

September 20, 2019

Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: File code CMS-1713-P

Dear Ms. Verma:

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, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, and DMEPOS Competitive Bidding (CBP) Proposed Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements" in the *Federal Register*, vol. 84, no. 151, pp. 38330–38421 (August 6, 2019). This proposed rule includes provisions that update the end-stage renal disease (ESRD) prospective payment system (PPS) for 2020, update the payment rate for services provided to individuals with acute kidney injury (AKI) when furnished in dialysis facilities, address the ESRD Quality Incentive Program (QIP), and revise the DMEPOS CBP. We appreciate your staff's ongoing efforts to administer and improve payment systems for ESRD and DMEPOS, particularly considering the competing demands on the agency.

Our ESRD-related comments begin with a general comment about the ESRD PPS and then address the following provisions in the proposed rule:

- Revising the transitional add-on payment adjustment (TDAPA) for drugs and biologics,
- Revising the TDAPA for calcimimetics,
- Requiring average sales price data for drugs and biologics paid under the TDAPA,
- Proposed calendar year (CY) 2020 update to the outlier policy,
- Implementing a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES), and
- Discontinuing the monitoring policy for erythropoiesis-stimulating agents (ESAs).

In addition, we reiterate prior comments about the accuracy of the cost reports that dialysis facilities submit to CMS and the ongoing CMS audit.

General comment

The ESRD bundle defines the set of ESRD-related services that are commonly provided during dialysis treatment. The ESRD PPS establishes a single payment amount for services commonly provided during dialysis treatments and additional payments for cases in which home dialysis training is provided or certain costs are extremely high. In the Commission's view, an important goal of the ESRD PPS is to give dialysis facilities an incentive to provide ESRD-related items and services as efficiently as possible. We think this goal is best achieved by relying on the ESRD bundle to the greatest extent possible when determining payment amounts. Bundled payment encourages judicious consideration of the items and services provided to dialysis patients and cost-conscious decision making. Including all items and services with a similar function in the bundle fosters competition for ESRD-related items and services and generates pressure to reduce prices. For example, both MedPAC and CMS analysis of ESAs has shown that price competition increased and ESA costs decreased after the market entry of a new ESA in 2015.^{1,2}

When CMS implemented the bundle in 2011, the agency argued for a broad interpretation of the items and services to be included in the bundle, and it established eleven functional categories for ESRD-related drugs included in the bundle. The CY 2016 final rule, which implemented the TDAPA for new dialysis drugs and biologics, established a policy to expand the bundle by adding new functional categories as new treatments options are developed. The revision to the TDAPA that CMS finalized in the CY 2019 ESRD PPS rulemaking, which expands the TDAPA policy to apply to functional categories of drugs already included in the bundle and the TPNIES policy included in the current proposed rule, undermine the integrity of the bundle and limit the competitive forces that generate price reductions. The Commission believes that it is important to maintain the ESRD bundle and not to create policies that would pay separately for items and services that are or should be included in the ESRD bundle.

We also reiterate comments from our August 31, 2018, comment letter noting that payments under the TDAPA for new dialysis drugs in an existing functional category are 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. Medicare is paying dialysis facilities twice for a drug that is included in an existing functional category and that is paid under the TDAPA (i.e., providers are paid both the TDAPA payment and the portion of the base rate that covers the

¹ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC. MedPAC.

² Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2017. Medicare program; end-stage renal disease prospective payment system, payment for renal dialysis services furnished to individuals with acute kidney injury, and End-Stage Renal Disease Quality Incentive Program. *Federal Register* 82, no. 127 (July 5): 31199.

cost of the functional category). CMS acknowledged the duplicate payment issue in the agency's CY 2017 final rule.³

Although we acknowledge that the Secretary has the authority to make adjustments to the ESRD PPS, the Commission believes (without weighing in on the applicability of statutory language) that the Secretary should maintain a single payment for items and services in the ESRD bundle. We note that the examples of such adjustments identified in statute (i.e., adjustments for providers of pediatric services, providers in rural areas, and geography) were introduced to the ESRD PPS in a budget-neutral manner (i.e., without establishing non-budget-neutral, separate payments). The Secretary now proposes to use the same authority to make adjustments that are not budget neutral and, in some cases, to establish separate, duplicative payments for ESRD bundle items.

The remainder of our comments address specific topics in the proposed rule.

