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Implementation of Changes in the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Payment for Dialysis Furnished for Acute Kidney Injury (AKI) in ESRD Facilities for Calendar Year (CY) 2021

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Note: **We revised this article to reflect the revised CR12011 issued on January 14, 2021. CMS revised the CR to rescind the requirement for reporting time on dialysis machine by removing the verbiage in the background and policy sections of the CR. We revised the article to rescind this requirement as shown in red print on pages 2 and 5 of the article. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.**

PROVIDER TYPES AFFECTED

This MLN Matters® Article is for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services to Medicare beneficiaries.

PROVIDER ACTION NEEDED

This article informs you about changes to the Calendar Year (CY) 2021 rate updates and policies for the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and changes to the payment for renal dialysis services provided to Medicare beneficiaries with Acute Kidney Injury (AKI) in ESRD facilities. Make sure your billing staffs are aware of these changes.

BACKGROUND

Effective January 1, 2011, the Centers for Medicare & Medicaid Services (CMS) implemented the ESRD PPS based on the requirements of Section 1881(b)(14) of the Social Security Act (the Act). The ESRD PPS provides a single per treatment payment to ESRD facilities that covers all of the resources used in furnishing an outpatient dialysis treatment. The ESRD PPS base rate is adjusted to reflect patient and facility characteristics that contribute to higher per treatment costs. Section 1881(b)(14)(F) of the Act requires an annual increase to the ESRD PPS base rate by an ESRD market basket increase factor, reduced by the productivity adjustment described in Section 1886(b)(3)(B)(xi)(II) of the Act. That is, the ESRD bundled (ESRDB) market basket increase factor minus the productivity adjustment will update the ESRD PPS base rate.

In accordance with Section 1834(r) of the Act, as added by Section 808(b) of the Trade Preferences Extension Act of 2015 (TPEA), CMS pays ESRD facilities for furnishing renal dialysis services to Medicare beneficiaries with AKI.

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The ESRD PPS includes Consolidated Billing (CB) requirements for limited Part B services included in the ESRD facility's bundled payment. CMS periodically updates the lists of items and services that are subject to Part B CB and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

Transitional Drug Add-on Payment Adjustment (TDAPA)

Under the ESRD PPS drug designation process, the TDAPA is available for new renal dialysis drugs and biological products that qualify under 42 Code of Federal Regulations (CFR) Section 413.234. CR 10065 implemented the TDAPA for calcimimetics effective January 1, 2018. The TDAPA policy was refined in CR 11514.

Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)

Beginning January 1, 2020, the ESRD PPS provides the TPNIES for new and innovative renal dialysis equipment and supplies that qualify under 42 CFR 413.236. The TPNIES payment is based on 65 percent of the MAC determined price. The TPNIES is paid for 2 calendar years, beginning on January 1, and ending on December 31. While the TPNIES applies to a new and innovative equipment or supply, the equipment or supply is not considered an outlier service. CR 11869 created the system changes necessary to implement the TPNIES.

Low-Volume Payment Adjustment (LVPA)

ESRD facilities that meet the definition of a low-volume facility under § 413.232(b) are eligible for the LVPA. In order to receive the LVPA under the ESRD PPS, an ESRD facility must submit a written attestation statement to its MAC confirming that it meets all of the requirements specified in § 413.232 and qualifies as a low-volume ESRD facility. Section 413.232(e) imposes a yearly November 1 deadline for attestation submissions. Beginning January 1, 2019, ESRD facilities may request an extraordinary circumstance exception to the November 1 deadline.

Rescinded: Machine Reported Dialysis Treatment Time

CMS is withdrawing the requirement for ESRD facilities to report the value code D6 for the total number of minutes of dialysis provided during the billing period.

Key Changes in CR 12011

Effective January 1, 2021, calcimimetics are no longer paid for under the ESRD PPS using the TDAPA (§ 413.234(c)) and instead are paid for through the ESRD PPS base rate. Also, effective January 1, 2021, calcimimetics are eligible for outlier payments as ESRD outlier services under 42 CFR 413.237.

Calcimimetics and AKI

As discussed in CR 10281, since the oral calcimimetic (HCPCS code J0604) is included under the ESRD PPS base rate effective January 1, 2021, this drug has transitioned to the bundled

payment amount. Therefore, no separate payment would be made for J0604 when it is furnished by an ESRD facility to an individual with AKI. With regard to the injectable calcimimetic (HCPCS code J0606), this drug is not indicated for AKI and therefore no bills should be submitted for Parsabiv in the AKI population.

TPNIES

There are no equipment or supplies that qualify for the TPNIES beginning January 1, 2021. When there is an equipment or supply eligible for the TPNIES, it will be flagged in the claims processing system for manual pricing by the MACs under 42 CFR 413.236(e). The MACs, on behalf of CMS, will establish prices for new and innovative renal dialysis equipment and supplies that meet the TPNIES eligibility criteria using verifiable information from the following sources of information, if available:

- the invoice amount, facility charges for the item, discounts, allowances, and rebates
- the price established for the item by other MACs and the sources of information used to establish that price
- payment amounts determined by other payers and the information used to establish those payment amounts
- charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant

When available, the MAC will publicly provide pricing information for equipment and supplies that are paid under the ESRD PPS using the TPNIES.

