CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 254	**Date: December 13, 2018**
	Change Request 11021

Transmittal 250, dated November 14, 2018, is being Rescinded and Replaced by Transmittal 254, dated, December 13, 2018 to correct a typos in Attachment B and Summary of Changes. 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) 2019

I. SUMMARY OF CHANGES: This Change Request (CR) implements the CY 2019 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 60.

EFFECTIVE DATE: January 1, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 7, 2019

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
R	11/60/ESRD PPS Case-Mix Adjustments

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: 254	Date: December 13, 2018	Change Request: 11021

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I. GENERAL INFORMATION

A. Background: Effective January 1, 2011, The CMS implemented the ESRD PPS based on the requirements of section1881(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 Calendar Year (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 808(b) of the Trade Preferences Extension Act of 2015 (TPEA), CMS pays ESRD facilities for furnishing renal dialysis services to Medicare beneficiaries with Acute Kidney Injury (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: Calendar Year 2019 ESRD PPS Updates

ESRD PPS base rate:

1. A 1.3 percent update to the CY 2019 payment rate. ($232.37 x 1.013 = $235.39).
2. A wage index budget-neutrality adjustment factor of 0.999506. ($235.39 × 0.999506 = $235.27)

Wage index:

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

The wage index floor will increase to 0.50.

Labor-related share:

The labor-related share should be updated to 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 $38.51.
2. For pediatric patients, the adjusted average outlier service MAP amount per treatment is $35.18.

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 $65.11 for adult patients.
2. The fixed dollar loss amount is $57.14 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 $0.75 per NDC per month for claims with dates of service on or after January 1, 2019. See Attachment A.

Consolidated Billing Requirements:

For CY 2019, there are no changes to the ESRD PPS CB 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.

New non-ESRD Healthcare Common Procedure Coding System (HCPCS) code

There is a new HCPCS Q5106 for Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units. This code will not be permitted on the type of bill 072x for an ESRD PPS claim. It is permitted for AKI claims as discussed in CR 10839.

CY 2019 AKI Dialysis Payment Rate for Renal Dialysis Services:

1. Beginning January 1, 2019, CMS will pay ESRD facilities $235.27 per treatment.
2. The labor-related share is 52.3 percent.
3. The AKI dialysis payment rate will be adjusted for wages using the same wage index that is used under the ESRD PPS.
4. The AKI dialysis payment rate is not reduced for the ESRD Quality Incentive Program (QIP).
5. The Transitional Drug Add-on Adjustment (TDAPA) 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	
11021.1	The ESRD PPS Pricer shall include all CY 2019 ESRD PPS updates.									ESRD Pricer
11021.2	FISS shall install and pay claims with the CY 2019 ESRD PPS Pricer for renal dialysis services furnished on or after January 1, 2019.					X				
11021.3	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; 3. Quality indicator for any applicable QIP adjustments.	X								
11021.4	Medicare contractors shall update the NDC dispensing fee for ESRD outlier services to $0.75 for claims with dates of service on or after January 1, 2019.					X				
11021.5	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, 2019.					X				
11021.6	Medicare contractors shall return to the provider type of bill 072x (ESRD PPS claims) when non-ESRD HCPCS are reported on the claim: Q5106 - Injection, epoetin alfa, biosimilar, (Retacrit) (for non-esrd use), 1000 units. **NOTE**: This is only for ESRD PPS claims. Q5106 is allowed for AKI claims as implemented in CR 10839.	X				X				

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11021.7	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	X				

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	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.					

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): Janae James, janae.james@cms.hhs.gov, Michelle Cruse, 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: 3

60 - ESRD PPS Case-Mix Adjustments

(Rev. 254, Issued: 12-13-18, Effective: 01-01-19, Implementation: 01-07-19)

The ESRD PPS includes patient-level adjustments (also known as the case-mix adjustments), facility-level adjustments, and training adjustments, as well as an outlier payment. Under the ESRD PPS, the beneficiary co-insurance amount is 20 percent of the total ESRD PPS payment, after the deductible (see §60.E of this chapter).

A. Patient-level case-mix adjustments

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients to account for case-mix variability. The adult case-mix adjusters include variables (age, body surface area (BSA), and low body mass index (BMI)) that were part of the basic case-mix adjusted composite rate payment system. In addition, the ESRD PPS implemented in CY 2011 includes adult case-mix adjustments for six comorbidity categories (three acute and three chronic) as well as the onset of renal dialysis. Pediatric patient-level adjusters (see §60.A.6 of this chapter), consist of combinations of two age categories and two dialysis modalities. Based on the refinement of the ESRD PPS, effective January 1, 2016, adult case-mix payment adjustments are made for four comorbidity categories (two acute and two chronic) as discussed below.

1. Adult case-mix adjusters

This section presents a list of the ESRD PPS case-mix adjusters for adults and provides several examples using the adult case-mix adjusters implemented in CY 2011 and refined in CY 2016. Any revisions to the case-mix adjusters will be published in subsequent rulemaking.

Adult Patient-Level Characteristics — Adjustment Value

	CY 2011-2015	Beginning CY 2016
Age: 18-44	1.171	1.257

Age: 45-59	1.013	1.068
Age: 60-69	1.000	1.070
Age: 70-79	1.011	1.000
Age: 80+	1.016	1.109
Body Surface Area	1.020	1.032
Low Body Mass Index (BMI <18.5)	1.025	1.017
Onset of Dialysis	1.510	1.327
Pericarditis	1.114	1.040
Bacterial pneumonia	1.135	---
Gastro-intestinal tract bleeding	1.183	1.082
Hereditary hemolytic or sickle cell anemia	1.072	1.192
Myelodysplastic syndrome	1.099	1.095
Monoclonal gammopathy	1.024	---

Calculating the ESRD PPS Adjusted Payment

The following example demonstrates the calculation of the ESRD PPS payment in an urban area with a wage index of 1.10. Before giving the particulars of the dialysis patient for the example, shown first is how to calculate the labor-adjusted base rate, which is the starting point for the computation of the case-mix adjusted base rate.

- Base rate: $230.39
- Labor-related share of base rate: $230.39 * 0 .50673 = $116.75
- Wage index adjusted labor-related share: $116.75 * 1.1000 = $128.42
- Non labor-related share of base rate: $230.39 * (1 - .50673) = $113.64
- Wage index adjusted base rate: $128.42 + $113.64 = $242.06

Provided next is the continuation of the example with the inclusion of the patient characteristics portion of the payment.

A 45 year old male Medicare beneficiary is 187.96 cm. (1.8796 m.) in height and weighs 95 kg. He receives dialysis in an ESRD facility on January 1, 2016.

Using the formula for BMI, note that the patient is not underweight, having a BMI of 26.89 kg/m^2, which is greater than the threshold value of 18.5 kg/m^2.