Revising the TDAPA for drugs and biologics

The Protecting Access to Medicare Act of 2014 (PAMA) required that CMS develop policies to determine how certain new dialysis drugs and biologics are incorporated into the PPS payment bundle. In the CY 2016 ESRD PPS final rule, CMS finalized a process for including new ESRD-related injectable or intravenous products into the ESRD PPS payment bundle:

- If a new injectable or intravenous product did not fit into an ESRD-related functional category,⁴ then the drug would be eligible for a TDAPA for at least two years, until ESRD use and spending data were available. CMS would base the TDAPA on the average sales (ASP) price plus 6 percent, or the wholesale acquisition cost (WAC) if ASP data were not available. When the TDAPA period ended, CMS would include the drug in the PPS payment bundle (by adding a new category); would modify the PPS base rate, if appropriate, to reflect changes to the functional categories; and would consider the drug for outlier payments.
- New injectable or intravenous products included in an ESRD-related functional category would not be eligible for a TDAPA; these products would be included in the ESRD PPS payment bundle without any change to the base rate.

Since 2018, the agency has paid for only one group of drugs, oral and injectable calcimimetics, under a TDAPA at each product's ASP plus 6 percent. Prior to 2018, Medicare paid for oral

³ "With regard to the application of the TDAPA for an injectable anemia management drug, the anemia management functional category is one of the drug categories for which we have included dollars in the base rate and that has been updated with the annual ESRD market basket percentage increase factor. As a result, there is no separate transitional drug-add-on payment adjustment available for drugs and biologicals that manage an ESRD beneficiary's anemia. As we stated above, the transitional drug add-on adjustment payment is intended to capture those drugs and biologicals that are not reflected in the base rate." (*Federal Register* 81, no. 214, November 4, 2016, page 77862.)

⁴ The ESRD PPS functional categories are: access management, anemia management, bone and mineral metabolism, cellular management, antiemetic, anti-infectives, antipruritic, anxiolytic, excess fluid management, fluid and electrolyte management including volume expanders, and pain management.

calcimimetics under Part D. CMS will include calcimimetics in the PPS bundle once the agency has sufficient utilization claims data for a rate setting analysis.

The CY 2019 ESRD PPS final rule made two important changes to the TDAPA provision. First, it expanded the TDAPA to include new ESRD products (including generic drugs and biosimilars) approved by the Food and Drug Administration (FDA) on or after January 1, 2020, that treat a condition for which there is an ESRD-related functional category. Second, the rule extended the TDAPA to functional categories of drugs that were, before 2011, paid under the prior ESRD payment system's prospective payment—the composite rate. As adopted in the 2019 rulemaking process, CMS will pay a TDAPA for all new products that fit into an ESRD-related functional category for two years; thereafter, CMS will include the drug in the PPS payment bundle but will make no modifications to the ESRD PPS base rate because there would be no changes to the functional categories. Once included in the ESRD PPS payment bundle, new products considered to be composite rate drugs would not be eligible for an outlier payment, but other new drugs would be eligible for outlier payments.

In addition to expanding the TDAPA, the CY 2019 ESRD PPS final rule changed the payment provisions and billing code requirements for all products (other than calcimimetics) paid under a TDAPA:

- CMS bases the TDAPA on the product's ASP plus 0 percent, or WAC if ASP data were not available. (Prior to CY 2019, products were paid on the basis of ASP plus 6 percent, or WAC if ASP data were not available.)
- Products are eligible for a TDAPA if they applied for a billing (Healthcare Common Procedure Coding System (HCPCS)) code. Prior to CY 2019, products were required to have been assigned a HCPCS code in order to be eligible for a TDAPA.

To address concerns from stakeholders about the broad nature of the TDAPA policy that was adopted in rulemaking for the CY 2019 ESRD PPS, the agency is proposing to refine the TDAPA eligibility criteria. CMS's proposal would exclude drugs from receiving a TDAPA that are included in an ESRD functional category and that the agency considers to be "not truly innovative," which would be determined based on FDA approval pathways. CMS's proposal would exclude:

- Generic drugs (i.e., drugs that the FDA approves under section 505(j) of the Federal Food, Drug, and Cosmetic Act).
- New drugs approved for a new dosage form (e.g., pill size, time-release forms, chewable or effervescent pills); new drugs approved for a new formulation (e.g., new inactive ingredient); new drugs approved that were previously marketed without a new drug application (NDA); and new drugs approved that changed from prescription to over-the-counter. CMS would identify these drugs using the NDA classification code that the FDA assigns to an NDA.

