CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10490	**Date: November 23, 2020**
	Change Request 12011

Transmittal 10451, dated November 6, 2020, is being rescinded and replaced by Transmittal 10490, dated, November 23, 2020 to revise the CY 2021 AKI dialysis payment rate for renal dialysis services reported in the policy section of this CR. All other information remains the same.

SUBJECT: 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

I. SUMMARY OF CHANGES: This Change Request (CR) implements the CY 2021 rate updates and policies for the ESRD PPS and implements the payment for renal dialysis services furnished to beneficiaries with AKI in ESRD facilities. This Recurring Update Notification applies to Publication 100-02, Medicare Benefit Policy Manual, Chapter 11, section 50.

EFFECTIVE DATE: January 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2021

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	N/A

III. FUNDING:
For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Recurring Update Notification

Attachment - Recurring Update Notification

Pub. 100-02	Transmittal: 10490	Date: November 23, 2020	Change Request: 12011

Transmittal 10451, dated November 6, 2020, is being rescinded and replaced by Transmittal 10490, dated, November 23, 2020 to revise the CY 2021 AKI dialysis payment rate for renal dialysis services reported in the policy section of this CR. All other information remains the same.

SUBJECT: 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

EFFECTIVE DATE: January 1, 2021
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 4, 2021

I. GENERAL INFORMATION

A. Background: Effective January 1, 2011, 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). CR 9598 implemented the payment for renal dialysis services and provides detailed information regarding payment policies.

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 consolidated billing and are therefore no longer separately payable when provided to ESRD beneficiaries by providers other than ESRD facilities.

<u>Transitional Drug Add-on Payment Adjustment (TDAPA)</u>

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) § 413.234. CR 10065 implemented the TDAPA for calcimimetics effective January 1, 2018. The TDAPA policy was refined in CR 11514.

<u>Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES)</u>

Beginning January 1, 2020, the ESRD PPS provides the TPNIES for new and innovative renal dialysis equipment and supplies that qualify under § 413.236. The TPNIES payment is based on 65 percent of the Medicare Administrative Contractor (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.

<u>Low-Volume Payment Adjustment (LVPA)</u>

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.

Machine Reported Dialysis Treatment Time

CMS contracted with a data contractor to conduct research and analysis to refine the case-mix adjustment model. A Technical Expert Panel (TEP) was held on December 6, 2018 to discuss options for improving data collection to refine the ESRD PPS case-mix adjustment model. Under current reporting practices, there are no data on the patient- and treatment-level variation in the cost of composite rate items and services included under the ESRD PPS. During the TEP, participants were given options for optimizing data collection on composite rate items and services and each option was specifically formulated to minimize reporting burden for ESRD facilities where possible. An option presented and preferred by TEP participants was reporting duration of dialysis on Medicare ESRD claims. The TEP participants strongly preferred to report this information on claims. CR 11871 created the system changes necessary for ESRD facilities to report the new D6 value code for the total number of minutes of dialysis provided during the billing period.

The final TEP report and other materials can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Educational_Resources.html. In addition, in the CY 2020 rulemaking, CMS included a Request for Information that focused on improving the reporting of composite rate costs under the ESRD PPS. The CY 2020 ESRD PPS final rule can be found at: https://www.govinfo.gov/content/pkg/FR-2019-11-08/pdf/2019-24063.pdf

B. Policy: TDAPA

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 § 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 § 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: (1) the invoice amount, facility charges for the item, discounts, allowances, and rebates; (2) the price established for the item by other MACs and the sources of information used to establish that price; (3) payment amounts determined by other payers and the information used to establish those payment amounts; and (4) charges and payment amounts required for other equipment and supplies that may be comparable or otherwise relevant.

When available, the MAC shall publically 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.

<u>LVPA Eligibility for Cost Reporting Periods Ending in 2020</u>

To receive the LVPA, an ESRD facility must provide an attestation statement to its MAC that the facility meets the criteria under § 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 shall 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. We note that 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.

MACs shall annualize the total dialysis treatments for those 6 months by multiplying by 2.

ESRD facilities will be expected to provide supporting documentation to the MACs upon request.

<u>Clarification for MAC LVPA Determinations</u>

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.

We understand 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 § 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. The MAC updates the low-volume indicator on the outpatient provider specific file (OSPF) allowing the LVPA for the ESRD facility beginning January 1, 2020. 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 and there is no change to the OPSF.