$BMI_{Patient} = weight_{kg} / height\ (m^2)$
$= 95/1.8796^2$
$= 95/3.5329$
$= 26.89$

The formula for calculation of a patient's BSA is:

- 0.007184 multiplied by height in meters $^{0.725}$ multiplied by weight in kg. $^{0.425}$
- or BSA = $0.007184 * height_{cm}$ $^{.725} * weight_{kg}$ $^{.425.}$

The BSA for the patient in this example is calculated as:

$BSA_{Patient} = 0.007184 * 187.96^{.725} * 95^{.425}$
$= 0.007184 * 44.5346 * 6.9268$
$= 2.2161$

Using the adult case-mix adjusters table shown above, the BSA multiplier of 1.032 is used. The patient's case-mix adjustment or payment multiplier (PM) based on his BSA of 2.2161 is computed as follows:

$PM_{BSA} = 1.032^{(2.2161-1.90)/0.1}$
$= 1.032^{3.161}$
$= 1.1047$

The example patient's PM would reflect the applicable case-mix adjustments from the adult case-mix adjusters table above for both age and BSA and may be expressed as:

$PM_{Patient} = PM_{age} * PM_{BSA}$
$= 1.068 * 1.1047$
$= 1.1798$

The example patient's ESRD payment rate for treatments furnished in his ESRD facility would be:

$242.06* 1.1798 = $285.58

NOTE: This example is computed without regard to other adjustments (e.g., outlier payments, training add-on, low-volume adjustment, etc.).

2. Patient Age

There are 5 age categories for adults (18-44; 45-59; 60-69; 70-79; and 80 and above) in the ESRD PPS and each category has a separate case-mix adjuster. Note that, when a

beneficiary reaches a birthday that results in a different age category, the age change is effective from the first day of the birthday month, regardless of the date the birthday occurs in that month. The case-mix adjustment factor corresponding to the age of the dialysis patient is multiplied by the wage index adjusted base rate as a step in the calculation of the ESRD PPS per treatment payment amount. The examples shown below draw on values from the table of the CY 2016 adult case-mix adjusters as well as the discussion of the wage adjusted ESRD PPS base rate found in the section above.

- Example 1: Mr. Taylor is 38 years of age and is classified in the 18-44 age group with an associated case-mix adjuster of 1.257. Applying the case-mix adjuster of 1.257 to the wage index adjusted base rate of $242.06 yields the age adjusted base rate amount of $304.27 ($242.06 x 1.257 = $304.27).

- Example 2: Mrs. Williams was born on July 4, 1936. On June 15, 2016, she is 79 years old and is classified in the 70-79 age category with a case-mix adjustment of 1.000 (the reference group). However, beginning with dialysis treatments occurring on and after July 1, 2016, she will move into the 80+ age group with an associated case-mix multiplier of 1.109.

- Example 3: Mr. Davis was born on September 29, 1971. For dialysis treatments occurring in August 2016, he is 44 years old and would be classified in the 18-44 age group with an associated case-mix adjuster of 1.257. Beginning with dialysis treatments occurring on and after September 1, 2016, he is classified in the 45-59 age category with a case-mix adjuster of 1.068 because he is considered to have attained age 45 on September 1.

3. Body Size: Low Body Mass Index (BMI) and/or Body Surface Area (BSA)

Low BMI and BSA are two measures used to estimate body size. Both measures are strong predictors of variation in costs and are closely associated with the duration and intensity of dialysis necessary to achieve a therapeutic dialysis target for ESRD patients. Both are objective measures that are computed using height and weight data located on the patient claim. The BMI and BSA are calculated for all beneficiaries. Low BMI is associated with higher costs due to additional resources that may be necessary to address malnutrition or frailty. BSA is associated with higher costs due to more time on the dialysis machine.

Although height and weight are taken at intervals throughout any given month of dialysis treatment, the measurements for the purpose of payment must be taken as follows:

- The dry weight of the patient is measured and recorded in kilograms immediately following the last dialysis session of the month.

- The patient height is measured and recorded in centimeters during the last dialysis session of the month. The measurement is required no less frequently than once per year.

The formula for the calculation of the BMI is weight in kilograms divided by height in meters squared, or kg/m^2. As an example, the designated low BMI adjustment factor of 1.017 (see §60.A.1 of this chapter) is only applied for those beneficiaries with a BMI value that is less than $18.5kg/m^2$ which is a clinical measure of being underweight and an indicator of malnutrition.

The formula for the calculation of the BSA is $BSA = w^{0.425} * h^{0.725} * 0.007184$ where w and h represent weight in kilograms and height in centimeters. The BSA factor is defined as an exponent equal to the value of the patient's BSA minus the reference BSA of 1.90 divided by 0.1. Using the example of adult adjusters above, the BSA adjustment factor of 1.032 is then exponentiated based on the calculated BSA factor as $1.032^{(BSA-1.90)/0.1}$. The reference BSA used to calculate the BSA is the national average among Medicare dialysis patients.

4. Onset of Dialysis

An ESRD facility may only receive the onset of dialysis adjustment for adult Medicare ESRD beneficiaries. The onset period is defined as the initial 120 days of outpatient maintenance dialysis, which is designated by the first date of when regular chronic dialysis began as reported on the CMS Form 2728. The onset of dialysis adjustment factor is a multiplier used in the calculation of the ESRD PPS per treatment payment amount for dialysis furnished in either an ESRD facility or home setting. For example, when a dialysis patient is not eligible for the Medicare ESRD benefit at the initiation of their maintenance dialysis, but is Medicare eligible at the end of 85 days, the onset of dialysis adjustment will be applied to the ESRD facility's ESRD PPS base rate for each treatment furnished in the following 35 days. However, if the patient is not Medicare eligible at any time during the initial 120 days of receiving maintenance dialysis, the onset of dialysis adjustment will not apply.

The onset of dialysis adjustment is a one-time adjustment. It is not applied when a patient changes ESRD facilities or after a failed transplant. If a patient changes or transfers to another ESRD facility during the initial 120 days, the new ESRD facility will only receive the onset of dialysis adjustment for the remaining time. In other words, the 120 day "clock" does not start over.

If the onset of dialysis adjustment is being applied to the ESRD PPS base rate, then those treatments would not be eligible for the comorbidity adjustment nor any applicable training adjustment(s). However, those treatments are eligible for an outlier payment when appropriate.

5. Comorbidity Categories

The two acute comorbidity categories are pericarditis and gastro-intestinal tract bleeding with hemorrhage. The two chronic comorbidity categories are myelodysplastic syndrome and hereditary hemolytic anemia (including sickle cell anemia). The related comorbidity diagnosis codes can be found at the CMS ESRD Payment Web site located at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Patient-Level-Adjustments.html*

NOTE: Prior to the refinement of the ESRD PPS, effective January 1, 2016, the ESRD PPS included payment adjustments for the comorbidity categories of bacterial pneumonia and monoclonal gammopathy.

