

§ 413.234, Nt.

(i) Total units of oral and injectable calcimimetics and total number of paid hemodialysis-equivalent dialysis treatments furnished, as derived from Medicare ESRD facility claims, that is, the 837-institutional form with bill type 072X, for the third and fourth quarters of calendar year 2018 and for the full calendar year 2019.

(ii) The weighted average ASP based on the most recent determinations by CMS.

(2) CMS uses the following methodology to calculate the average per treatment payment amount for calcimimetics that is added to the ESRD PPS base rate:

(i) Determines utilization of oral and injectable calcimimetics by aggregating the total units of oral and injectable calcimimetics in paragraph (f)(1) of this section.

(ii) Determines a price for each form of the drug by calculating 100 percent of the values from the most recent calendar quarter ASP calculations available to the public for the oral and injectable calcimimetic.

(iii) Calculates the total calcimimetic expenditure amount by multiplying the utilization of the oral and injectable calcimimetics determined in paragraph (f)(2)(i) of this section by their respective prices determined in paragraph (f)(2)(ii) of this section and adding the expenditure amount for both forms.

(iv) Calculates the average per treatment payment amount by dividing the total calcimimetic expenditure amount determined in paragraph (f)(2)(iii) of this section by the total number of paid hemodialysis-equivalent dialysis treatments in the third and fourth quarter of calendar year 2018 and the full calendar year 2019.

(v) Calculates the amount added to the ESRD PPS base rate by reducing the average per treatment payment amount determined in paragraph (f)(2)(iv) of this section by 1 percent to account for the outlier policy under § 413.237.

[80 FR 69077, Nov. 6, 2015, as amended at 83 FR 57070, Nov. 14, 2018; 84 FR 60803, Nov. 8, 2019; 85 FR 71485, Nov. 9, 2020]

EFFECTIVE DATE NOTE: At 87 FR 67302, Nov. 7, 2022, § 413.234 paragraph (a) was amended by adding the word “functional” before the

42 CFR Ch. IV (10–1–23 Edition)

word “equivalent” in the definition of “Oral-only drug”, effective Jan. 1, 2025.

§ 413.235 Patient-level adjustments.

Adjustments to the per-treatment base rate may be made to account for variation in case-mix. These adjustments reflect patient characteristics that result in higher costs for ESRD facilities.

(a) CMS adjusts the per treatment base rate for adults to account for patient age, body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.

(b) CMS adjusts the per treatment base rate for pediatric patients in accordance with section 1881(b)(14)(D)(iv)(I) of the Act, to account for patient age and treatment modality.

(c) CMS provides a wage-adjusted add-on per treatment adjustment for home and self-dialysis training.

[75 FR 49201, Aug. 12, 2010]

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

(a) *Basis and definitions.* (1) Effective January 1, 2020, this section establishes an add-on payment adjustment to support ESRD facilities in the uptake of new and innovative renal dialysis equipment and supplies under the ESRD prospective payment system under the authority of section 1881(b)(14)(D)(iv) of the Social Security Act.

(2) For purposes of this section, the following definitions apply:

Capital-related asset. Asset that an ESRD facility has an economic interest in through ownership (regardless of the manner in which it was acquired) and is subject to depreciation. Equipment obtained by the ESRD facility through operating leases are not considered capital-related assets.

Depreciation. The amount that represents a portion of the capital-related asset's cost and that is allocable to a period of operation.

Home dialysis machines. Hemodialysis machines and peritoneal dialysis cyclers in their entirety (meaning that one new part of a machine does not make the entire capital-related asset

new) that receive FDA marketing authorization for home use and when used in the home for a single patient.

Particular calendar year. The year in which the payment adjustment specified in paragraph (d) of this section would take effect.

Straight-line depreciation method. A method in accounting in which the annual allowance is determined by dividing the cost of the capital-related asset by the years of useful life.

Useful life. The estimated useful life of a capital-related asset is its expected useful life to the ESRD facility, not necessarily the inherent useful or physical life.