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. The MAC updates the low-volume indicator on the OPSF allowing the LVPA for the ESRD facility beginning January 1, 2020. 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 update the low-volume indicator on the OPSF and 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 shall review ESRD facility requests for adjustments and determine if adjustments are necessary to correct payments. Adjustments shall be completed within 90 days of receiving the ESRD facility's request.

<u>Wage Index</u>

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 percent 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 percent in CY 2021 (that is, no cap would be applied to the reduction in the wage index for the second year (CY 2022)).

Outpatient Provider Specific File (OPSF) Changes

To facilitate the implementation of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's final wage index in CY 2020, MACs must populate the two (2) supplemental wage index fields added in the OPSF through CR 11707 for all of the ESRD facilities who were active in CY 2020.

1. **Supplemental Wage Index** - used for the prior calendar year wage index value
2. **Supplemental Wage Index Indicator** - used to indicate the value in the "Supplemental Wage Index" field is the prior calendar year wage index

MACs must follow the steps below to ensure the appropriate values are applied in the Supplemental Wage Index and Supplemental Wage Indicator fields:

1. If the ESRD facility was **not active** for CY 2020, then skip all of the below steps and leave the "Supplemental Wage Index" and "Supplemental Wage Index Indicator" fields blank. If the ESRD facility was **active** for CY 2020, then follow the steps below.
2. Update the value of "Supplemental Wage Index Indicator" to be "1".
3. Validate the accuracy of the ESRD facility's Federal Information Processing Standards (FIPS) state and county codes.
4. Validate the accuracy of the ESRD facility's CY 2020 CBSA based on the facility's FIPS state and county codes and the CBSA delineations defined in OMB Bulletin No. 17–01.
    - Note that ESRD facilities located in a "Micropolitan Statistical Area" are considered rural under the ESRD PPS and should be assigned the appropriate 2-digit state code as their CBSA for the purposes of determining their wage index.
5. Using the Final CY 2020 ESRD PPS Wage Index file "CMS-1713-F ESRD PPS & AKI Wage Index (ZIP)" available online at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices-Items/CMS-1713-F, identify the corresponding CY 2020 wage index value for the ESRD facility's CY 2020 CBSA, and add this wage index value to "Supplemental Wage Index" field.

ESRD facilities may confirm their CY 2021 CBSA delineation status and wage index value on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices.

Machine Reported Dialysis Treatment Time

Effective January 1, 2021, CMS is implementing Value Code (VC) D6:

Title (short descriptor): The total number of minutes of dialysis provided during the billing period.

Designation: NM (Non-monetary)

Definition: The machine reported number of minutes (rounded to the nearest whole minute) of dialysis treatment time. The total count includes only the minutes spent dialyzing. The duration begins when the treatment starts and ends when the treatment is complete. The units reported must exceed 1.

The provider counts only the minutes spent dialyzing. It reports in whole minutes (Rounded to the nearest whole minute and reported left of the decimal).

ESRD facilities are required to report VC D6 on ESRD claims, for in-facility or home hemodialysis maintenance, training, or retraining treatments. The following bullets provide further explanation of what VC D6 must report:

- A single, aggregated value derived from each dialysis treatment time furnished to a single ESRD beneficiary during one billing period
- Dialysis treatment time includes only the time the ESRD beneficiary spends being dialyzed by the dialysis machine and does not include any other time spent at the facility (or in another treatment setting)
- The total count includes all the minutes the ESRD beneficiary spends being dialyzed over the course of all dialysis treatment sessions during the billing period
- The count begins when the dialysis treatment starts and ends when the treatment is complete
- Be collected from a dialysis machine's recorded dialysis minutes treatment time
- Be reported in whole minutes (rounded to the nearest whole minute and reported left of the decimal)
- Exceed 1

Example: A patient is dialyzed 3 hours per day, 3 days a week, for 4 weeks. The ESRD facility would report 2160 minutes (that is, (60 x 3) x (3 x 4) = 2160) as "0002160.00" in VC D6.

This data will be used for future comprehensive updates to the ESRD PPS. There is no change in payment to ESRD facilities.

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.

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.

Consolidated Billing Requirements:

The current version of the CB requirements are available on the CMS webpage: https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/ESRDpayment/Consolidated_Billing.html.