The ESRD facility is responsible for obtaining documentation of the presence of an acute or chronic comorbidity. If an ESRD facility is unaware of the existence of a comorbidity because it does not impact the facility's costs, then the ESRD facility should not expect to receive a comorbidity adjustment. The comorbidity payment adjustment is only applied if the appropriate diagnosis code, specified under one of the categories above, is identified on the ESRD claim. Comorbidities other than the two acute and the two chronic conditions identified above do not qualify for a comorbidity adjustment. Even if an ESRD patient has or has had one of the four conditions that would qualify for a comorbidity payment adjustment, the condition must be currently active and have an effect on the cost of care for the ESRD facility to be eligible to receive the adjustment.

To qualify for the comorbidity adjustment there must be adherence to diagnosis coding requirements. Diagnosis codes are updated annually as stated in Pub. 100-04, Chapter 23, section 10, are posted at http://www.cms.gov/Medicare/Coding/ICD10/index.html*, and are effective each October 1st.*

For transfer patients, it is expected that ESRD facilities will work together on the appropriate transfer of information to facilitate appropriate billing for dialysis services. The counting of treatments for an acute comorbidity adjustment is based on the patient and not on the ESRD facility. Therefore, counting does not restart when a beneficiary moves to a new ESRD facility, but rather continues for the remaining 4 months.

a. Duration of Acute Comorbidity Adjustment

Payment for an acute comorbidity adjustment begins in the month in which the diagnosis is established, and lasts for the next 3 consecutive patient months. A patient month is any month in which a dialysis treatment is furnished, and an acute comorbidity applies.

The acute diagnosis comorbidity adjustment is applied to each dialysis treatment for 4 patient months. If a second comorbidity is diagnosed during that period (either acute or chronic), then the adjustment is made using the higher adjustment factor. At no time is an adjustment applied for more than one comorbidity.

When there is a recurrence of an acute comorbidity within the 4 patient month period, there will not be an extension of the 4 patient month adjustment. A recurrence is defined as a new episode of a comorbidity that was previously experienced by an individual beneficiary. However, if the recurrence happens after the completion of the 4 month period, then a new comorbidity adjustment for 4 months would start.

- Example – A male patient has been receiving hemodialysis since January 2010. He had a 2-week hospitalization due to a fracture in mid-January 2016. During his stay in the hospital, he was diagnosed with gastro-intestinal tract bleeding with hemorrhage on January 20, 2016. He resumed his outpatient maintenance dialysis on January 29, 2016. The 4 patient months in which the patient's ESRD facility would be eligible to have the comorbidity adjustment applied to each dialysis treatment are January through April 2016.

b. Duration of Chronic Comorbidity Adjustment

The chronic diagnosis comorbidity adjustment is applicable only when the comorbidity has an effect on the cost of dialysis care and when that chronic diagnosis comorbidity appears on the claim. The adjustment does not automatically continue each month. When an acute diagnosis comorbidity with a higher adjustment value is applicable at the same time a chronic comorbidity applies, then the higher adjustment will be applied for 4 patient months, and then revert to the lower chronic comorbidity payment adjustment factor.

6. Pediatric case-mix adjusters: Age and dialysis modality

Pediatric patients are beneficiaries with ESRD who are under the age of 18. The same base rate is used for adult and pediatric patients, which is also adjusted by the area wage index. However, the base rate for pediatric patients is not adjusted for case-mix as adjustments used for adult patients. The pediatric payment adjustments use only two age categories (<13, age 13-17) and dialysis modality (PD or HD).

The pediatric case-mix adjusters, applicable for CY 2011, are shown below. These values are presented for the purpose of demonstrating the computations shown in the examples in the following sections. Any revisions to the case-mix adjusters will be published in subsequent rulemaking.

Based on the two classification categories for age and modality, there are four pediatric classification groups.

Pediatric Patient-Level Characteristics	Adjustment Value	
	CY 2011-2015	Beginning CY 2016
Age: <13, Modality: PD	1.033	1.063
Age:<13, Modality: Hemo	1.219	1.306
Age:13-17, Modality: PD	1.067	1.102
Age:13-17, Modality: Hemo	1.277	1.327

ESRD facilities do not receive the low-volume adjustment, described in §60.B.1, or the rural adjustment, described in §60.B.3, for pediatric beneficiaries. However, they are eligible for training add-on and outlier payments (described in §60.C and §60.D, of this chapter respectively).

The following example demonstrates the calculation of the payment rate for a pediatric patient who receives dialysis at an ESRD facility and is located in an urban area with a wage index of 1.10. The example also shows the application of the training add-on for eligible training treatments. Before giving the particulars of the pediatric dialysis patient, shown first is the calculation of the labor-adjusted base rate of $242.06, which is the starting point for the computation of the case-mix adjusted base rate.

- Base rate: $230.39
- Labor-related share of base rate: $230.39 * 0.50673 = $116.75
- Wage index adjusted labor-related share: $116.75 * 1.1000 = $128.42
- Non labor-related share of base rate: $230.39 * (1 -0.50673) = $113.64
- Wage index adjusted base rate: $128.42 + $113.64 = $242.06

Provided next is the characteristics of the pediatric patient and continue with the example.

- Andrew, a 12 year old male, has been on CCPD since June 2010. His mother, who assists him with his dialysis at home, is no longer able to assist with dialysis beginning May 10, 2016. His aunt, who lives nearby, has agreed to be the caregiver and assist him with his dialysis. The aunt required 17 training sessions at an ESRD facility in order to become knowledgeable and skilled sufficiently to perform this role. These training sessions began May 16 and ended June 10. The above pediatric classification table reveals that Andrew's pediatric dialysis classification group is cell 1, with an associated patient multiplier of 1.063. During the months of May and June 2016, the ESRD payment rate per HD-equivalent treatment would be:

  $242.06 * 1.063 = $257.31

- However, the ESRD facility is entitled to receive payment for a maximum of 15 training treatments furnished in connection with a new caregiver. Because the amount of the training add-on is adjusted by the ESRD facility's wage index (1.10), the amount of the training add-on is calculated as follows:

  Training rate: $50.16 Wage index:
  1.10
  Training payment: $50.16 * 1.10 = $55.18

- For the maximum number of 15 training treatments for which the training adjustment may be provided in connection with a PD patient, the payment rate, including the training add-on, would be:

  ($242.06 * 1.063 + $55.18) = $312.49

  NOTE: This example is computed without regard to other adjustments (e.g., outlier payments.)

B. Facility-level adjustments

There are three facility-level adjustments in the ESRD PPS. The first adjustment accounts for ESRD facilities furnishing a low-volume of dialysis treatments. The second adjustment reflects urban and rural differences in area wage levels using an area wage index developed from Core Based Statistical Areas (CBSAs). The third is a rural adjustment beginning in CY 2016.