CMS is not proposing to apply substantial clinical improvement criteria to determine a drug's or biologic's eligibility for a TDAPA payment. Although CMS contends that biosimilar products do not offer a new treatment method, the agency will continue to pay a TDAPA for these products because their exclusion "would disadvantage this sector of biological products in a space where we are trying to support technological innovation." According to the agency, "While the products [biosimilars] themselves may not be innovative, CMS believes that the technology used to develop the products is sufficiently new and innovative to warrant a TDAPA payment at this time."⁵

Comment

We commend CMS for reconsidering the TDAPA eligibility criteria and proposing a standard that is stricter than the one that the agency adopted in the CY 2019 ESRD PPS rulemaking. However, the Commission believes that a substantial clinical improvement standard is the best way to ensure taxpayer and beneficiary dollars are spent to improve patient care or outcomes. CMS's approach relies on FDA approval pathways using a standard that is less stringent than a clinical improvement standard for all drugs and biologics that fit into an ESRD functional category. For example, the proposed TDAPA policy would include biosimilars that fit into an ESRD functional category even though CMS acknowledges that these products may not be innovative. CMS should not pay more for a new technology without evidence that it improves outcomes for Medicare beneficiaries.

As the Commission said in our comments on the ESRD PPS proposed rule for CY 2019,⁶ CMS should apply a clinical improvement standard to the TDAPA for *all* drugs and biologics that fit into an ESRD functional category, ensuring that taxpayer and beneficiary dollars result in improved patient care or outcomes. Applying a clinical improvement standard in the TDAPA policy is consistent with:

- Medicare's payment for certain new technologies under the outpatient PPS (OPPS) and inpatient PPS (IPPS).
- CMS's proposal to apply the IPPS substantial clinical improvement standard (specified in section 412.87(b)(1)) to the add-on payment for new ESRD equipment and supplies.

The Commission has long held that Medicare should pay similar rates for similar care. To protect the well-being of beneficiaries and ensure good value for the Medicare program and taxpayers,

⁵ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. 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) fee schedule amounts, DMEPOS competitive bidding (CBP) proposed amendments, standard elements for a DMEPOS order, and master list of DMEPOS items potentially subject to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements. *Federal Register* 84, no. 151 (August 6): 34313.

⁶ Medicare Payment Advisory Commission. 2018. Comment letter on CMS's proposed notice 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, 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." August 31.

Medicare should not pay more for technologies that have not yet been proven to provide better outcomes for beneficiaries. Therefore, a new technology should not qualify for the TDAPA if there is no evidence that it is an improvement relative to existing care. CMS could structure a TDAPA clinical improvement similar to the standard that the agency uses to pay for new technologies under the inpatient PPS (specified in section 412.87(b)(1)).

CMS should not use FDA's approval processes as a proxy for or in place of a substantial clinical improvement criteria to determine TDAPA eligibility. Participation in FDA's approval pathways on its own does not necessarily reflect improvements in outcomes nor the appropriateness of increased payment for Medicare beneficiaries. As we discuss in this letter's comment about the transitional add-on payment adjustment for new ESRD equipment and supplies, the Commission also believes that the Medicare program, not the FDA, should adjudicate spending determinations based on the specific needs of the Medicare population. The Commission recognizes the unique roles across federal agencies with respect to approving new technologies for marketing in the U.S. and increasing payment for Medicare beneficiaries. The evaluation of the evidence of whether a new technology improves Medicare beneficiaries' outcomes should rest with CMS.

Finally, CMS should not make duplicative payments for a new product assigned to a functional category by paying under the TDAPA for two years in addition to paying for its functional category under the ESRD PPS base rate. For example, the agency could reduce the TDAPA amount to reflect the amount already included in the base rate. CMS should also consider paying a reduced percentage of the estimated incremental cost of the new drug as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices (as the agency is proposing for the transitional add-on payment for new ESRD equipment and supplies).

Revising the TDAPA payment for calcimimetics

In 2020, CMS is proposing to reduce the payment rate for the TDAPA for calcimimetics, drugs that treat secondary hyperparathyroidism in dialysis patients,⁷ from ASP plus 6 percent to 100 percent of ASP. CMS states that the first two years of the TDAPA (in 2018 and 2019) has provided ESRD facilities with sufficient time to address administrative complexities and overhead costs that may have arisen with regard to furnishing the calcimimetics. CMS also believes that the agency needs to take into account the financial burden that increased payments place on beneficiaries and Medicare expenditures; in 2018, Medicare spending for calcimimetics totaled \$1.2 billion. In last year's rulemaking, CMS codified its proposal that all other TDAPA drugs are paid at 100 percent of each product's ASP.

