paymentbasics

OUTPATIENT DIALYSIS SERVICES PAYMENT SYSTEM

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The policies discussed in this document were current as of September 30, 2024. This document does not reflect proposed legislation or regulatory actions.

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425 I Street, NW Suite 701 Washington, DC 20001 ph: 202-220-3700 www.medpac.gov Individuals with end-stage renal disease (ESRD)—irreversible loss of kidney function—require either dialysis or kidney transplantation to survive. In 1972, the Social Security Act extended all Medicare Part A and Part B benefits to individuals with ESRD who are entitled to receive Social Security benefits. In 2022, there were nearly 290,000 fee-for-service (FFS) Medicare ESRD beneficiaries on dialysis, representing about 1 percent of all FFS Medicare beneficiaries.

Because of the scarcity of kidneys available for transplantation, most patients with ESRD (69 percent) receive maintenance dialysis. Medicare spending for outpatient dialysis and injectable drugs administered during dialysis was about \$8.8 billion in 2022 and is a predominant share of revenues for dialysis facilities.

Beginning in 1983, Medicare paid dialysis facilities a predetermined rate (the composite rate) intended to cover a specific bundle of services provided to patients in a given dialysis treatment. To improve provider efficiency, Medicare implemented a modernized prospective payment system (PPS) for outpatient dialysis services in 2011. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) broadened the payment bundle to include dialysis drugs, laboratory tests, and other ESRD-related items and services that were previously separately billable. MIPPA also required CMS to implement a pay-forperformance program beginning in 2012. Table 1 summarizes the key features of the dialysis PPS.

Defining the care that Medicare buys

Medicare covers two methods of dialysis—hemodialysis and peritoneal dialysis. In hemodialysis, a patient's blood is cycled through a dialysis machine, which filters

out body waste. Eighty-three percent of all dialysis patients undergo hemodialysis typically three times per week in dialysis facilities. Peritoneal dialysis uses the lining of the peritoneal cavity to filter excess waste products, which are then drained from the abdomen. Patients undergo peritoneal dialysis five to seven times per week in their homes.

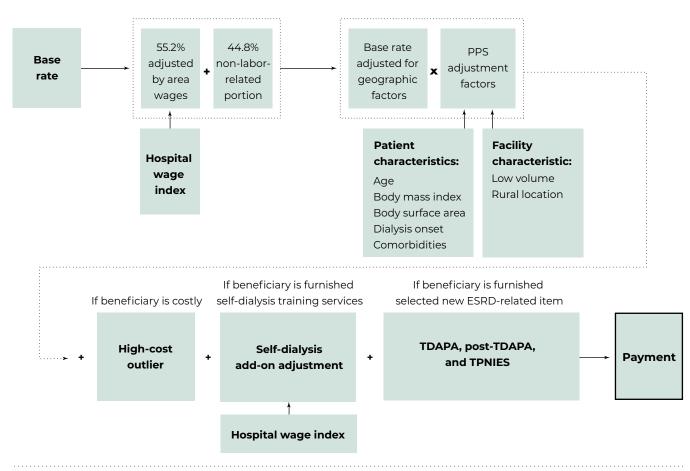
The unit of payment is a single dialysis treatment. Although different equipment, supplies, and labor are needed for hemodialysis and peritoneal dialysis, the payment system that began in 2011 does not differentiate payment based on dialysis method for adults. Medicare's payment rate is based on a regimen of three dialysis treatments per week.

Under the dialysis PPS, facilities are paid a single case-mix-adjusted payment that includes composite rate services and ESRD-related drugs, laboratory services, and medical equipment and supplies. The ESRD drugs included under the broader payment bundle are (1) Part B ESRD-related drugs (including injectable erythropoietin, iron, and vitamin D analogs, and their oral equivalents); and (2) Part D oral ESRD-related drugs with or without an injectable equivalent.¹

Setting the payment rates

The base payment for each dialysis treatment is intended to cover all operating and capital costs that efficient providers would incur in furnishing dialysis treatment episodes in dialysis facilities or in patients' homes. For 2024, the base payment rate is \$271.02 for both freestanding facilities and for hospital-based facilities (Figure 1). The base rate is adjusted for differences in labor costs by multiplying the labor-related portion of the base payment amount (55.2 percent) by a version of the hospital wage index.

