment period for the post-TDAPA add-on payment adjustment, which would enable the collection and analysis of sufficient cost report information and would address the concerns that commenters raised about the effectiveness of the ESRD PPS market basket price proxies to account for the costs of new renal dialysis drugs and biological products going forward by allowing CMS to incorporate data showing trends in use over an adequate period of time."[23]

It is not clear why CMS is reconsidering the ESRD drug proxies so soon after the CY 2023 ESRD rulemaking, when CMS rebased and revised the ESRDB market basket to reflect the 2020 cost structure of ESRD facilities and revised the price index, including all the cost categories and price proxies used in the index. When CMS finalized the two-year TDAPA policy during CY 2019 rulemaking, the agency did not raise any concerns about the appropriateness of the ESRDB market basket to account for price changes of the drugs and biologicals reflected in the base rate. In the Commission's view, a post-TDAPA period is not needed to collect and analyze cost report data. If CMS has concerns about the price proxies for ESRD drugs used in the ESRDB market basket, CMS can conduct the necessary analyses, without creating the post-TDAPA policy.

Furthermore, we question the utility of current cost reports to evaluate whether the ESRDB market basket accounts for price changes of new ESRD drugs. The Medicare cost reports do not require providers to report the cost of each new item or product paid under a TDAPA or a TPNIES.[24] CMS should explain how it will analyze the costs of a specific drug paid under the TDAPA without granular cost data specific to each TDAPA/post-TDAPA drug. CMS should require that providers report the cost of each drug paid under a TDAPA and each piece of equipment or supply paid under a TPNIES as soon as possible. Such data would permit CMS, policymakers, and researchers to monitor providers' cost and evaluate the profitability of each new item paid for under an add-on payment policy.

Although we strongly disagree with the implementation of a post-TDAPA policy, CMS's proposed *per claim* add-on payment approach provides better incentives for more judicious use of a new ESRD drug rather than a *per use* add-on payment approach. The Commission has repeatedly said that paying on a per unit basis for a drug incentivizes its use (to the extent clinically possible). If CMS finalizes the post-TDAPA policy, the agency should proceed with a per claim add-on payment.

In addition, if CMS decides to implement an add-on payment adjustment for ESRD drugs in existing ESRD functional categories after their TDAPA period ends, we reiterate that the agency should:

- pay a reduced percentage (proposed to be 65 percent) of the payment for the drug during the post-TDAPA period, as a way to share risk with dialysis providers and provide some

[23] Centers for Medicare & Medicaid Services 2023, *op cit*.
[24] As of January 2023, CMS started to require that providers enter the payments received under the TDAPA and TPNIES policies in their Medicare cost reports.

incentive for price competition.[25] CMS uses such an approach in setting the add-on payment for the TPNIES.

- limit a post-TDAPA payment adjustment to products that represent a substantial clinical improvement (SCI) compared with products in the bundle.[26] The Commission has repeatedly said that if the agency adopts an add-on payment for drugs, CMS should require that the new product be an advance in medical technology that substantially improves beneficiaries' outcomes relative to technologies in the PPS payment bundle. Without a clinical superiority requirement, Medicare will pay outside the PPS bundle for a drug no more effective than a product paid for under the bundle, even when the cost of the existing product is reflected in the ESRD PPS payment. The agency included such a criterion for substantial clinical improvement when it implemented the TPNIES in 2020.

In order to ensure affordability for beneficiaries and taxpayers and promote price competition between drugs, CMS should modify its methods for calculating the initial add-on payment during the post-TDAPA period. By establishing the first-year post-TDAPA payment on the latest available calendar quarter of ASP pricing data, which is based on manufacturers' pricing decisions, we are concerned that some manufacturers might unnecessarily increase the price of the drug in that quarter. Establishing the years 2 and 3 post-TDAPA payments based on the ESRDB market basket assumes that the price of a new drug always increases during the post-TDAPA period. CMS contends that the "post-TDAPA add-on payment adjustment would result in competition between new and existing renal dialysis drugs and biological products, and that this competition would serve to drive down prices of such new renal dialysis drugs and biological products over time."[27] But the proposed payment method does not account for a scenario that the manufacturer of the new product would lower its price in the post-TDAPA period in order to be price competitive with existing or other newly launched drugs.

