

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10671	Date: March 16, 2021
	Change Request 12188

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: April 5, 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/revise 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

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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.

B. Policy: The January 2021 ESRD PRICER did not apply the 50 cent network reduction fee to all dialysis treatments for ESRD beneficiaries as required by Section 9335(j) of OBRA 1986 to IPD revenue code 0831 and ultrafiltration revenue code 0881 resulting in an error. The revised PRICER is correcting the aforementioned error. Contractors shall load the revised ESRD PRICER effective April 1, 2021.

The CY 2021 ESRD PPS Updates (Remain Unchanged)

ESRD PPS base rate:

- A wage index budget-neutrality adjustment factor of 0.999485. ($\$239.33 \times 0.999485 = \239.21).
- An addition of \$9.93 to the ESRD PPS base rate to account for calcimimetics in the ESRD PPS bundled payment amount. ($\$239.21 + \$9.93 = \$249.14$).
- A 1.6 percent update. ($\$249.14 \times 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:

- 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.
- 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, and they 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-Service-Payment/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		D M E	Shared- System Maintainers			Other	
		A	B		H H H	M I S S	V C S		C M W F
12188.1	Medicare contractors shall install and pay claims with the revised CY 2021 ESRD PPS Pricer for renal dialysis services furnished on or after January 1, 2021. This revised PRICER will apply the network reduction to revenue codes 0831 and 0881 for ESRD claims.					X			ESRD Pricer

Number	Requirement	Responsibility							
		A/B MAC		D M E	Shared- System Maintainers			Other	
		A	B		H H H	F M V C	M C M S		C W F
12188.2	Contractors shall not perform adjustments for claims. Adjustment requirements will be provided in subsequent instructions to the MACs.	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility					
		A/B MAC			D M E	C E D I	
		A	B	H H H			
12188.3	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): Simone Dennis, 410-786-6041 or simone.dennis@cms.hhs.gov, Wendy Jones, 410-786-3004 or wendy.jones@cms.hhs.gov, Katherine Cooney, 410-786-7535 or katherine.cooney@cms.hhs.gov.

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

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ATTACHMENTS: 1

CY 2021 Outlier Services

Oral and Other Equivalent Forms of Injectable Drugs¹

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 <i>72789005801³</i>	Calcitriol 0.25 mcg capsules	\$0.49
00093735301 23155011901 23155066301 51407017001 63304024001 64380072406 69452020820	Calcitriol 0.5 mcg capsules	\$0.81
00054312041 63304024159 <i>64980044715³</i>	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 <i>60429083830⁴</i> 65862093830 <i>69452014713⁴</i>	Paricalcitol 4 mcg capsule	\$14.01
00054033819 00955172050 <i>68084087225⁴</i> <i>68084087295⁴</i>	Doxercalciferol 0.5 mcg capsule	\$5.49
00054038819 00955172150	Doxercalciferol 1 mcg capsule	\$10.97
00054033919 00955172250	Doxercalciferol 2.5 mcg capsule	\$12.81
<i>55513007330³</i>	<i>CINACALCET 30 MG ORAL TABLET [SENSIPAR]</i>	<i>\$27.84</i>
<i>55513007430³</i>	<i>CINACALCET 60 MG ORAL TABLET [SENSIPAR]</i>	<i>\$55.71</i>
<i>55513007530³</i>	<i>CINACALCET 90 MG ORAL TABLET [SENSIPAR]</i>	<i>\$83.70</i>

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