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.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12011.1	The ESRD PPS Pricer shall include all CY 2021 ESRD PPS updates.									ESRD Pricer
12011.2	Medicare contractors shall install and pay claims with the CY 2021 ESRD PPS Pricer for renal dialysis services furnished on or after January 1, 2021.					X				
12011.3	Medicare contractors shall update the provider file for ESRD facilities as necessary to reflect: 1. Attested low volume facilities if applicable; 2. Revised Core-Based Statistical Area(CBSA) codes if applicable;	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	3. Quality indicator for any applicable QIP adjustments.									
12011.3.1	Medicare contractors shall extend the attestation deadline for payment year 2021 until December 31, 2020.	X								
12011.3.2	Medicare contractors shall identify and adjust claims for payment year 2021 for claims processed prior to the LVPA status being updated.	X								
12011.3.2.1	Medicare contractors shall complete adjustments within 90 days of updating providers LVPA status.	X								
12011.3.3	Medicare contractors shall not discontinue an ESRD facilities LVPA status due to an increase in their treatment counts for cost reporting periods ending in 2020 that are COVID-related: • 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 shall annualize the total dialysis treatments for those 6 months by multiplying by 2).	X								
12011.3.4	Medicare contractors shall 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.	X								
12011.3.5	Medicare contractors shall review ESRD facility requests for adjustments and determine if adjustments are necessary to correct payments based on the LVPA policy.	X								
12011.3.5.1	Medicare contractors shall complete adjustments within 90 days of receiving the ESRD facility's request and determining that claims must be adjusted to correct payment based on the LVPA policy.	X								
12011.3.6	Medicare contractors shall ensure the appropriate values are applied in the Supplemental Wage Index and Supplemental Wage Indicator fields by following the instructions in the policy section of this change request.	X								

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12011.4	Medicare contractors shall update the NDC dispensing fee for ESRD outlier services to $0.58 for claims with dates of service on or after January 1, 2021.					X				
12011.5	Medicare contractors shall update the list of items and services that qualify as outlier services according to the updated list in Attachment A, effective January 1, 2021.					X				
12011.6	Medicare contractors shall update the TDAPA codes: • Discontinue processing the TDAPA for J0604 and J0606 when billed with modifier AX on Type of Bill 72X for from dates on or after January 1, 2021. • No new drugs being added.					X				
12011.7	Medicare contractors shall update the TPNIES codes list: • *No TPNIES codes are applicable for this update.* **NOTE**: No items have been approved for TPNIES beginning January 1, 2021.					X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12011.8	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X				

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A
"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Michelle Cruse, 443-478-6390 or michelle.cruse@cms.hhs.gov, Simone Dennis, 202-631-2971 or Simone.Dennis@cms.hhs.gov, Wendy Jones, Wendy.Jones@cms.hhs.gov (Claims Processing).

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 1

CY 2021 Outlier Services

Oral and Other Equivalent Forms of Injectable Drugs[1]

NDC[2]	Drug Product	Mean Unit Cost
30698014301 30698014323	Rocaltrol (calcitriol) 0.25 mcg capsules	*$0.89*
30698014401	Rocaltrol (calcitriol) 0.5 mcg capsules	*$2.86*
30698091115	Rocaltrol (calcitriol) 1 mcg/mL oral solution (15ml/bottle)	*$15.37*
00054000713 00054000725 00093735201 23155011801 23155011803 23155066201 23155066203 43353003409 43353003430 43353003481 43353013809 43353013830 43353063309 43353063330 43353063381 43353099809 51407016901 51407016930 60687034501 60687034511 63304023901 63304023930 64380072304 64380072306 69452020713 69452020720 *72789005801*[3]	Calcitriol 0.25 mcg capsules	*$0.49*
00093735301 23155011901 23155066301 51407017001 63304024001 64380072406 69452020820	Calcitriol 0.5 mcg capsules	*$0.81*
00054312041 63304024159 *64980044715*[3]	Calcitriol 1 mcg/mL oral solution (15ml/bottle)	*$7.00*
00074903630	Zemplar (paricalcitol) 1 mcg capsule	*$13.79*