Thus, CMS should use the per treatment approach (as proposed) to establish the post-TDAPA payment rate but modify the calculation of the payment rate in the first year of the post-TDAPA period as follows:

- Set the first-year post-TDAPA payment rate based on total treatments in the most recent available 12 months of claims data (i.e., during the second year of the TDAPA period) and total expenditures based on the lower of:

    - ASP + 0 percent *from the most recent quarter of pricing data* multiplied by the utilization of the drug in the most recent available 12 months of claims data, or
    - The average ASP + 0 percent *from the most recent 4 quarters of pricing data* multiplied by utilization of the drug in the most recent available 12 months of claims data.

[25] Medicare Payment Advisory Commission. 2022, *op cit*.
[26] Medicare Payment Advisory Commission. 2022, *op cit*.
[27] Centers for Medicare & Medicaid Services. 2023, *op cit*.

This "lower of" approach for year 1 would provide a safeguard to ensure it would not be possible for a manufacturer to increase the price of its product in a single quarter in order to yield a higher add-on payment in year 1 (and which would carry forward into years 2 and 3).

CMS should use the following approach for years 2 and 3:

- Set the second-year post-TDAPA payment rate based on the first-year post-TDAPA add-on payment rate updated by the lower of (1) the ESRDB market basket, or (2) the change in the average annual ASP between the second year of the TDAPA period and the first year of the post-TDAPA period.
- Set the third-year post-TDAPA payment rate based on the second-year post-TDAPA payment rate updated by the lower of: (1) the ESRDB market basket, or (2) the change in the average annual ASP between the first and second year of the post-TDAPA period.

This approach for updating the year 2 and year 3 add-on amounts based on the lower of the change in the ESRD market basket or the change in ASP for the post-TDAPA drug would enable the Medicare program and beneficiaries to share in the savings if price competition among products leads to slower price growth (or price decreases) for the post-TDAPA drug.

In addition, the agency should reduce any add-on amount (TDAPA and post-TDAPA payments) to reflect the amount for products already included in the base rate's functional category. Doing so would better protect the affordability of this policy for beneficiaries and taxpayers. Establishing an offset will take on greater fiscal importance to beneficiaries and taxpayers for new drugs in a widely used functional category (e.g., anemia drugs). Effective October 1, 2023, Jesduvroq, a drug indicated to treat anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months, qualifies for the TDAPA.[28] CMS should not make duplicative payments for a new product by paying both an add-on payment and paying for related services under the ESRD PPS base rate.

Proposal to measure patient-level utilization: "Time on machine"

CMS is proposing to require ESRD facilities to report the "time on machine," which is the amount of time in minutes that a beneficiary spends receiving an in-center hemodialysis treatment, on ESRD PPS claims.[29] Such data would be used to evaluate and monitor the accuracy of Medicare's payments for patient-level adjustment factors under the ESRD PPS.

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[28] In February 2023, the FDA approved Jesduvroq, and its manufacturer filed a TDAPA application with CMS. Among dialysis patients enrolled in a randomized, open-label, Phase III trial (funded by the drug's manufacturer), researchers concluded that Jesduvroq was noninferior to (i.e., not worse than) currently marketed ESAs (Epogen or Aranesp) in the treatment of anemia and in the incidence of adverse cardiovascular events. Singh, A. K., K. Carroll, V. Perkovic, et al. 2021. Daprodustat for the treatment of anemia in patients undergoing dialysis. *New England Journal of Medicine* 388, no. 25: 2325–2335.

[29] In 2020, CMS issued sub-regulatory guidance that would have required ESRD facilities to report the total number of minutes of dialysis provided during the billing period on ESRD PPS claims. After a large dialysis organization submitted a petition concerning the reporting requirement, the Secretary rescinded the requirement in 2021, finding that notice-and-comment rulemaking was required for CMS to impose such a requirement.