1. Low-Volume Adjustment

ESRD facilities that qualify as being low-volume can receive the low-volume payment adjustment (LVPA) applied to each dialysis treatment they furnish beginning on or after January 1, 2011. For CY 2011 the payment adjustment was 18.9 percent, and beginning January 1, 2016, the payment adjustment is 23.9 percent.

a. Low-Volume Criteria

To be eligible for the low-volume adjustment, an ESRD facility must meet specific criteria:

- The ESRD facility must have furnished less than 4,000 dialysis treatments in each of the 3 cost reporting years preceding its payment year. This 3 year eligibility period is based on the ESRD facility's as-filed or final settled 12- consecutive month cost reports.
    - The term "payment year" is the period of time that is used for determining payment to ESRD facilities, which is a calendar year. The ESRD PPS is based on a calendar year which begins January 1 of each year.
    - The eligibility years are defined as the 3 years preceding the payment year and are based on cost reporting periods. Specifically, the cost reporting periods that end in the 3 years immediately preceding the payment year. The cost reporting periods must report costs for 12 consecutive months.
    - For purposes of determining eligibility for the low-volume adjustment, the number of "treatments" is the total number of treatments furnished to Medicare and non-Medicare patients. For peritoneal dialysis (PD) patients, 1 week of PD is considered equivalent to 3 hemodialysis (HD) treatments. For example, a patient on PD for 21 days would have (21/7) x 3 or 9 HD-equivalent treatments. See §50.A.4 of this chapter for more information on hemodialysis equivalent treatments.

- The ESRD facility must not have opened, closed, or received a new provider number due to a change in ownership, (see Pub. 100-07, chapter 3, §3210), in the 3 years preceding the payment year.

    - *T*his 3 year period is based on the ESRD facility's as-filed or final settled 12-consecutive month cost reports that end in the 3 years immediately preceding the ESRD PPS payment year.

    - An ESRD facility is determined to be "opened" when the ESRD facility is a new establishment newly surveyed by the state and Medicare, is certified for Medicare participation, receives a provider number, and begins furnishing Medicare certified outpatient maintenance dialysis treatments.

    - If there is a change in ownership that does not result in a change in provider number but does cause a change in the fiscal year reporting to that of the new provider, the A/B MAC (A) should combine the reporting periods for determining eligibility to the LVPA.

      For example, prior to a change of ownership (CHOW), Facility A had a cost reporting period that spanned January 1 through December 31. Facility A had a CHOW mid-year that did not result in a new provider transaction access number (PTAN) but caused a break in the cost reporting period. The A/B MAC (A) would add Facility A's cost report that spanned January 1 through May 31 to its cost report that spanned June 1 through December 31 to verify the total treatment count. The other situation that could occur is when a CHOW results in a change of the original fiscal period. For example, prior to a CHOW, Facility B had a cost reporting period that spanned January 1 through December 31 and, based on its cost reports for 2012 and 2013, it met the LVPA eligibility criteria. Then, Facility B had a CHOW in the beginning of 2014 that did not result in a new PTAN, but changed its cost reporting period to that of its new owner, October 1, 2014, through September 30, 2015. This scenario would create a short and a long cost report that would not total 12 months that the A/B MAC (A) would need to review for verification. That is, Facility B would have a cost report that spanned January 1, 2014, through July 31, 2014 (7 months) and a cost report that spanned August 1, 2014 through September 30, 2015 (14 months). In this situation, the A/B MAC (A) should combine the two non-standard cost reporting periods that in combination may exceed 12-consecutive months and prorate the data to equal a full 12-consecutive month period.

    - *Beginning January 1, 2019, if there is a CHOW that results in a change in provider number due to a facility-type change (for example, hospital based dialysis facility to independent dialysis facility) and the new owner accepts the Medicare agreement, the ESRD facility can qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. This policy does not extend to CHOWs where a new PTAN is issued for any other reason.*

    - Effective January 1, 201*9*, ESRD *facilities that change their fiscal year end for cost reporting purposes, outside of a CHOW, qualify for the LVPA if they otherwise meet the LVPA eligibility criteria. When this occurs, the MACs will combine the two nonstandard cost reporting periods of less than 12 months to equal a full 12- consecutive month period or combine the two non-standard cost*

reporting periods, that in combination may exceed 12-consecutive months, and prorate the data to equal a full 12-consecutive month period. This does not impact or change requirements for reporting, as established by the MACs, or those set forth in § 413.24(f)(3).

- Effective January 1, 2016, the ESRD facility must not be located within 5 road miles of another ESRD facility under common ownership. The geographic proximity criterion is applicable to all ESRD facilities that are Medicare certified to furnish outpatient maintenance dialysis treatments. For the purpose of determining the number of treatments furnished by the ESRD facility, the number of treatments considered furnished by the ESRD facility would be equal to the aggregate number of treatments furnished by the other ESRD facilities that are both under common ownership, and 5 road miles or less from the ESRD facility in question.

  For example, ESRD facility A received its Medicare certification on February 1, 2011, allowing them to bill and receive payment for outpatient maintenance dialysis that they furnish to Medicare beneficiaries. ESRD facility A will need to meet the low-volume criteria for 3 years. When the ESRD facility A submits its attestation to the A/B MAC (A), the A/B MAC (A) will need to consider ESRD facility A's ownership and the ownership of all of the ESRD facilities located within a 5 road mile radius or less when determining total treatments. A/B MACs (A) shall use the Provider Enrollment, Chain, and Ownership System (PECOS) (or the most recent available Medicare enrollment system) to locate the ESRD facility's ownership information. A/B MACs (A) shall refer to 42 CFR §421.404(a) when determining common ownership.

  Prior to January 1, 2016, ESRD facilities that were Medicare certified prior to January 1, 2011, were grandfathered into the geographic proximity criterion.

  NOTE: The low-volume adjustment does not apply to dialysis treatments provided to pediatric patients.

b. ESRD Facility Attestation Instruction for Low-Volume Adjustment

In order to receive the low-volume adjustment under the ESRD PPS, each individual ESRD facility must submit an attestation statement each year to its A/B MAC (A). The attestation must state that the ESRD facility qualifies as a low-volume facility in accordance with 42 CFR §413.232 as described above. Specifically, the attestation states that the ESRD facility was low-volume for the first 2 eligibility years and that they will be for the third eligibility year, that is, the cost reporting period ending in the year that immediately precedes the payment year. In most cases, the A/B MACs (A) will not have received the third eligibility year's cost report and will rely on the attestation in order to allow the application of the adjustment. November 1st of each year is the mandatory deadline for the submission of attestations for ESRD facilities that believe they are eligible to receive the low-volume payment adjustment.

Beginning January 1, 2019, ESRD facilities may request an extraordinary circumstance exception to the November 1 deadline. In order to request an extraordinary circumstance exception, the facility is required to submit a narrative explaining the rationale for the exception to their MAC. The MAC will evaluate the narrative to determine if an exception is justified. The determination will be final, with no appeal.