Figure 1 Dialysis prospective payment system in 2024



Note: PPS (prospective payment system), ESRD (end-stage renal disease), TDAPA (transitional drug add-on payment adjustment), TPNIES (transitional add-on payment adjustment for new and innovative equipment and supplies). This figure represents the dialysis PPS for beneficiaries 18 and older. For beneficiaries under 18: (1) the base rate, adjusted for geographic factors, is multiplied by patient case-mix characteristics (age and dialysis method); (2) the low-volume adjustment and rural factors do not apply; (3) the outlier payment policy and add-on for self-dialysis training do apply; and (4) for calendar years 2024 through 2026, CMS will apply a per treatment transitional add-on payment adjustment of 30 percent of the per treatment payment amount. The payment rate may be reduced by up to 2 percent for facilities that do not achieve or make progress toward specified quality measures.

Source: MedPAC analysis of CMS's final rule for the end-stage renal disease prospective payment system for calendar year 2024.

Patient-level adjustments—For adults, the wage-adjusted base rate is then adjusted for case mix using the following measures:

- age (18-44, 45-59, 60-69, 70-79, ≥80 years);
- two body measurement variables (body surface area and body mass index);
- specific acute and chronic comorbidities;
 and
- onset of dialysis (for the first four months a patient receives dialysis).

For children (under the age of 18), CMS adjusts the base rate by age and dialysis

modality. For calendar years 2024 through 2026, CMS will apply a transitional pediatric ESRD add-on payment adjustment (TPEAPA), a transitional add-on payment adjustment equaling 30 percent of the per treatment payment amount, for dialysis services provided to pediatric patients.

Facility-level adjustments—CMS makes two facility-level adjustments to the base rate. First, CMS adjusts the base rate by 23.9 percent to account for the costs that low-volume facilities incur. A low-volume facility is defined as one that furnishes fewer than 4,000 treatments in each of the

Table 1 Key features of the prospective dialysis payment system

Payment method feature

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Payment bundle	 Composite rate services (i.e., dialysis services paid for under the former PPS, which include nursing, dialysis equipment and supplies social services, and certain laboratory tests and drugs) Part B injectable dialysis drugs and their oral equivalents ESRD-related laboratory tests Selected ESRD Part D drugs Self-dialysis training services
Unit of payment	Single dialysis treatment
Self-dialysis training services adjustment	Yes
Beneficiary-level adjustments	 For adults: age, dialysis onset, body surface area, body mass index, specific acute (pericarditis, gastrointestinal tract bleeding or hemorrhage) and chronic (hereditary hemolytic or sickle cell anemias, myelodysplastic syndrome) patient comorbidities For pediatric patients: age, dialysis method
Transitional pediatric ESRD add-on payment adjustment	 For pediatric patients: per treatment add-on payment adjustment of 30 percent of the per treatment payment amount
Facility-level adjustments	Wage indexLow-volume adjustmentAdjustment for rural location
Outlier policy	Applies to the portion of the broader payment bundle composed of the drugs and services that were previously separately billable
Transitional add-on payment adjustments for selected new ESRD-related items	Pays facilities an add-on payment for the following qualifying new ESRD items: (1) drugs and biologics and (2) equipment and supplies
Quality incentive program	For 2024, 16 measures

Note: PPS (prospective payment system), ESRD (end-stage renal disease). Payments for pediatric patients are not eligible for the low-volume or rural adjustments. The Transitional Pediatric ESRD Add-On Payment Adjustment is for calendar years 2024 through 2026 only.

Source: MedPAC analysis of CMS 2021-2024 final ESRD rules.

three years before the payment year and that has not opened, closed, or received a new provider number due to a change in ownership during the three-year period. In addition, CMS considers the proximity to other commonly owned facilities within five miles of the facility in question.

CMS also includes an adjustment (of 0.8 percent applied to the base PPS rate) for all facilities located in rural areas.

Quality incentive adjustment-The bundled payment rate is reduced by up to 2 percent for facilities that do not achieve or make progress toward specified quality measures.

Outlier payments

CMS pays facilities an outlier payment when a beneficiary's payment per treatment for outlier services exceeds

a threshold, which is the beneficiary's predicted payment amount per treatment for the outlier services plus a fixed dollar loss amount. Outlier services include drugs, laboratory services, and other items that facilities separately billed under the old payment method. Services that are paid under a transitional add-on payment policy are not eligible for outlier payments. The outlier threshold amount for 2024 is \$108 for adults. Medicare pays 80 percent of the facilities' costs above the threshold.