Comment

In our 2018 comments on the ESRD PPS proposed rule for CY 2019, we said that there is good rationale for CMS's proposal to change the basis for the TDAPA from ASP plus 6 percent to ASP with no percentage add-on. The ASP plus 6 percent policy was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. While

⁷ Calcimimetics fall within the ESRD PPS's bone and mineral metabolism functional category.

the policy never stated what cost the “+6 percent” was intended to cover, we note that applying the policy to dialysis facilities is considerably different from reimbursing physicians. First, the variation in physicians’ purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for dialysis facilities. If the intent of the “+6 percent” was to address acquisition price variation, we believe that rationale is diminished for dialysis facilities. Second, we note that the TDAPA is in addition to the ESRD base rate, which already includes reimbursement for the cost of storage and administration of ESRD-related drugs. Therefore, if the intent of the “+6 percent” was to address storage and administration costs, we believe these costs are already addressed through the ESRD bundle and thus do not warrant the additional 6 percent. We thus support CMS’s proposal to change the basis of the TDAPA for calcimimetics to ASP with no percentage add-on.

Requiring average sales price data for drugs and biologics paid under the TDAPA

The payment rate for drugs and biologics paid under the TDAPA is based on each product’s ASP. If ASP data are not available, then the product is priced based on its WAC; if WAC is not available, then the price for the product is based on the drug manufacturer’s invoice. Beginning in 2020, CMS proposes to no longer apply the TDAPA for a product if the agency does not receive:

- a full calendar quarter of ASP data within 30 days of the last day of the third calendar quarter after the agency begins applying the TDAPA for that product, or
- the latest full calendar quarter of ASP data for the product, beginning no later than two-calendar quarters after the agency determines that the latest full calendar quarter of ASP data is not available.

If CMS does not receive the required data, the agency would no longer apply the TDAPA for the product beginning no later than two calendar quarters after CMS determines a full calendar quarter of ASP data is not available. This proposal partly stems from concerns that: (1) the TDAPA policy could incentivize drug manufacturers who do not have Medicaid drug rebate agreement to delay or never submit ASP data from CMS in order for ESRD facilities to receive an increased TDAPA for their products; and (2) the lack of ASP data will unnecessarily inflate Medicare spending. In the proposed rule, CMS states that the TDAPA for one form of the calcimimetics was based on WAC for two quarters and was more expensive than ASP.

Comment

The Commission supports CMS’s proposal to withhold payment under the TDAPA if manufacturers do not submit ASP data to the agency. In our June 2017 report to the Congress, we recommended that CMS require all manufacturers of products paid under Part B to submit ASP data and impose penalties for the failure to report.⁸ Failing to report ASPs can impact prices for Part B drugs in several ways. For drugs with partially complete ASP data—that is, drugs for which

⁸ Medicare Payment Advisory Commission. 2017. *Report to the Congress: Medicare and the health care delivery system*. Washington, DC. MedPAC.

some manufacturers report ASPs but others do not—payment rates based on only the reported ASP data might not accurately reflect average prices of all manufacturers. For drugs with no ASP data—that is, drugs for which no manufacturer reports ASPs—CMS might resort to pricing drugs using alternative and potentially inflated measures of price such as WACs. The Health and Human Services Office of Inspector General has found that: (1) a number of drug manufacturers are not required to report their ASP data; and (2) some manufacturers that are required to submit ASP data fail to do so. Requiring that all manufacturers of Part B drugs report ASP data would improve the accuracy of CMS’s drug prices and help prevent CMS from relying on other, less optimal prices, such as WACs, particularly when CMS revises the ESRD PPS base rate to include calcimimetics or drugs in a new functional category in the payment bundle.

Proposed CY 2020 update to the outlier policy

The outlier policy in the ESRD PPS reimburses some of a facility’s cost for patients with very high costs for items and services that were separately billable prior to the implementation of the ESRD PPS.⁹ The goal of the outlier policy is to distribute 1 percent of total spending to the cases with the highest costs for these services by reimbursing 80 percent of costs above a certain threshold. Each year, CMS estimates the outlier threshold based on two values, the average spending on separately billable services (or Medicare Allowable Payment (MAP) amount)) and the amount of spending above the MAP that is necessary to meet the 1 percent of total spending target for the outlier policy (Fixed Dollar Loss (FDL) amount). The outlier threshold is the sum of the MAP and the FDL dollar amounts. CMS uses the most recently available claims data (from two calendar years prior to the payment year) to project MAP and FDL amounts for the following payment year.

The outlier policy is funded by withholding 1 percent of total expected spending, while the remaining 99 percent of spending funds all other ESRD PPS payment rates (base rate, case-mix adjustment factors, and home training payments). 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 (and vice versa if the outlier threshold is set too low). As shown in the table below, over the past several years, the outlier threshold has been too high to fully pay out outlier payments, despite the fact that CMS has generally decreased the threshold each year.

Year	2011	2012	2013	2014	2015	2016	2017	2018
Outlier threshold (adults)	\$238	\$219	\$170	\$149	\$137	\$138	\$128	\$120
Outlier payment percent	0.30%	0.20%	0.50%	0.80%	0.93%	0.78%	0.80%	0.50%*

Source: CMS final rules for calendar years (CYs) 2011–2019, except *CMS proposed rule for CY 2020.