00074903730	Zemplar (paricalcitol) 2 mcg capsule	*$27.83*
10888500102 49483068703 55111066330 60429048130 60429083630 64980022503 65862093630 68382033006 69387010330 69452014513	Paricalcitol 1 mcg capsule	*$4.36*
10888500202 49483068803 55111066430 60429048230 60429083730 64980022603 65862093730 68382033106 69387010430 69452014613	Paricalcitol 2 mcg capsule	*$8.74*
10888500302 49483068903 55111066530 60429048330 *60429083830*[4] 65862093830 *69452014713*[4]	Paricalcitol 4 mcg capsule	*$14.01*
00054033819 00955172050 *68084087225*[4] *68084087295*[4]	Doxercalciferol 0.5 mcg capsule	*$5.49*
00054038819 00955172150	Doxercalciferol 1 mcg capsule	*$10.97*
00054033919 00955172250	Doxercalciferol 2.5 mcg capsule	*$12.81*
55513007330[3]	*CINACALCET 30 MG ORAL TABLET [SENSIPAR]*	*$27.84*
55513007430[3]	*CINACALCET 60 MG ORAL TABLET [SENSIPAR]*	*$55.71*
55513007530[3]	*CINACALCET 90 MG ORAL TABLET [SENSIPAR]*	*$83.70*

00378619793[3] *00904706704*[3] *16714007801*[3] *16729044010*[3] *16729044015*[3] *42543096104*[3] *47335037983*[3] *51407029530*[3] *60687052511*[3] *60687052521*[3] *64380088304*[3] *65862083130*[3] *67877050330*[3] *69097041002*[3] *70436000704*[3] *76282067430*[3]	*CINACALCET 30 MG ORAL TABLET*	*$15.27*
00378619693[3] *16714007901*[3] *16729044110*[3] *16729044115*[3] *42543096204*[3] *47335038083*[3] *51407029630*[3] *64380088404*[3] *65862083230*[3] *67877050430*[3] *69097041102*[3] *70436000804*[3] *76282067530*[3]	*CINACALCET 60 MG ORAL TABLET*	*$36.44*
00378619593[3] *16714008001*[3] *16729044210*[3] *16729044215*[3] *42543096304*[3] *47335060083*[3] *51407029730*[3] *64380088504*[3] *65862083330*[3] *67877050530*[3] *69097041202*[3] *70436000904*[3] *76282067630*[3]	*CINACALCET 90 MG ORAL TABLET*	*$52.37*

[1] Outlier services imputed payment amounts. Oral or other equivalent forms of Part B injectable drugs included in the ESRD PPS bundle (notwithstanding the delayed implementation of ESRD-related oral-only drugs effective 1/1/2025).

[2] The mean dispensing fee of the NDCs listed above is ***$0.58***. This amount will be applied to each NDC included fee on the monthly claim. We will limit 1 dispensing per NDC per month. Providers should report the quantity in the smallest available unit. This is necessary because Medicare is using the mean per unit cost in calculating the outlier. For example, if the provider reports NDC 00054312041 Calcitriol 1 mcg/ml oral solution (15/ml/bottle) reported and uses the full 15 ml bottle, the quantity is as 15, not 1. This allows for the most accurate calculation for the outlier.

[3] *Effective January 1, 2021, the renal dialysis service qualifies as an outlier service.*
[4] *Effective January 1, 2021, the renal dialysis service is no longer an active NDC and therefore does not qualify as an outlier service.*

Laboratory Tests

CPT/HCPCS	Short Description
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82379	Assay of carnitine
82570	Assay of urine creatinine
82575	Creatinine clearance test
82607	Vitamin B-12
82652	Vit d 1, 25-dihydroxy
82668	Assay of erythropoietin
82728	Assay of ferritin
82746	Blood folic acid serum
83540	Assay of iron
83550	Iron binding test
83970	Assay of parathormone
84134	Assay of prealbumin
84466	Assay of transferrin
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85041	Automated rbc count
85044	Manual reticulocyte count
85045	Automated reticulocyte count
85046	Reticyte/hgb concentrate
85048	Automated leukocyte count
86704	Hep b core antibody, total
86705	Hep b core antibody, igm
86706	Hep b surface antibody
87040	Blood culture for bacteria
87070	Culture, bacteria, other
87071	Culture bacteri aerobic othr
87073	Culture bacteria anaerobic
87075	Cultr bacteria, except blood
87076	Culture anaerobe ident, each
87077	Culture aerobic identify
87081	Culture screen only
87340	Hepatitis b surface ag, eia
87341	Hepatitis b surface ag, eia
G0499	Hepb screen high risk indiv

Equipment and Supplies

HCPCS	Short Description
A4657	Syringes with or with needle, each
A4913	Miscellaneous dialysis supplies, not otherwise specified