In the future, there will be two unclassified HCPCS codes available for purposes of payment under the TPNIES that can be used while waiting for the assignment of a permanent HCPCS code:

- A4913 Miscellaneous dialysis supplies, not otherwise specified
- E1699 Dialysis equipment, not otherwise specified

When reporting HCPCS code A4913 or E1699 for purposes of payment under the TPNIES, ESRD facilities must report the following information in the remarks field of the claim when billing for a TPNIES eligible equipment or supply. MACs may consider this information for pricing and may request more information from the ESRD facility. MACs may also provide public local messaging to the ESRD facilities in their respective jurisdictions.

- HCPCS
- Description of item
- Billed amount to Medicare
- Invoice amount and number of units on invoice
- Wholesale amount per item
- Discount/rebate amount per item (even if bulk discount)

Future sub-regulatory guidance will be issued to advise when to use HCPCS codes A4913 or

E1699 for purposes of payment under the TPNIES.

Note: When HCPCS code A4913 is reported on the claim without the AX modifier, the item continues to be considered an eligible outlier service as established in CR 7064.

LVPA Eligibility for Cost Reporting Periods Ending in 2020

To receive the LVPA, an ESRD facility must provide an attestation statement to its MAC that the facility meets the criteria under 42 CFR 413.232 which is also discussed in Pub. 100-02, Chapter 11, Section 60.B.1.b. The attestation deadline for payment year 2021 has been extended until December 31, 2020, due to the extraordinary circumstance of COVID-19 for all ESRD facilities requesting the LVPA.

Also, for ESRD facilities that have an increase in their treatment counts for cost reporting periods ending in 2020 that are COVID-related such that the increase prevents them from qualifying for the LVPA, CMS will hold these facilities harmless from losing the LVPA. Specifically, these ESRD facilities must attest no later than December 31, 2020, that:

- While it furnished 4,000 or more treatments in its cost-reporting period ending in 2020, the number of treatments exceeding the allowed threshold to otherwise qualify for the LVPA was due to temporary patient shifting as a result of the COVID-19 PHE, and
- Their total dialysis treatments for any 6 months (consecutive or nonconsecutive) of that period is less than 2,000. (MACs will annualize the total dialysis treatments for those 6 months by multiplying by 2.)

MACs will rely on the facility's attestation instead of using total dialysis treatments furnished in cost reporting periods ending in 2020 for purposes of determining LVPA eligibility for payment years 2021, 2022, and 2023. There is no change in LVPA eligibility, attestation requirements, or in the MAC verification process for an ESRD facility's cost reporting period ending in 2018 and 2019. ESRD facilities will be expected to provide supporting documentation to the MACs upon request.

Clarification for MAC LVPA Determinations

In an ESRD facility's attestation for the third eligibility year, which is the cost reporting year immediately preceding the payment year, a facility attests that it will be eligible for the adjustment. This attestation typically occurs prior to the MAC having the facility's cost report for the third eligibility year, in which case the MAC relies on the facility's attestation to determine if the facility qualifies for the LVPA.

When an ESRD facility qualifies for the adjustment, the LVPA would be applied to all the Medicare-eligible treatments for the entire payment year. If the MAC subsequently determines, however, that the ESRD facility failed to qualify for the LVPA, and the facility had already begun to receive the adjustment to which the MAC has determined it is not entitled, the MAC would reprocess the claims to remove and recoup the low-volume payments.

CMS understands that in some instances, MACs may be discontinuing LVPA payments to a facility in the payment year for which the facility is eligible for the adjustment. However, the

established policy is such that, if an ESRD facility meets the LVPA eligibility criteria in 42 CFR 413.232, it is entitled to the payment adjustment for the entire payment year. Two scenarios have been identified as needing guidance on this policy:

Scenario A

The MAC approves an ESRD facility to receive the LVPA for payment year 2020 based on their attestation received on November 1, 2019. Upon receipt and review of the cost report for periods ending in 2019 (usually the 12/31 cost report is accepted after the first of the year), the MAC finds that the ESRD facility did not exceed 4,000 treatments. The ESRD facility's attestation is validated.

During 2020, the ESRD facility reports to the MAC that they have gone over 4,000 treatments. The ESRD facility is entitled to the LVPA for the entire 2020 year because they met the definition of low-volume for cost reporting periods ending in 2017, 2018, and 2019. However, the ESRD facility would not be eligible for the LVPA beginning January 1, 2021 since they have exceeded the treatment threshold for cost reporting periods ending in 2020.

Scenario B

The MAC approves an ESRD facility to receive the LVPA for payment year 2020 based on their attestation received November 1, 2019. Upon receipt and review of the cost report for periods ending in 2019 (usually the 12/31 cost report is accepted after the first of the year), the MAC finds that the ESRD facility exceeded 4,000 treatments. The MAC should reprocess claims to recoup the LVPA for 2020.