For CY 2020, CMS proposes to update the outlier services MAP amounts and FDL amounts using 2018 claims data, which CMS believes will bring outlier payments closer to the 1 percent target. In

⁹ The remainder of the ESRD bundle is made up of items and services that were included in the composite rate, used for dialysis payments prior to 2011. Items and services that were formerly separately billable are generally drugs, labs, and related services.

reference to the update of outlier services MAP and FDL amounts, CMS states “... *beginning in CY 2020, the total expenditure amount includes payments made for calcimimetics under the TDAPA policy (calculated to be \$21.15 per treatment).*”¹⁰

Comment

We recognize the great difficulty in estimating an outlier threshold such that the 1 percent of the ESRD PPS spending target is met by the outlier policy. We also note that in every year since the ESRD PPS was implemented in 2011, the outlier threshold has been reduced and yet still turns out to have been set too high. This phenomenon suggests a declining trend in spending for separately billable services for dialysis patients with very high spending on those services. Each year, CMS states that updating the base year of data used to calculate the outlier threshold should bring the outlier payments closer to the targeted 1 percent, but this strategy alone does not appear effective.

The Commission suggests that CMS consider modeling alternative approaches to establishing the outlier threshold and use an approach that reflects the trend in separately billable spending over time. Other CMS payment systems use trend information when establishing similar payment policies. For example, in establishing county benchmark rates, the Medicare Advantage program uses a prediction method that accounts for utilization trends for specific services combined with the most recent available prices. Such an approach could produce a more reliable outlier threshold estimate and may result in the outlier payment amounts that, on average, are closer to the target.

Finally, in the discussion of updating the outlier services MAP and FDL amounts, CMS should clarify the reference to calcimimetic payments being included in total expenditure amounts (as noted above). It is not clear how CMS is using calcimimetic expenditure data to estimate the CY 2020 MAP and FDL amounts. CMS has previously said that TDAPA payments (including payments for calcimimetics) are not eligible for outlier payments and that the 1 percent target for outlier payments is based on total ESRD PPS expenditures.¹¹

Given that CMS has said that total ESRD expenditure amounts for 2020 include payments for calcimimetics that are paid under a TDAPA policy, we believe CMS proposes to target 1 percent

¹⁰ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. 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) fee schedule amounts, DMEPOS competitive bidding (CBP) proposed amendments, standard elements for a DMEPOS order, and master list of DMEPOS items potentially subject to a face-to-face encounter and written order prior to delivery and/or prior authorization requirements. *Federal Register* 84, no. 151 (August 6): 38361.

¹¹ 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. 220 (November 14): 56943.

of total expenditures, including TDAPA payments in 2020, when establishing the FDL amount.¹² However, the outlier pool has been funded through a 1 percent reduction in the base rate (that was applied in 2011 and has remained in effect in each subsequent year by applying all annual updates to the reduced base rate) and therefore does not account for TDAPA payments for calcimimetics, which are currently an add-on payment to the base rate. CMS has not proposed a budget-neutral method for funding the outlier policy in 2020 that accounts for the additional ESRD expenditures from payments for calcimimetics under TDAPA policy. CMS should maintain a budget-neutral outlier policy either by excluding TDAPA payments for calcimimetics from the total ESRD expenditures so that the 1 percent outlier payment target does not include TDAPA payments (i.e., the policy applied to TDAPA payments for calcimimetics in 2018 and 2019), or by reducing TDAPA payments by 1 percent so that funding for the outlier policy accounts for TDAPA payments for calcimimetics.

Implementing a transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES)

The agency is proposing an add-on payment for certain new ESRD-related equipment and supplies under a “transitional add-on payment adjustment for new and innovative equipment and supplies” (TPNIES). CMS would pay the TPNIES to facilities for two calendar years, after which the equipment or supply would: (1) be included in the PPS payment bundle without any change to the ESRD PPS base rate and (2) be eligible for outlier payments.