(b) *Eligibility criteria.* CMS provides for a transitional add-on payment adjustment for new and innovative equipment and supplies (as specified in paragraph (d) of this section) to an ESRD facility for furnishing a covered equipment or supply only if the item:

(1) Has been designated by CMS as a renal dialysis service under §413.171;

(2) Is new, meaning within 3 years beginning on the date of the Food and Drug Administration (FDA) marketing authorization;

(3) Is commercially available by January 1 of the particular calendar year, meaning the year in which the payment adjustment would take effect;

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

(5) Is innovative, meaning it meets the criteria specified in §412.87(b)(1) of this chapter; and

(6) Is not a capital-related asset, except for capital-related assets that are home dialysis machines.

(c) *Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications.* CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified

in paragraph (b) of this section and announce the results in the FEDERAL REGISTER as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for DMEPOS items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

(d) *Transitional add-on payment adjustment for new and innovative equipment and supplies.* A new and innovative renal dialysis equipment or supply will be paid for using a transitional add-on payment adjustment for new and innovative equipment and supplies based on 65 percent of the MAC-determined price, as specified in paragraph (e) of this section. For capital-related assets that are home dialysis machines, payment is based on 65 percent of the pre-adjusted per treatment amount, as specified in paragraph (f)(1)(ii) of this section.

(1) The transitional add-on payment adjustment for new and innovative equipment and supplies is paid for 2-calendar years.

(2) Following payment of the transitional add-on payment adjustment for new and innovative equipment and supplies, the ESRD PPS base rate will not be modified and the new and innovative renal dialysis equipment or supply will be an eligible outlier service as provided in §413.237, except a capital-related asset that is a home dialysis machine will not be an eligible outlier service as provided in §413.237.

(e) *Pricing of new and innovative renal dialysis equipment and supplies.* (1) The Medicare Administrative Contractors (MACs) on behalf of CMS will establish prices for new and innovative renal dialysis equipment and supplies that meet the eligibility criteria specified in paragraph (b) of this section using verifiable information from the following sources of information, if available:

(i) The invoice amount, facility charges for the item, discounts, allowances, and rebates;

(ii) The price established for the item by other MACs and the sources of information used to establish that price;

(iii) Payment amounts determined by other payers and the information used to establish those payment amounts; and

(iv) Charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

(2) [Reserved]

(f) *Pricing of new and innovative renal dialysis equipment and supplies that are capital-related assets that are home dialysis machines.* (1) The MACs calculate a pre-adjusted per treatment amount, using the prices they establish under paragraph (e) of this section for a capital-related asset that is a home dialysis machine, as defined in paragraph (a)(2) of this section, as follows:

(i) Calculate an annual allowance to determine the amount that represents the portion of the cost allocable to 1 year, using the straight-line depreciation method, by dividing the MAC-determined price by its useful life of 5 years.

(ii) Calculate a per treatment amount for use in calculating the pre-adjusted per treatment amount by dividing the annual allowance, as determined in paragraph (f)(1)(i) of this section, by the expected number of treatments.

(iii) Calculate a pre-adjusted per treatment amount to determine the amount that is adjusted by the 65 percent under paragraph (d) of this section, by subtracting the average per treatment offset amount (as determined using the data sources and methodology specified in paragraphs (f)(2) and (3) of this section, respectively, of this section) from the per treatment amount (as determined in paragraph (f)(1)(ii) of this section) to account for the costs already paid through the ESRD PPS base rate for current home dialysis machines that ESRD facilities already own.

(2) The methodology specified in paragraph (f)(3) of this section for determining the average per treatment

offset amount uses the following data sources:

(i) Dialysis machine and equipment cost, total cost across all dialysis modalities, the number of hemodialysis-equivalent home dialysis treatment counts, and the number of hemodialysis-equivalent total treatment counts are obtained from renal facility cost reports (CMS form 265–11) and hospital cost reports (CMS form 2552–10) using calendar years 2017–2019 cost reports.