However, for new or resubmitted attestations applicable to payment years 2011 to 2015, to allow A/B MACs (A) and facilities adequate time to review policy clarifications related to the low volume adjustment, the attestation deadline was extended to December 31, 2014. For attestations applicable to payment year 2016, the attestation deadline is extended to December 31, 2015, to allow A/B MACs (A) and facilities adequate time to review policy changes finalized in the CY 2016 ESRD PPS final rule. A/B MACs (A) have a maximum of 60 days to verify attestations for implementation of the low-volume adjustment beginning January 1 of the following payment year.
A/B MACs (A) shall notify the ESRD facilities no later than September 1 of each year that they need to submit the low-volume attestation no later than November 1st of each year in order to receive the adjustment the following payment year. A/B MACs (A) may not accept attestations submitted after the mandatory deadline. If an ESRD facility is receiving the low-volume payment adjustment and will qualify for the adjustment in the subsequent payment year they must submit another attestation. If the ESRD facility does not submit an attestation, the A/B MAC (A) should no longer apply the low-volume payment adjustment beginning January 1st of the next payment year and the ESRD facility cannot receive the low-volume payment adjustment until the following payment year.

An ESRD facility should notify its A/B MAC if it determines that it did not maintain low-volume status for its cost reporting period ending immediately preceding the payment year or if it finds that it will not remain low-volume for any subsequent cost reporting year. The A/B MAC (A) is responsible to reconcile incorrect payments made to ESRD facilities retroactively, if needed, to ensure overpayments have not been made. If an A/B MAC (A) determines that an ESRD facility has received the low-volume adjustment in error, the A/B MAC (A) is required to adjust all of the ESRD facility's affected claims to remove the adjustment within 6 months of finding the error.

The A/B MAC (A) shall:

- Recoup low-volume adjustment payments made to an ESRD facility that failed to meet the low-volume adjustment criteria defined in 42 CFR §413.232(b)(1). Recoupment shall occur when the A/B MAC (A) receives the as-filed cost report for the third eligibility year and finds that the ESRD facility did not meet the eligibility criteria. Recoupment shall also occur if any cost reports used for eligibility are subsequently found to have not met the low-volume criteria, for example, reopening or appeals. A/B MACs (A) shall reprocess claims paid during the payment year in which the ESRD facility incorrectly received the low-volume payment adjustment.

- Recoup low-volume adjustment payments made to an ESRD facility that failed to meet the low-volume adjustment criteria defined in 42 CFR §413.232(b)(2). A/B MACs (A) shall use PECOS (or most recent Medicare enrollment system) to locate the ESRD facility's ownership information at the time of verification to determine if the ESRD facility is in the process of a CHOW. A/B MACs
(A) shall use the current owner provided in PECOS. If the ESRD facility was in the process of a CHOW, recoupment shall occur when the CHOW is effective and the new owner is assigned a new provider number. A/B MACs
(A) shall reprocess claims paid during the payment year in which the ESRD facility incorrectly received the low-volume payment adjustment.

If an ESRD facility does not remain low-volume for each of the 3 years (described above in §60.B.1.a) immediately preceding the payment year, the ESRD facility cannot be

eligible for the adjustment until it can demonstrate again that for 3 years it has met the low-volume criteria.

Example - Provider 21-25XX is an independent ESRD facility that has a June 30th cost report year end.
The ESRD facility concluded in October 2010 that it met the criteria of a low- volume facility. For its cost reporting periods, 7/1/2007 – 6/30/2008, 7/1/2008 – 6/30/2009, and 7/1/2009 – 6/30/2010, it did not open, close, or have a change of ownership and furnished less than 4,000 dialysis treatments in each of those cost reporting periods. In October 2010, the ESRD facility sent its A/B MAC (A) an attestation stating that it believes that it meets the low-volume criteria and would like to begin to receive the low-volume adjustment. The A/B MAC (A) receives the attestation on November 1st and then has 60 days (that is, until December 30th) to verify if the ESRD facility qualifies as a low-volume facility. On December 28th the A/B MAC (A) was able to verify that provider 21-25XX met the criteria and allowed for the adjustment to be applied to each dialysis treatment the ESRD facility furnished beginning January 1, 2011.

Determining Low-Volume Eligibility in Hospitals with Multiple Subunits and Satellites

A hospital may be affiliated with multiple hospital-based ESRD facilities. In addition, an individual hospital-based ESRD facility may have several locations that are subsumed under it, billing under the same ESRD facility provider number.

Verification of an ESRD facility's low-volume status is based on the A/B MAC's (A) review of the total treatment count on an ESRD facility's (or a hospital's) cost report. In the situation where a hospital has multiple locations of a hospital-based ESRD facility under its governing body, the aggregate cost and treatment data of all of the locations (not just the treatment count of one of the subunits or satellite entities) are reported on the hospital's cost report I series. In the case where a hospital has multiple locations and treatment counts are aggregated in the hospital's cost report, the A/B MAC (A) may consider other supporting documentation which may include individual facility treatment counts, rather than the hospital's cost report alone. The hospital must provide the documentation to support the total treatment count for all the facilities that make up the total treatment count on the cost report for the A/B MAC (A) to review, even if not all the facilities are applying for the low volume adjustment.

2. Wage index

The wage index adjustment is applied when calculating the ESRD PPS payment in order to account for geographic differences in area wage levels. Each ESRD facility's payment is adjusted using the wage index for the CBSA in which the ESRD facility is located. Rural ESRD facilities use the statewide average.

The wage index values and the budget neutrality adjustment factor are updated during rulemaking, are issued via annual Recurring Update Notifications, and are posted on the ESRD Payment Webpage.

3. Rural adjustment

Beginning January 1, 2016, the ESRD PPS provides a 1.008 percent payment adjustment for ESRD facilities located in a rural CBSA.

C. Training and Retraining Add-On Payment

A training add-on payment adjustment is available under the ESRD PPS. The training add-on payment is computed by using the national average hourly wage for nurses from the Bureau of Labor Statistics. The payment accounts for 1.5 hours of nursing time for each training treatment that is furnished and is adjusted by the geographic area wage index. The training add-on payment applies to both peritoneal dialysis and hemodialysis training treatments, and added to the ESRD PPS payment, when a training treatment is provided by a Medicare certified training ESRD facility. An ESRD facility may bill a maximum of 25 training sessions per patient for hemodialysis training, and 15 sessions for CCPD and CAPD training. ESRD facilities should not expect additional reimbursement beyond the maximum sessions. CMS expects that ESRD patients who opt for home dialysis are good candidates for home dialysis training, and will successfully complete their method of training before reaching the maximum number of allotted training treatments. For more information regarding dialysis training, see §30.2 of this chapter. For more information regarding retraining, see §30.2.E of this chapter.