An ESRD-related equipment and supply would be eligible for the TPNIES if the item: (1) is new, defined as being granted marketing authorization by the FDA on or after January 1, 2020; (2) has applied for a HCPCS billing code; (3) is not a capital-related asset;¹³ and (4) is truly innovative, defined as meeting the substantial clinical improvement (SCI) criteria that is based on the criteria used to determine a new technology’s eligibility for the new technology add-on payment (NTAP) under the IPPS in section 412.87(b)(1). Specifically, a technology is considered innovative under the IPPS’s new technology add-on payment policy if it “...represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.” In the final rule for the FY 2020 IPPS, CMS explains that the totality of the circumstances will be considered when making a determination that a technology represents an advance that substantially improves, relative to services or technologies previously available, the

¹² To implement the outlier policy for 2020, we believe that CMS is proposing to: (1) calculate the outlier payment pool based on 1 percent of 2020 total expected expenditures for the ESRD PPS (including TDAPA payments for calcimimetics); (2) calculate a loss amount for each patient month using 2018 claims data by subtracting the predicted MAP (estimated payment for separately billable items and services) from the imputed MAP (estimated cost of providing separately billable items and services); (3) through an iterative process, calculate the FDL amount such that if 80 percent of any loss amount above the FDL were reimbursed through the outlier policy, the total outlier payments for all eligible patient months would equal 1 percent of 2020 total expected expenditures for the ESRD PPS (including TDAPA payments for calcimimetics); and (4) determine outlier payment eligibility and outlier payment amounts based only on spending for outlier-eligible items and services using 2020 claims data.

¹³ CMS defines capital-related assets as an asset that a provider has an economic interest in through ownership (as set forth in the Provider Reimbursement Manual, chapter 1, section 104.1). The agency includes the following items as examples of capital-related assets: dialysis machines, water purification systems and systems designed to clean dialysis filters for reuse.

diagnosis or treatment of beneficiaries. The evaluation criteria that the agency codified in the FY 2020 IPPS final rule for determining whether a new technology represents an advance under the IPPS's NTAP include:

- The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The technology diagnoses a medical condition in a population for which the condition is currently undetectable.
- The technology improves clinical outcomes relative to technologies previously available by: reducing adverse events, decreasing subsequent diagnostic or therapeutic interventions or providing the ability to diagnose a medical condition earlier in a population than currently available methods, decreasing future hospitalizations or physician visits, improving activities of daily living or quality of life, or improving medication adherence.¹⁴

In this rule proposing updates to the CY 2020 ESRD PPS, the agency is seeking comment on whether to use FDA's pre-market approval and De Novo pathways as a proxy for or in place of the proposed substantial clinical improvement criteria.

Due to the absence of data indicating a market price, Medicare Administrative Contractors (MACs) would determine the payment of new equipment and supplies paid under the add-on adjustment taking into account: invoice amounts; facilities' charges for the item reported on its claims and their discounts, allowances, or rebates; the price established for the item by other MACs and the sources of information used to establish the price; payment amounts determined by other payers and the information used to establish those payment amounts; and charges and payment amounts, required for other equipment and supplies that may be comparable or otherwise relevant. To mitigate Medicare spending resulting from the TPNIES, CMS is proposing that the new item's payment rate would be set at 65 percent of the price that the MACs establish. The percentage amount (65 percent) that the MACs would apply to calculate the TPNIES payment is derived from the percentage amount that Medicare uses in the IPPS to pay for new technology (specified in section 412.88). The agency is seeking comment on whether to explicitly link the ESRD TPNIES payment percentage to the IPPS NTAP mechanism's maximum add-on payment percentage (currently set at 65 percent).

Comment

The Commission recognizes the need to promote beneficiary access to new technologies that improve outcomes while preserving the incentives within a prospective payment system for

¹⁴ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2019. Medicare program; hospital inpatient prospective payment system for acute care hospitals and the long-term care hospital prospective payment system and policy changes and fiscal year 2020 rates; quality reporting requirements for specific providers; Medicare and Medicaid promoting interoperability programs requirements for eligible hospitals and critical access hospitals; final rule. *Federal Register* 84, no. 159 (August 16): 42044–42701.

efficiency.¹⁵ However, we also believe that it is important to maintain the structure of the ESRD PPS and not create policies that would unbundle services covered under the ESRD PPS or create incentives that encourage high launch prices of technologies. We are also mindful of the potential that new technologies may turn out to be less effective than initially thought, or in some cases even potentially harmful. In the IPPS FY 2002 final rule, the Secretary stated that “...it is in the best interest of Medicare beneficiaries to proceed very carefully with respect to the incentives created to quickly adopt new technology.”¹⁶

Consequently, if CMS proceeds with its proposal to apply the TPNIES policy to new ESRD-related equipment and supplies, we believe that 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. We support the agency’s proposal to use the IPPS substantial clinical improvement standard for new IPPS technology that is set forth in section 412.87(b)(1) for the ESRD PPS TPNIES.

