

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 262	Date: November 8, 2019
	Change Request 11506

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) 2020

I. SUMMARY OF CHANGES: This Change Request (CR) implements the CY 2020 rate updates 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, 2020

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 6, 2020

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

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EFFECTIVE DATE: January 1, 2020

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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) as added by section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (ACA) established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket increase factor, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. 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.

CY 2019 Outlier Services list

With regard to the calculation for CY 2019 outlier payments, a correction was made to the CY 2019 Outlier Services list for the oral equivalent drug, Paricalcitol 4 mcg capsule, applicable to claims with dates of service in 2019. Active National Drug Codes (NDC) associated with Paricalcitol 4 mcg capsule were inadvertently removed in CR 11021. This could have resulted in an underpayment of outlier payments for ESRD facilities that furnished those drugs. The NDCs are listed in Attachment B. ESRD facilities that believe the inclusion of these NDCs on the CY 2019 outlier services list may impact their outlier payments for claims in 2019, should submit adjustments to their claims within 6 months from the effective date of this instruction. Contractors will be instructed to override timely filing if necessary.

B. Policy: Calendar Year 2020 ESRD PPS Updates

ESRD PPS base rate:

1. A 1.7 percent update to the CY 2019 payment rate. ($\$235.27 \times 1.017 = \239.27).
2. A wage index budget-neutrality adjustment factor of 1.000244. ($\$239.27 \times 1.000244 = \239.33)

Wage index:

The wage index adjustment will be updated to reflect the latest available wage data.

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:

1. For adult patients, the adjusted average outlier service MAP amount per treatment is \$35.78.
2. For pediatric patients, the adjusted average outlier service MAP amount per treatment is \$32.32.

CMS made the following updates to the fixed dollar loss (FDL) amount that is added to the predicted MAP to determine the outlier threshold:

1. The fixed dollar loss amount is \$48.33 for adult patients.
2. The fixed dollar loss amount is \$41.04 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 retrieved 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 \$0.64 per NDC per month for claims with dates of service on or after January 1, 2020. See Attachment A.

Consolidated Billing Requirements:

The long descriptor for the Healthcare Common Procedure Coding System (HCPCS) code Q5105 was revised from Injection, epoetin alfa, biosimilar, (retacrit) (for esrd on dialysis), 100 units to Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit) (For ESRD on dialysis), 100 units to be consistent with the FDA nomenclature.

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.

Revised non-ESRD HCPCS code:

The long descriptor for HCPCS code Q5106 was revised from Injection, epoetin alfa, biosimilar, (retacrit) (for non-esrd use), 1000 units to Injection, Epoetin Alfa-epbx, Biosimilar, (Retacrit) (for non-ESRD use), 1000 units. This code is not permitted on the type of bill 072x for an ESRD PPS claim. It is permitted for AKI claims as discussed in CR 10839.

CY 2020 AKI Dialysis Payment Rate for Renal Dialysis Services:

1. Beginning January 1, 2020, CMS will pay ESRD facilities \$239.33 per treatment.
2. The labor-related share is 52.3 percent.
3. The AKI dialysis payment rate is adjusted for wages using the same wage index that is used under the ESRD PPS.

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E D I C A N	C O N T R A C T I N G O F F I C E R
		A	B	H H H		
11506.7	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): Lindsay Pulliam, 410-786-8674 or Lindsay.Pulliam2@cms.hhs.gov, Michelle Cruse, 410-786-7540 or michelle.cruse@cms.hhs.gov.

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: 2

CY 2020 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	\$0.88
30698014401	Rocaltrol (calcitriol) 0.5 mcg capsules	<i>\$2.83</i>
30698091115	Rocaltrol (calcitriol) 1 mcg/mL oral solution (15ml/bottle)	<i>\$15.27</i>
00054000713 00054000725 00093735201 23155011801 23155011803 23155066201 23155066203 43353003409 43353003430 43353003481 43353013809 43353013830 43353063309 43353063330 43353063381 43353099809 <i>51407016901³</i> <i>51407016930³</i> <i>60687034501³</i> <i>60687034511³</i> 63304023901 63304023930 <i>63629732301⁴</i> <i>63629732302⁴</i> 64380072304 64380072306 69452020713 69452020720	Calcitriol 0.25 mcg capsules	<i>\$0.50</i>