Transitional add-on payments for new technologies

In 2016, CMS established a drug designation process (as statutorily mandated) for determining when ESRDrelated oral-only drugs are no longer oral only and therefore must be paid under the ESRD PPS instead of under Part D. Under the process, once the Food and Drug Administration (FDA) approves an equivalent injectable product (or other non-oral forms), CMS pays facilities for both the oral and non-oral products under a transitional drug add-on payment adjustment (TDAPA) until sufficient claims data (at least two years' worth) for ratesetting analysis are available; thereafter, all forms of the product will be included in the PPS bundle.

Because an injectable equivalent of the oral calcimimetic was approved by the FDA in 2017, between 2018 and 2020, injectable and oral calcimimetics qualified for the TDAPA under the ESRD PPS. Beginning in 2021, CMS included both the injectable and oral calcimimetics in the PPS bundle and accounted for the calcimimetics' cost by adding \$9.93 to the PPS base rate.

Other qualifying ESRD-related drugs and biologics that the FDA approves on or after January 1, 2020, are eligible for a transitional add-on payment as well:

 Medicare pays a TDAPA for certain new products (excluding generic drugs and drugs with certain types of new drug applications) that treat a condition included in 1 of 11 ESRD

- functional categories of products that are covered under the PPS. After the two-year TDAPA period ends, CMS includes the drug in the PPS bundle, without any change to the ESRD PPS base rate.
- Medicare pays a TDAPA for new
 ESRD products that treat a condition
 for which there is no ESRD-related
 functional category for at least two
 years. Once sufficient claims-based
 utilization data are available, CMS
 includes the drug in the PPS bundle,
 and the base rate is modified, as
 appropriate, to account for the new
 product in the bundle.

Under the TDAPA policy, Medicare pays facilities 100 percent of each product's Part B average sales price. As of 2024, per regulation under the post-TDAPA policy, CMS applies an add-on payment adjustment to all FFS dialysis payments for ESRD beneficiaries for three years following the end of the two-year TDAPA period for a new ESRD drug in an existing functional category. The amount of this add-on payment adjustment is based on the use of the drug during the most recent 12-month period for which data are available.²

In addition, as of 2020, there is an add-on payment—the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES)—for ESRD-related equipment and supplies that meet certain criteria, including newness and substantial clinical improvement. Equipment and supplies that are considered a capital asset are not eligible for TPNIES, with the exception of home dialysis machines when used for a single patient in the home. For a two-year period, Medicare pays 65 percent of a qualifying technology's cost using information from invoices and other relevant sources. Thereafter, the piece of equipment or supply is included in the PPS payment bundle, without any change to the ESRD PPS base rate.

In 2024, three new ESRD drugs are paid under the TDAPA policy for new drugs

in an existing ESRD functional category. The TDAPA for Korsuva (to treat pruritus) began April 1, 2022, and ended March 31, 2024, while the TDAPA for Jesduvroq (to treat anemia) began October 1, 2023, and will end September 30, 2025. The TDAPA for Defencath (to reduce the incidence of catheter-related bloodstream infections) began July 1, 2024, and will end June 30, 2026. In 2024, no ESRD-related equipment or supply was paid for under the TPNIES policy.

Self-dialysis training add-on payment

In 2024, the dialysis training add-on payment is \$95.60 per treatment. CMS pays for up to 15 training sessions for peritoneal dialysis and 25 sessions for hemodialysis.

Payment updates

Medicare payments to dialysis facilities are updated annually by the ESRD market basket, which measures the price increases for goods and services that facilities buy to provide patient care, reduced by a productivity adjustment. ■

- Currently, phosphate binders are the only drugs that fall into this category; however, statutory and regulatory provisions have delayed their inclusion in the payment bundle until 2025.
- To calculate the post-TDAPA, CMS divides expenditures for the new product (based on FFS utilization of the product during the most recent 12-month period and the most recent calendar quarter of the product's average sales price data) divided by the total number of dialysis treatments during the same period. The payment adjustment is case mix adjusted and set at 65 percent of estimated expenditure levels for the given new dialysis drug.