(A) Dialysis machine and equipment costs are obtained by summing lines 8.01 through 17.02 from Worksheet B, Column 4 for renal facility cost reports, and by summing lines 2 through 11 from Worksheet I–2 for hospital cost reports.

(B) Total cost across all dialysis modalities are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 2 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 2 for the hospital cost reports.

(C) Hemodialysis-equivalent total treatment counts are obtained by summing lines 8.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 1 through 10 from Worksheet I–4, Column 1 for the hospital cost reports.

(D) Hemodialysis-equivalent home dialysis treatment counts are obtained by summing lines 14.01 through 17.02 from Worksheet C, Column 1 for renal facility cost reports, and by summing lines 7 through 10 from Worksheet I–4, Column 1 for the hospital cost reports. In both renal facility and hospital cost reports, home Continuous Ambulatory Peritoneal Dialysis and home Continuous Cyclic Peritoneal Dialysis are reported as patient weeks, so a conversion factor of 3 is applied to obtain hemodialysis-equivalent treatment counts.

(ii) [Reserved]

(3) CMS uses the following methodology to calculate the average per treatment offset amount for home dialysis machines that is subtracted from the per treatment amount as determined in paragraph (f)(1)(ii) of this section to determine the pre-adjusted per treatment amount specified in paragraph (f)(1)(iii) of this section:

(i) Calculates annualized values for calendar year 2018 at the ESRD facility level for the metrics specified in paragraph (f)(2)(i) of this section by dividing the numbers of days the cost report spanned to compute a per-day metric, then multiplying the resulting value by the number of days in 2018 the cost report covered to compute the metrics attributable to the period covered by the cost report in 2018. Next, for ESRD facilities with multiple cost reports covering 2018 the resulting metrics are aggregated. Finally, each ESRD facility's aggregated metrics are annualized to cover the full calendar year 2018. The annualization factor for an ESRD facility is the total number of days in 2018 divided by the total days in 2018 covered by the ESRD facility's cost report(s).

(ii) Calculates an estimated home dialysis machine and equipment cost for each ESRD facility by multiplying the annualized dialysis machine and equipment cost determined in paragraph (f)(3)(i) of this section by the ESRD facility's hemodialysis-equivalent home dialysis treatment percentage. The hemodialysis-equivalent home dialysis treatment percentage for each facility is calculated by dividing annualized hemodialysis-equivalent home treatment count determined in paragraph (f)(3)(i) of this section by annualized hemodialysis-equivalent treatment count across all modalities determined in paragraph (f)(3)(i) of this section.

(iii) Calculates an average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 by dividing the sum of the estimated home dialysis machine and equipment cost in paragraph (f)(3)(ii) of this section across all ESRD facilities by the sum of annualized hemodialysis-equivalent home treatment counts determined in paragraph (f)(3)(i) of this section across all facilities.

(iv) Calculates the amount subtracted from the pre-adjusted treatment amount determined in paragraph (f)(1)(iii) of this section by inflating the average home dialysis machine and equipment cost per home dialysis treatment for calendar year 2018 determined in paragraph (f)(3)(iii) to calendar year 2021. The average home dialysis machine and equipment cost per

home dialysis treatment for calendar year 2018 is inflated to calendar year 2021 by multiplying this value by the payment rate update factor required under section 1881(b)(14)(F)(i) of the Social Security Act for calendar years 2019, 2020, and 2021. This value is then divided by a scaling factor to be converted to the ESRD PPS payment scale. The scaling factor is calculated by dividing the calendar year 2018 total cost per treatment inflated to calendar year 2021 by the average ESRD PPS payment per treatment projected for calendar year 2021.

(v) Effective January 1, 2022, CMS annually updates the amount determined in paragraph (f)(3)(iv) of this section by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor.

[84 FR 60805, Nov. 8, 2019, as amended at 85 FR 71486, Nov. 9, 2020]

§413.237 Outliers.

(a) The following definitions apply to this section.

(1) *ESRD outlier services* are the following items and services that are included in the ESRD PPS bundle:

(i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B.

(iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025.

(v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in §413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in §413.236, after the payment period has ended.