CMS would also evaluate whether the data could be used to refine the existing patient-level adjustment factors under the ESRD PPS. The agency would use the time-on-machine data to disaggregate facility-level composite rate costs (as obtained from the cost reports) and assign them to the patient-month level. Valid, accurate time-on-machine data has the potential to be used by CMS to refine the payment adjustment factors currently used under the ESRD PPS by allowing for a single-equation methodology. Currently, under the ESRD PPS, CMS uses a two-equation regression to estimate the case-mix adjustments to the base payment rate for adults.[30] The Commission has repeatedly advised CMS to develop payment adjustment factors using a single-equation methodology that accounts for variation in the cost of providing the full PPS payment bundle out of concerns that multiplying coefficients from the facility-level and patient-level regressions (with different bases) could diminish the accuracy of the combined coefficients.[31]

Comment

We reiterate our support of CMS collecting time-on-machine data from ESRD facilities on ESRD PPS claims. In our comments on the ESRD PPS proposed rule for CY 2022, we said that CMS should explore using time on a dialysis machine per treatment, which was discussed at CMS's Technical Evaluation Panel (TEP), to apportion composite rate costs (such as labor and capital-related costs) that are currently only observable at the facility level to the patient or treatment level for use in the case-mix adjustment. We also support CMS's proposal to collect time-on-machine data on the administrative claims that ESRD facilities submit to CMS. In implementing this proposal, the Commission urges the agency to:

- Be mindful of the potential for increased administrative burden on ESRD facilities. Some ESRD providers have said that collecting such data would be burdensome.[32] Consequently, CMS should consider collecting the utilization data for an established (finite) time period. That is, the agency could collect such data for only as long as the data are needed to explore refining the payment adjustment factors under the ESRD PPS.
- Collect per treatment time-on-machine data for dialysis beneficiaries enrolled in Medicare Advantage (MA) plans. Enrollment of dialysis beneficiaries in MA plans increased dramatically between December 2020 and January 2021, rising from 27 percent to 36 percent; by December 2021, the share of dialysis beneficiaries enrolled in MA plans exceeded 40 percent.[33] Collecting and evaluating time-on-machine data would provide additional information for the agency to identify, assess, and address potential health disparities among both FFS and MA dialysis beneficiaries.

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[30] To estimate the case-mix adjustments, CMS currently uses a two-equation regression methodology that includes: (1) a facility-level regression model that uses ESRD cost reports; and (2) a patient-level regression model that uses ESRD PPS claims.

[31] Medicare Payment Advisory Commission. 2015. Comment letter to CMS on the ESRD prospective payment system and the ESRD Quality Incentive Program. August 6.
Medicare Payment Advisory Commission. 2021. Comment letter to CMS on the ESRD prospective payment system and the ESRD Quality Incentive Program. August 30.

[32] Centers for Medicare & Medicaid Services. 2023, *op cit*.

[33] Medicare Payment Advisory Commission. 2023, *op cit*.

Low-volume payment adjustment (LVPA) and development of a new payment adjustment based on geographic isolation

The LVPA, which increases a facility's base rate by 23.9 percent, applies to facilities with fewer than 4,000 total treatments in each of the three years before the payment year. For these years, a facility's total treatment volume is equal to the sum of (1) the treatments furnished by that facility and (2) the treatments furnished by facilities under common ownership and within five road miles of that facility. The rural payment adjustment, which increases a facility's base rate by 0.8 percent, applies to all facilities located in rural areas, regardless of treatment volume or proximity to other dialysis facilities.

CMS has included a request for information on modifying the current LVPA methodology and on the possible creation of a new payment adjustment that would increase payment to geographically isolated ESRD facilities. First, the agency is soliciting comments regarding potential changes to the LVPA methodology, including maintaining a single threshold, establishing LVPA tiers, and/or utilizing a continuous function. Second, the agency is requesting information on geographic isolation to determine if ESRD facilities that are currently considered rural would benefit from a geographic isolation adjustment. In the proposed rule, CMS contends that combining the low-volume and isolation adjustment would not comport with the statutory requirements and limitations for the LVPA. The new geographically based payment adjustment may consider local dialysis need (LDN) instead of basing payment strictly upon a rural designation.

Comment

The Commission has repeatedly raised concerns that neither the LVPA nor the rural adjustment accurately targets facilities that both are critical to beneficiary access and have high costs warranting a payment adjustment.[34] In 2017, about 40 percent of LVPA facilities were located within five miles of the next closest facility, while some 385 facilities that did not receive the LVPA were isolated (and therefore necessary for beneficiary access to care) and incurred substantially higher-than-average costs per treatment. In addition, in 2017, about half of all rural facilities were high volume, and 30 percent of rural facilities were within five miles of the next closest facility.