00093735301 23155011901 23155066301 <i>51407017001³</i> 63304024001 64380072406 69452020820	Calcitriol 0.5 mcg capsules	\$0.77
00054312041 63304024159	Calcitriol 1 mcg/mL oral solution (15ml/bottle)	\$7.44
<i>00074903630³</i> <i>00074431730⁴</i>	Zemplar (paricalcitol) 1 mcg capsule	\$13.58
<i>00074903730³</i> <i>00074431430⁴</i>	Zemplar (paricalcitol) 2 mcg capsule	\$27.54
10888500102 49483068703 55111066330 60429048130 60429083630 64980022503 65862093630 <i>68382026606⁴</i> 68382033006 69387010330 69452014513	Paricalcitol 1 mcg capsule	\$3.56
10888500202 49483068803 55111066430 60429048230 60429083730 64980022603 65862093730 <i>68382026706⁴</i> <i>68382033106³</i> 69387010430 69452014613	Paricalcitol 2 mcg capsule	\$7.32
<i>10888500302³</i> <i>49483068903³</i> <i>55111066530³</i> <i>60429048330³</i> <i>60429083830³</i> <i>65862093830³</i> <i>69452014713³</i>	<i>Paricalcitol 4 mcg capsule</i>	\$19.24

00054033819 00955172050 <i>66993018550⁴</i> 68084087225 68084087295	Doxercalciferol 0.5 mcg capsule	<i>\$9.13</i>
00054038819 00955172150 <i>66993018650⁴</i>	Doxercalciferol 1 mcg capsule	<i>\$17.38</i>
00054033919 00955172250 <i>66993018750⁴</i>	Doxercalciferol 2.5 mcg capsule	<i>\$20.38</i>

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 *\$0.64*. 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, 2020, the renal dialysis service qualifies as an outlier service*

⁴ *Effective January 1, 2020, 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

Injectable Drugs and Biologicals^{1,2}

HCPCS	Short Description	HCPCS Code Dosage	Payment Limit
J0131	Acetaminophen injection	10 MG	\$0.461
J0698	Injection, cefotaxime sodium, per gm	Per GM	\$2.332
J0884	Argatroban ESRD dialysis 1mg	1 MG	\$1.194
J1443	Inj ferric pyrophosphate cit	0.1 MG of iron	\$0.043
J1444	Fe pyro cit pow 0.1 mg iron	0.1 MG of iron	\$0.030

¹ Effective January 1, 2018, pricing methodologies available in section 1847A of the Act, as appropriate, are used to price drugs and biologicals for the outlier calculation when ASP pricing data is not available (82 FR 50745).

²Average Sales Price (ASP) payment limits for Healthcare Common Procedure Coding System (HCPCS) codes in this chart are not published in the ASP Drug Pricing Files at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html>

ASP-based payment limits in this chart are updated quarterly based on data that is submitted to CMS by drug manufacturers. Payment limits for other renal dialysis service Part B drugs and biologicals appear in the ASP Drug Pricing Files, and with the exception of composite rate drugs and drugs reported with the AY modifier, are included in the outlier calculation.

Attachment B
CY 2019 Outlier Services

Oral and Other Equivalent Forms of Injectable Drugs¹

NDC²	Drug Product	Mean Unit Cost
30698014301 30698014323	Rocaltrol (calcitriol) 0.25 mcg capsules	\$0.88
30698014401	Rocaltrol (calcitriol) 0.5 mcg capsules	\$2.82
30698091115	Rocaltrol (calcitriol) 1 mcg/mL oral solution (15ml/bottle)	\$15.29
00054000725 00054000713 00093735201 23155011801 23155011803 23155066201 23155066203 43353003409 43353003430 43353003481 43353013809 43353013830 43353063309 43353063330 43353063381 43353099809 63304023901 63304023930 63629732301 63629732302 64380072304 64380072306 69452020713 69452020720	Calcitriol 0.25 mcg capsules	\$0.54
00093735301 23155011901 23155066301 63304024001 64380072406 69452020820	Calcitriol 0.5 mcg capsules	\$0.77
00054312041 63304024159	Calcitriol 1 mcg/mL oral solution (15ml/bottle)	\$7.36
00074431730	Zemplar (paricalcitol) 1 mcg capsule	\$13.37

00074431430	Zemplar (paricalcitol) 2 mcg capsule	\$27.20
10888500102 49483068703 55111066330 60429048130 60429083630 64980022503 65862093630 68382026606 68382033006 69387010330 69452014513	Paricalcitol 1 mcg capsule	\$4.69
10888500202 49483068803 55111066430 60429048230 60429083730 64980022603 65862093730 68382026706 69387010430 69452014613	Paricalcitol 2 mcg capsule	\$9.23
<i>10888500302³ 49483068903³ 55111066530³ 60429048330³ 60429083830³ 65862093830³ 69452014713³</i>	<i>Paricalcitol 4 mcg capsule</i>	<i>\$18.86</i>
00054033819 00955172050 66993018550 68084087225 68084087295	Doxercalciferol 0.5 mcg capsule	\$9.05
00054038819 00955172150 66993018650	Doxercalciferol 1 mcg capsule	\$17.69
00054033919 00955172250 66993018750	Doxercalciferol 2.5 mcg capsule	\$22.52

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 **\$0.75**. 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, 2019, the renal dialysis service qualifies as an outlier service

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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
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