D. Outlier Policy

The ESRD PPS provides additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care when applicable. Outlier payments are based on a comparison of the predicted Medicare allowable payment (MAP) per treatment to actual incurred expenditure per treatment for services which were or would have been considered separately billable prior to the implementation of the ESRD PPS. ESRD outlier services include:

- Drugs and biologicals used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

- Laboratory tests used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B;

- Medical or surgical supplies used to administer drugs and biologicals used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; and

- Drugs and biologicals used for the treatment of ESRD that were or would have been, prior to January 1, 2011, separately billable under Part D. Implementation of renal dialysis service oral-only drugs has been delayed until January 1, 2025.

The list of renal dialysis services that are included as outlier services may be found at http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage.

NOTE: All renal dialysis service Part B drugs and biologicals reported with a HCPCS code that is on the ASP List are included for outlier payments (with the exception of composite rate drugs). The laboratory tests that comprise the AMCC panel do not qualify for an outlier, see §20.2.A for information regarding the 50/50 rule.

ESRD facilities may receive outlier payments for the treatment of both adult and pediatric dialysis patients. An ESRD facility is eligible for an outlier payment if its actual or

imputed MAP amount per treatment for ESRD outlier services exceeds a threshold. The MAP amount represents the average incurred amount per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted ESRD outlier services MAP amount per treatment (which is case-mix adjusted) plus the fixed dollar loss amount. In accordance with 42 CFR §413.237(c), facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold.

For example, the average outlier services MAP amount per treatment for pediatric and adult dialysis patients for CY 2016 were $39.20 and $50.81, respectively. After multiplication by applicable patient and facility specific adjusters to yield a predicted outlier services MAP amount, a fixed amount is added (the "fixed dollar loss" amount) to determine the outlier threshold. The fixed dollar loss amounts for CY 2016 were $62.19 for pediatric patients and $86.97 for adult patients. The CY 2016 values of the average outlier services MAP amount and the fixed dollar loss amount are used below for the purpose of following the outlier payment computation. These values may be revised as a result of subsequent rulemaking.

In computing the MAP amount, the adjusters used are:

Adult Characteristics	Adjustment Value	
	CY 2011-2015	Beginning CY 2016
Age: 18-44	0.996	1.044
Age: 45-59	0.992	1.000
Age: 60-69	1.000	1.005
Age: 70-79	0.963	1.000
Age: 80+	0.915	0.961
Body Surface Area	1.014	1.000
Low Body Mass Index (BMI <18.5)	1.078	1.090

Onset of Dialysis	1.450	1.409
Pericarditis	1.354	1.209
Bacterial pneumonia	1.422	---
Gastro-intestinal tract bleeding	1.571	1.426
Hereditary hemolytic or sickle cell anemia	1.225	1.999
Myelodysplastic syndrome	1.309	1.494
Monoclonal gammopathy	1.074	---
Low-volume facility adjustment	0.975	0.955
Rural facility adjustment	---	0.978

Pediatric Characteristics Adjustment Value

	CY 2011-2015	Beginning CY 2016
Age: <13, Modality: PD	0.319	0.410
Age: <13, Modality: Hemo	1.185	1.406
Age: 13-17, Modality: PD	0.476	0.569
Age: 13-17, Modality: Hemo	1.459	1.494

Both the adult and pediatric CY 2016 separately billable case-mix adjusters are presented for the purpose of following the outlier payment computations shown below and may be revised as a result of subsequent rulemaking.

1. Outlier Payment Calculation

The outlier payment computations use the case-mix adjusters for separately billable services. These adjusters are applied to the relevant outlier services MAP amount for either adult or pediatric patients discussed above to obtain the predicted MAP amount for outlier services, reflecting all patient-specific and any facility-specific adjustments.

The following example shows how outlier payments are calculated under the ESRD PPS. For further information on the calculation of a patient's BSA, see §60.A.1. The pricing amounts for laboratory services qualifying as outlier services are based on the clinical laboratory fee schedule. For injectable drugs and biologicals, pricing is based on the latest available quarterly average sales price plus 6 percent (ASP + 6) methodology. For formerly Part D drugs with an injectable version, pricing is based on national average drug prices based on the Medicare Prescription Drug Plan Finder. For medical/surgical supplies, pricing is based on prices established by the local A/B MAC (A). For further information regarding A/B MAC (A) pricing of medical/surgical supplies, see Pub. 100- 04, chapter 8, §20.1.

2. Example of Outlier Payment

Ms. Brown is a 66 year old ESRD patient and is 167.64 cm. tall, weighs 105 kg., and has a recent diagnosis of GI bleeding. She does not qualify for a low BMI adjustment.

Ms. Brown's BSA is 2.1284.

The list of adjusters in §D reveals that the separately billable multiplier for BSA is 1.000. Ms. Brown's case-mix adjustment based on her BSA of 2.1284 is 1.000.
Step 1: Determine the predicted, ESRD outlier services MAP amount using the product of all applicable case-mix adjusters.

The patient-level outlier services case-mix adjusters are identified in the list in §D:

66 years old: 1.005, BSA: 1.000, and GI bleeding: 1.426:
= 1.005 * 1.000 * 1.426
= 1.4331

The adjusted, average, ESRD outlier services MAP amount
= $50.81

The adjusted, average ESRD outlier services MAP amount * product of the outlier services case-mix adjusters:
= $50.81 * 1.4331 = $72.82

Step 2: Determine the imputed average, per treatment, ESRD outlier services MAP amount based on utilization of all separately billable services on the monthly ESRD facility bill

Assume the imputed monthly ESRD outlier services amount = $4,000 and that the corresponding total number of treatments in the month = 10

The imputed, average, per treatment, outlier services MAP amount
= $4,000/10 = $400

Step 3: Add the fixed dollar loss amount to the predicted, ESRD outlier services MAP amount

The fixed dollar loss amount = $86.97. The predicted ESRD outlier services MAP amount = $72.82
= $72.82 + $86.97 = $159.79

Step 4: Calculate outlier payment per treatment

Outlier payment = imputed average, per treatment, outlier services MAP amount minus (predicted ESRD outlier services MAP amount plus the fixed dollar loss amount) * loss sharing percentage:
= ($400.00-$159.79) * .80 = $240.21 * .80 = $192.17

The outlier payments for Ms. Browns' 10 treatments would be: 10 * $192.17 =
$1,921.70

E. Co-Insurance

Eighty percent of the total ESRD PPS payment amount for renal dialysis services furnished by ESRD facilities to ESRD beneficiaries is paid by Medicare. ESRD beneficiaries are responsible for the remaining 20 percent after the deductible. Therefore, the beneficiary co-insurance amount under the ESRD PPS is 20 percent of the total ESRD PPS payment, which includes the ESRD PPS base rate, all applicable adjustments, any applicable training add-on amounts, and any applicable outlier payments. For example, under the ESRD PPS the patient's co-insurance liability is based on the payment made to the ESRD facility and NOT on specific renal dialysis items and services. Therefore, any renal dialysis service drug or biological or laboratory service furnished to a beneficiary would NOT require a co-insurance amount because the renal dialysis service drug or biological or laboratory service is included in the payment made to the ESRD facility.