In our June 2020 report to the Congress, we recommended that CMS replace the current LVPA and rural adjustment with a single payment adjustment—a low-volume and isolated (LVI) adjustment—to better protect isolated, low-volume dialysis facilities that are critical to ensure beneficiary access to dialysis services. A single payment adjustment that considers both a facility's distance to the nearest facility and its treatment volume would eliminate extra payments to low-volume facilities in close proximity to another facility and to high-volume rural facilities and instead would target extra payments to low-volume and isolated facilities. A combined LVI adjustment would require the facility to be both isolated and to have a low treatment volume. The

[34] Medicare Payment Advisory Commission. 2020, *op cit*.

Commission asserts that separate adjustments for low volume, isolation, and rural location are not needed in the ESRD PPS.

The Commission's approach would define facilities that are low volume and isolated based on both a facility's distance from the nearest facility (regardless of ownership) and its total treatment volume. MedPAC's illustrative LVI policy would have applied to 575 freestanding and hospital-based dialysis facilities, compared with the 336 facilities receiving the current LVPA and the 1,257 facilities receiving the rural adjustment in 2017. The LVI policy would not have applied to facilities that furnished a high volume of treatments because their economies of scale generally result in lower costs per treatment, on average, than low-volume facilities. Nor would the LVI policy have applied to facilities near another dialysis facility because such facilities are not the sole providers of dialysis services in their communities and thus are not critical to maintaining access to care.

If CMS considers a tiered volume approach, the Commission suggests that the agency consider the following categories that we modeled in our June 2020 report to the Congress:

- *Category 1:* facilities with fewer than 4,000 treatments in each of the 3 years preceding the payment year
- *Category 2:* facilities that had fewer than 5,000 treatments in each of the preceding 3 years (excluding Category 1)
- *Category 3:* facilities that had fewer than 6,000 treatments in each of the preceding 3 years (excluding Categories 1 and 2)

As an alternative, CMS could explore a continuous adjustment factor that would apply the same eligibility criteria for facility isolation (i.e., no other facilities within five miles), but would replace the three low-volume categories with a single factor multiplied by facility treatment volume below a threshold (e.g., factor × [6,000 – facility volume]). On the one hand, a continuous adjustment might be more challenging to administer than a categorical approach. To determine the value of a facility's continuous adjustment, the facility would need to attest to whether the number of treatments provided in each of the three preceding years was lower than the 7,000-treatment threshold. For example, before the payment year, facilities would also need to provide CMS an estimate of the average annual number of treatments provided across the three years preceding the payment year (i.e., average of actual treatment volume for the first two years of this period and the projected treatment volume for the third year still in progress) and multiply that number by the continuous adjustment factor. This process is slightly more complicated than determining a facility's categorical LVI adjustment (and current LVPA adjustment), which only requires facilities to check whether the number of treatments provided in each of the three preceding years is lower than a threshold. Because of these differences, providers could calculate and predict Medicare rates more easily under a categorical approach. On the other hand, a continuous adjustment could provide greater accuracy than a categorical adjustment if it is calculated with the empirically determined number of maximum treatments using accurate dialysis cost report data.

According to the proposed rulemaking, using a continuous function would potentially expand LVPA eligibility to the most ESRD facilities. In the Commission's view, the adjustment for low volume and isolation should not apply to all facilities, regardless of the approach used (continuous or categorical).

If CMS decides to pursue the LDN approach to determine facility isolation, then we reiterate our comments made during the CY 2022 rulemaking that the agency should:

- Ensure that the methods used to determine the LVPA are transparent. For example, CMS's TEP discussed that a regression model would be used to adjust for differences between hypothetical and actual demand. The specification of such a model and its results should be available on CMS's website and published in the *Federal Register*. In addition, CMS should discuss how frequently the model would be updated.
- Discuss how census tracts changing over time would impact the accuracy of the LVPA, how this approach would respond to rapid increases in population growth in a given census area, and how the approach would address the anticipated increase in home dialysis use.[35]

Conclusion

MedPAC appreciates the opportunity to comment on this proposed rule. The Commission values the ongoing collaboration between CMS and MedPAC staff on technical policy issues, and we look forward to continuing this productive relationship. If you have any questions, or require clarification of our comments, please feel free to contact Dana Kelley, MedPAC's Deputy Director, at (202) 220-3700.

Sincerely,

Michael E. Chernew, Ph.D.
Chair

[35] Medicare Payment Advisory Commission. 2021, op cit.