CMS should create functional categories for new ESRD-related equipment and supplies, as it has done when establishing the ESRD TDAPA for drugs and biologics and the outpatient PPS’s pass-through payment policy for devices. Such functional categories would define the equipment and supplies that are included in the ESRD PPS payment bundle. Establishing functional categories for ESRD-related equipment and supplies could facilitate the agency’s analysis of whether a new ESRD-related item is in an existing functional category and whether it substantially improves beneficiaries’ outcomes relative to existing technology in the bundle. Consistent with our August 31, 2018, comments about the TDAPA that CMS proposed and subsequently finalized in the ESRD PPS rulemaking for CY 2019, we do not support paying separately through transitional add-on payments for new technologies that fit into an existing functional category.

CMS should not use FDA’s approval processes, including pre-market approval and De Novo pathways, as a proxy for or in place of the proposed substantial clinical improvement criteria. In our recent comments on the IPPS proposed rule for FY 2020, we said that:

- The Commission maintains that the Medicare program, not the FDA, should adjudicate spending determinations based on the specific needs of the Medicare population.
- The FDA’s role in the drug and device development process as a regulator is distinct and separate from the role of CMS as a payer. The FDA regulates whether a device or pharmaceutical is “safe and effective” for its intended use by consumers. The FDA

¹⁵ Medicare Payment Advisory Commission. 2019. Comment letter on CMS’s proposed notice entitled “Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Hospital Prospective Payment System, and Proposed Policy Changes and Fiscal Year 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Rule.” June 21.

¹⁶ Centers for Medicare & Medicaid Services, Department of Health and Human Services. 2001. Medicare program; payment for new medical services and new technologies under the acute care hospital inpatient prospective payment system; final rule. *Federal Register* 66, no. 174 (September 7): 46901–46925.

approval process may or may not include the new device or pharmaceutical's safety or effectiveness with regard to the Medicare population.

- There have been many examples where devices approved through expedited FDA approval have not resulted in improvements in care relative to existing technologies. For example, a review of several studies that presented clinical trial evidence of certain approved devices under the FDA's Priority Review Program (also superseded by the Breakthrough Device Program) found that 4 out of 9 expert advisory panel reviews did not find the devices to be effective and, as of May 23, 2018, recalls had been issued for 6 of 14 devices. The Commission is concerned about inappropriate incentives (through increased payment) for providers to use new technology without proven safety or efficacy.

Regarding CMS's proposal to pay 65 percent of the technology's cost, we support the agency's proposal to pay a reduced percentage of the new item's cost as a way to share risk with dialysis providers and provide some disincentive for the establishment of high launch prices. CMS should not explicitly link the ESRD TPNIES payment percentage to the IPPS NTAP mechanism's maximum add-on payment percentage. The agency would have greater flexibility about any future changes to the ESRD PPS payment percentage if it was not explicitly linked to the IPPS payment percentage. In addition, CMS should not make duplicative payments for new ESRD-related equipment and supplies by paying under the TPNIES for two years and paying for an item with a similar purpose or use that is already paid under the ESRD PPS base rate. For example, the agency could reduce the TPNIES payment amount to reflect the amount already included in the base rate.

We agree with CMS's proposal that TPNIES payment should be based on the price established by the MACs (using information from invoices and other relevant sources of information) but only for the first two calendar quarters after CMS begins applying the TPNIES. Thereafter, CMS should set the price of new equipment and supplies using a method based on pricing data collected directly from each manufacturer, similar to how the agency establishes the average sales price (ASP) for Part B drugs. The ASP for a Part B drug reflects the average price realized by the manufacturer for its sales broadly across different types of purchasers and for patients with different types of insurance coverage. It is based on the manufacturer's sales to all purchasers (with certain exceptions) net of manufacturer rebates, discounts, and price concessions. There is a two-quarter lag in the data used to set ASP-based payment rates. An approach similar to how CMS collects ASP data would increase the consistency of pricing data and should lead to more accurate payment rates for items paid under the TPNIES. Similar to the TDAPA for ESRD drugs and biologics, CMS should link payment of the TPNIES to a requirement that equipment and supply manufacturers submit ASP-like data to the agency.

It is unclear whether CMS's proposal excludes capital-related assets that are leased from receiving a TPNIES. In the proposed rule, the agency's definition of a capital-related asset refers to the Provider Reimbursement Manual (Chapter 1, Section 104.1), which does not distinguish between capital-related items that are purchased versus those that are leased. In the final rule, CMS should clarify whether a capital asset that is leased would qualify for TPNIES status.

In terms of the TPNIES review process, the Commission supports transparent and predictable processes with established routines for the agency, stakeholders, and the public. The proposed

annual process of review for TPNIES qualification provides manufacturers a forum for feedback and questions, and it provides other stakeholders with opportunities to participate in the process.

Finally, CMS should publish in the final rule an estimate of the increase in beneficiaries' and taxpayers' spending due to the proposed policy change and the method used to develop the estimate.