In the event a claim is reprocessed and the amount that was paid to the ESRD facility changes, the ESRD facility is responsible for reconciling with the ESRD patient any overpayment or underpayment of co-insurance or deductible amounts paid to the ESRD facility.

Attachment A
CY 2019 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	*$0.88*
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*[3] *23155066203*[3] 43353003409 *43353003430*[3] 43353003481 43353013809 43353013830 43353063309 *43353063330*[3] 43353063381 43353099809 63304023901 63304023930 63629732301 63629732302 64380072304 64380072306 *69452020713*[3] *69452020720*[3]	Calcitriol 0.25 mcg capsules	*$0.54*
00093735301 23155011901 *23155066301*[3] 63304024001 64380072406 *69452020820*[3]	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*[3] 69387010330 69452014513	Paricalcitol 1 mcg capsule	*$4.69*
10888500202 49483068803 55111066430 60429048230 60429083730 64980022603 65862093730 68382026706 69387010430 69452014613	Paricalcitol 2 mcg capsule	*$9.23*
10888500302[4] *55111066530*[4] *60429048330*[4] *69452014713*[4] *49483068903*[4] *60429083830*[4] *65862093830*[4]	Paricalcitol 4 mcg capsule	
58468012001[4]	Hectorol (doxercalciferol) 0.5 mcg capsule	
58468012401[4]	Hectorol (doxercalciferol) 1 mcg capsule	
58468012101[4]	Hectorol (doxercalciferol) 2.5 mcg capsule	
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*
54482014407[5]	Carnitor (levocarnitine) 330 mg tablet	
54482014508[5]	Carnitor (levocarnitine) 1GM/10ML oral solution (118mL/bottle)	

64980050312[5] *50383017104*[5]	Levocarnitine 1GM/10ML oral solution (118mL/bottle)	
64980013009[5] *50383017290*[5]	Levocarnitine 330 mg tablet	

[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

[4] Effective January 1, 2019, the renal dialysis service is no longer an active NDC and therefore does not qualify as an outlier service.

[5] Effective January 1, 2019, the drug is not indicated for dialysis related carnitine deficiency and is therefore not considered to be a renal dialysis 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	$0.375
J0884	Argatroban ESRD dialysis 1mg	1 MG	$1.228

[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).

[2]Average 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/MedicareFee-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 ESRD PPS CONSOLIDATED BILLING LIST

Note: This is not an all-inclusive list. All injectable drugs and biologicals and their oral or other form of administration, laboratory tests, supplies, and services provided for the treatment of ESRD are included in the ESRD PPS.

DME ESRD SUPPLY HCPCS FOR ESRD PPS CONSOLIDATED BILLING EDITS

HCPC	Long Description
A4216	STERILE WATER, SALINE AND/OR DEXTROSE, DILUENT/FLUSH, 10 ML
A4217	STERILE WATER/SALINE, 500 ML
A4218	STERILE SALINE OR WATER, METERED DOSE DISPENSER, 10 ML
A4450	TAPE, NON-WATERPROOF, PER 18 SQUARE INCHES
A4452	TAPE, WATERPROOF, PER 18 SQUARE INCHES
A6215	FOAM DRESSING, WOUND FILLER, STERILE, PER GRAM
A6216	GAUZE, NON-IMPREGNATED, NON-STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
A6402	GAUZE, NON-IMPREGNATED, STERILE, PAD SIZE 16 SQ. IN. OR LESS, WITHOUT ADHESIVE BORDER, EACH DRESSING
E0210	ELECTRIC HEAT PAD, STANDARD

DME ESRD SUPPLY HCPCS NOT PAYABLE TO DME SUPPLIERS

HCPC	Long Description
A4215	NEEDLE, STERILE, ANY SIZE, EACH
A4244	ALCOHOL OR PEROXIDE, PER PINT
A4245	ALCOHOL WIPES, PER BOX
A4246	BETADINE OR PHISOHEX SOLUTION, PER PINT
A4247	BETADINE OR IODINE SWABS/WIPES, PER BOX
A4248	CHLORHEXIDINE CONTAINING ANTISEPTIC, 1 ML
A4651	CALIBRATED MICROCAPILLARY TUBE, EACH
A4652	MICROCAPILLARY TUBE SEALANT
A4653	PERITONEAL DIALYSIS CATHETER ANCHORING DEVICE, BELT, EACH
A4657	SYRINGE, WITH OR WITHOUT NEEDLE, EACH

A4660	SPHYGMOMANOMETER/BLOOD PRESSURE APPARATUS WITH CUFF AND STETHOSCOPE
A4663	BLOOD PRESSURE CUFF ONLY
A4670	AUTOMATIC BLOOD PRESSURE MONITOR
A4671	DISPOSABLE CYCLER SET USED WITH CYCLER DIALYSIS MACHINE, EACH
A4672	DRAINAGE EXTENSION LINE, STERILE, FOR DIALYSIS, EACH
A4673	EXTENSION LINE WITH EASY LOCK CONNECTORS, USED WITH DIALYSIS
A4674	CHEMICALS/ANTISEPTICS SOLUTION USED TO CLEAN/STERILIZE DIALYSIS EQUIPMENT, PER 8 OZ
A4680	ACTIVATED CARBON FILTER FOR HEMODIALYSIS, EACH
A4690	DIALYZER (ARTIFICIAL KIDNEYS), ALL TYPES, ALL SIZES, FOR HEMODIALYSIS, EACH
A4706	BICARBONATE CONCENTRATE, SOLUTION, FOR HEMODIALYSIS, PER GALLON
A4707	BICARBONATE CONCENTRATE, POWDER, FOR HEMODIALYSIS, PER PACKET
A4708	ACETATE CONCENTRATE SOLUTION, FOR HEMODIALYSIS, PER GALLON
A4709	ACID CONCENTRATE, SOLUTION, FOR HEMODIALYSIS, PER GALLON
A4714	TREATED WATER (DEIONIZED, DISTILLED, OR REVERSE OSMOSIS) FOR PERITONEAL DIALYSIS, PER GALLON
A4719	"Y SET" TUBING FOR PERITONEAL DIALYSIS
A4720	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 249CC, BUT LESS THAN OR EQUAL TO 999CC, FOR PERITONEAL DIALYSIS
A4721	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 999CC BUT LESS THAN OR EQUAL TO 1999CC, FOR PERITONEAL DIALYSIS
A4722	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 1999CC BUT LESS THAN OR EQUAL TO 2999CC, FOR PERITONEAL DIALYSIS
A4723	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 2999CC BUT LESS THAN OR EQUAL TO 3999CC, FOR PERITONEAL DIALYSIS