ESRD facilities that believe they may have had their LVPA discontinued in a payment year for which they were entitled, should contact their MAC within 90 days and request for their claims to be reprocessed. MACs will review ESRD facility requests for adjustments and determine if adjustments are necessary to correct payments. Adjustments should be completed within 90 days of receiving the ESRD facility's request.

Wage Index

For CY 2021, CMS adopted the most recent Core-Based Statistical Area (CBSA) delineations as described in the September 14, 2018 Office of Management and Budget (OMB) Bulletin No. 18-04. As a result, several counties now have new CBSA numbers. In addition, CMS applied a 5% cap on any decrease in an ESRD facility's wage index from the ESRD facility's final wage index in CY 2020. This transition will be phased in over 2 years, where the reduction in an ESRD facility's wage index is capped at 5% in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)).

Rescinded: Machine Reported Dialysis Treatment Time

The policy for reporting the duration of dialysis on Medicare ESRD claims and the applicable requirements for reporting value code D6 have been rescinded.

Calendar Year 2021 ESRD PPS Updates

ESRD PPS Base Rate

A wage index budget-neutrality adjustment factor of 0.999485. ($239.33 × 0.999485 = $239.21). An addition of $9.93 to the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment amount. ($239.21 + $9.93 = $249.14). A 1.6 percent update. ($249.14 x 1.016 = $253.13). **The CY 2021 ESRD PPS base rate is $ 253.13.**

Wage Index

The CY 2021 ESRD PPS wage index is updated to reflect the latest available hospital wage data. Implementation of new OMB delineations with a 5 percent cap transition policy. **The wage index floor is 0.5000.**

Labor-Related Share

The labor-related share is 52.3 percent.

Outlier Policy

CMS made the following updates to the adjusted average outlier service Medicare Allowable Payment (MAP) amount per treatment:

- For adult patients, the adjusted average outlier service MAP amount per treatment is $50.92.
- For pediatric patients, the adjusted average outlier service MAP amount per treatment is $30.88.

CMS made the following updates to the Fixed Dollar Loss (FDL) amount that is added to the predicted MAP to determine the outlier threshold:

- The fixed dollar loss amount is $122.49 for adult patients.
- The fixed dollar loss amount is $44.78 for pediatric patients.

CMS made the following changes to the list of outlier services:

- Renal dialysis drugs that are oral equivalents to injectable drugs are based on the most recent prices obtained from the Medicare Prescription Drug Plan Finder, are updated to reflect the most recent mean unit cost. In addition, CMS will add or remove any renal dialysis items and services that are eligible for outlier payment. See Attachment A of CR 12011.
- The mean dispensing fee of the National Drug Codes (NDCs) qualifying for outlier consideration is revised to $0.58 per NDC per month for claims with dates of service on or after January 1, 2021. See Attachment A of CR 12011.

For outlier consideration, revenue code 0636 with HCPCS code J0604 should not be used. Instead, since beginning January 1, 2021, cinacalcet is an oral drug eligible for consideration as an ESRD outlier service, ESRD facilities should report revenue code 250 with the drug's NDC. CMS prices these drugs using national average drug prices based on the Medicare Prescription Drug Plan Finder. A list of oral and other forms of injectable renal dialysis drugs that are eligible outlier services is available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Outlier_Services. For more information, please see Pub. 100-02, Medicare Benefit Policy Manual, Chapter 11, §20.3.C and Pub. 100-04, Medicare Claims Processing Manual, Chapter 8, §60.2.1.2.

CB Requirements

The current version of the CB requirements are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.

CY 2021 AKI Dialysis Payment Rate for Renal Dialysis Services

Beginning January 1, 2021, CMS will pay ESRD facilities $253.13 per treatment. The labor-related share is 52.3 percent. The AKI dialysis payment rate is adjusted for wages using the same wage index that is used under the ESRD PPS. The AKI dialysis payment rate is not reduced for the ESRD Quality Incentive Program (QIP). The TDAPA does not apply to AKI claims. The TPNIES does not apply to AKI claims.

ADDITIONAL INFORMATION

The official instruction, CR 12011, issued to your MAC regarding this change is available at https://www.cms.gov/files/document/r10568bp.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
January 19, 2021	We revised this article to reflect the revised CR12011 issued on January 14, 2021. CMS revised the CR to rescind the requirement for reporting time on dialysis machine by removing the verbiage in the background and policy sections of the CR. We revised the article to rescind this requirement as shown in red print on pages 2 and 5 of the article. Also, we revised the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
December 2, 2020	We revised this article to add information for reporting the use of cinacalcet by ESRD facilities (on page 8). Beginning January 1, 2021,

Date of Change	Description
	cinacalcet is an oral drug eligible for consideration as an ESRD outlier service. ESRD facilities should report revenue code 250 with the drug's NDC. All other information remains the same.
November 23, 2020	We revised the article to reflect a revised CR 12011. The CR revision changed the CY 2021 AKI dialysis payment rate for renal dialysis services. We made that change in the Calendar Year 2021 ESRD PPS Updates section of the article. We also changed the CR release date, transmittal number, and the web address of the CR. All other information remains the same.
November 9, 2020	Initial article released.