Discontinuing the monitoring policy for erythropoiesis-stimulating agents (ESAs)

CMS is proposing to discontinue the application of the ESA monitoring policy (EMP) under the ESRD PPS. CMS used the EMP in establishing the 2011 ESRD PPS base rate; payments for epoetin alfa in excess of 500,000 units per month were capped at 500,000 units and a similar cap was applied to darbepoetin alfa. The agency has continued to apply the EMP to help ensure the proper dosing of ESAs and provide a safeguard against the overuse of ESAs, particularly where the consumption of other separately billable services may be high, in order to obtain outlier payments.¹⁷ According to CMS, the EMP is no longer needed to address potential over-use of ESAs due to implementation of the ESRD PPS and FDA relabeling of ESAs.

Comment

The implementation of the ESRD PPS in 2011 created incentives for dialysis providers to furnish services more efficiently by reducing previous incentives inherent in the former payment method (when Medicare paid according to the number of units furnished to beneficiaries) to overutilize drugs and biologics. Under the ESRD PPS, in which all ESRD-related drugs are included in the payment bundle, dialysis providers have been more judicious in providing all drugs, including ESAs. For example, between 2010 and 2017, use of all ESRD-related drugs paid under the ESRD PPS has declined by 12 percent per year.¹⁸ The decline in the use of ESRD drugs under the PPS has occurred without any negative effect on clinical outcomes.

By contrast, the TDAPA, which will pay providers separately for nearly all dialysis drugs and biologics that the FDA approves on or after January 1, 2020, may promote excess provision of ESRD-related products (to the extent clinically possible). Paying according to the number of units administered gives providers greater profits from larger doses than smaller doses (as long as Medicare's payment rate exceeds providers' costs). In addition to increased and unnecessary spending for beneficiaries and taxpayers, overuse of drugs can have negative clinical consequences. Because of the incentive for potential overuse of drugs paid under the TDAPA, CMS should not discontinue the EMP. The Commission urges CMS to establish a formal

¹⁷ Under the current EMP (specified in the Medicare Claims Processing Manual): (1) MACs apply a 25 percent reduction in the reported ESA dose on the claim when the hematocrit/hemoglobin level exceeded a certain value, unless the ESRD facility reported a modifier to indicate the dose was being decreased; (2) ESRD facilities report each patient's three-month rolling average hematocrit/hemoglobin level so that the MACs know when to apply a 50 percent reduction in the reported ESA dose on the claim; and (3) medically unlikely edits (MUE) are applied to ESA claims (for example, the MUE for epoetin alfa claims is reduced to 400,000 units from 500,000).

¹⁸ Medicare Payment Advisory Commission. 2019. *Report to the Congress: Medicare payment policy*. Washington, DC. MedPAC.

monitoring policy for all products that are paid under the TDAPA to address their potential for overuse.

Auditing dialysis facilities' cost reports

PAMA required that the Secretary of Health and Human Services conduct audits of Medicare cost reports beginning in 2012 for a representative sample of freestanding and hospital-based facilities furnishing dialysis services, consistent with a prior MedPAC recommendation. To support this effort, the law authorized the Secretary to transfer \$18 million (in fiscal year 2014) from the Federal Supplementary Medical Insurance Trust Fund to CMS's program management. In September 2015, CMS awarded a contract to conduct the audit.

Comment

CMS should release the final results of the audit. In the final rule for the CY 2019 ESRD PPS, CMS said that the audit process is complete and the audit staff are reviewing the findings. The Commission has repeatedly discussed the importance of auditing the cost reports that dialysis facilities submit to CMS to ensure that the data are accurate. First, inaccurate cost report data could affect the ESRD PPS's payment adjustment factors and ESRD market basket index, which are derived from this data source. Second, accurate accounting of costs is essential for assessing facilities' financial performance under Medicare. The Medicare margin is calculated from this data source, and policymakers consider the margin (and other factors) when assessing the adequacy of Medicare's payments for dialysis services. If costs are overstated, then the Medicare margin is understated. Third, it has been more than 15 years since cost reports were audited, and in 2011, the outpatient dialysis payment system underwent a significant change, which might have affected how facilities report their costs. Fourth, historically, facilities' cost reports have included costs that Medicare does not allow.

MedPAC appreciates the opportunity to comment on this proposed rule. The Commission also values the ongoing cooperation and collaboration between CMS and MedPAC staff on technical policy issues. We look forward to continuing this productive relationship.

If you have any questions, or require clarification of our comments, please feel free to contact James E. Mathews, MedPAC's Executive Director at (202) 220-3700.

Sincerely,



Francis J. Crosson, M.D.
Chairman