A4724	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 3999CC BUT LESS THAN OR EQUAL TO 4999CC, FOR PERITONEAL DIALYSIS
A4725	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 4999CC BUT LESS THAN OR EQUAL TO 5999CC, FOR PERITONEAL DIALYSIS
A4726	DIALYSATE SOLUTION, ANY CONCENTRATION OF DEXTROSE, FLUID VOLUME GREATER THAN 5999CC, FOR PERITONEAL DIALYSIS
A4728	DIALYSATE SOLUTION, NON-DEXTROSE CONTAINING, 500 ML
A4730	FISTULA CANNULATION SET FOR HEMODIALYSIS, EACH
A4736	TOPICAL ANESTHETIC, FOR DIALYSIS, PER GRAM
A4737	INJECTABLE ANESTHETIC, FOR DIALYSIS, PER 10 ML
A4740	SHUNT ACCESSORY, FOR HEMODIALYSIS, ANY TYPE, EACH
A4750	BLOOD TUBING, ARTERIAL OR VENOUS, FOR HEMODIALYSIS, EACH
A4755	BLOOD TUBING, ARTERIAL AND VENOUS COMBINED, FOR HEMODIALYSIS, EACH
A4760	DIALYSATE SOLUTION TEST KIT, FOR PERITONEAL DIALYSIS, ANY TYPE, EACH
A4765	DIALYSATE CONCENTRATE, POWDER, ADDITIVE FOR PERITONEAL DIALYSIS, PER PACKET
A4766	DIALYSATE CONCENTRATE, SOLUTION, ADDITIVE FOR PERITONEAL DIALYSIS, PER 10 ML
A4770	BLOOD COLLECTION TUBE, VACUUM, FOR DIALYSIS, PER 50
A4771	SERUM CLOTTING TIME TUBE, FOR DIALYSIS, PER 50
A4772	BLOOD GLUCOSE TEST STRIPS, FOR DIALYSIS, PER 50
A4773	OCCULT BLOOD TEST STRIPS, FOR DIALYSIS, PER 50
A4774	AMMONIA TEST STRIPS, FOR DIALYSIS, PER 50
A4802	PROTAMINE SULFATE, FOR HEMODIALYSIS, PER 50 MG
A4860	DISPOSABLE CATHETER TIPS FOR PERITONEAL DIALYSIS, PER 10
A4870	PLUMBING AND/OR ELECTRICAL WORK FOR HOME HEMODIALYSIS EQUIPMENT
A4890	CONTRACTS, REPAIR AND MAINTENANCE, FOR HEMODIALYSIS EQUIPMENT
A4911	DRAIN BAG/BOTTLE, FOR DIALYSIS, EACH
A4913	MISCELLANEOUS DIALYSIS SUPPLIES, NOT OTHERWISE SPECIFIED
A4918	VENOUS PRESSURE CLAMP, FOR HEMODIALYSIS, EACH

A4927	GLOVES, NON-STERILE, PER 100
A4928	SURGICAL MASK, PER 20
A4929	TOURNIQUET FOR DIALYSIS, EACH
A4930	GLOVES, STERILE, PER PAIR
A4931	ORAL THERMOMETER, REUSABLE, ANY TYPE, EACH
A6204	SURGICAL DRESSING
A6250	SKIN SEALANTS, PROTECTANTS, MOISTURIZERS, OINTMENTS, ANY TYPE, ANY SIZE
A6260	WOUND CLEANSERS, STERILE, ANY TYPE, ANY SIZE
E1500	CENTRIFUGE, FOR DIALYSIS
E1510	KIDNEY, DIALYSATE DELIVERY SYST. KIDNEY MACHINE, PUMP RECIRCULAT- ING, AIR REMOVAL SYST, FLOWRATE METER, POWER OFF, HEATER AND TEMPERATURE CONTROL WITH ALARM, I.V.POLES, PRESSURE GAUGE, CONCENTRATE CONTAINER
E1520	HEPARIN INFUSION PUMP FOR HEMODIALYSIS
E1530	AIR BUBBLE DETECTOR FOR HEMODIALYSIS, EACH, REPLACEMENT
E1540	PRESSURE ALARM FOR HEMODIALYSIS, EACH, REPLACEMENT
E1550	BATH CONDUCTIVITY METER FOR HEMODIALYSIS, EACH
E1560	BLOOD LEAK DETECTOR FOR HEMODIALYSIS, EACH, REPLACEMENT
E1570	ADJUSTABLE CHAIR, FOR ESRD PATIENTS
E1575	TRANSDUCER PROTECTORS/FLUID BARRIERS, FOR HEMODIALYSIS, ANY SIZE, PER 10
E1580	UNIPUNCTURE CONTROL SYSTEM FOR HEMODIALYSIS
E1590	HEMODIALYSIS MACHINE
E1592	AUTOMATIC INTERMITTENT PERITIONEAL DIALYSIS SYSTEM
E1594	CYCLER DIALYSIS MACHINE FOR PERITONEAL DIALYSIS
E1600	DELIVERY AND/OR INSTALLATION CHARGES FOR HEMODIALYSIS EQUIPMENT
E1610	REVERSE OSMOSIS WATER PURIFICATION SYSTEM, FOR HEMODIALYSIS
E1615	DEIONIZER WATER PURIFICATION SYSTEM, FOR HEMODIALYSIS
E1620	BLOOD PUMP FOR HEMODIALYSIS, REPLACEMENT
E1625	WATER SOFTENING SYSTEM, FOR HEMODIALYSIS
E1630	RECIPROCATING PERITONEAL DIALYSIS SYSTEM
E1632	WEARABLE ARTIFICIAL KIDNEY, EACH
E1634	PERITONEAL DIALYSIS CLAMPS, EACH
E1635	COMPACT (PORTABLE) TRAVEL HEMODIALYZER SYSTEM

E1636	SORBENT CARTRIDGES, FOR HEMODIALYSIS, PER 10
E1637	HEMOSTATS, EACH
E1639	SCALE, EACH
E1699	DIALYSIS EQUIPMENT, NOT OTHERWISE SPECIFIED

LABS SUBJECT TO ESRD CONSOLIDATED BILLING

CPT/ HCPC	Short Description
80047	Basic Metabolic Panel (Calcium, ionized)
80048	Basic Metabolic Panel (Calcium, total)
80051	Electrolyte Panel
80053	Comprehensive Metabolic Panel
80069	Renal Function Panel
80076	Hepatic Function Panel
82040	Assay of serum albumin
82108	Assay of aluminum
82306	Vitamin d, 25 hydroxy
82310	Assay of calcium
82330	Assay of calcium, Ionized
82374	Assay, blood carbon dioxide
82379	Assay of carnitine
82435	Assay of blood chloride
82565	Assay of creatinine
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
83735	Assay of magnesium
83970	Assay of parathormone
84075	Assay alkaline phosphatase
84100	Assay of phosphorus
84132	Assay of serum potassium

84134	Assay of prealbumin
84155	Assay of protein, serum
84157	Assay of protein by other source
84295	Assay of serum sodium
84466	Assay of transferrin
84520	Assay of urea nitrogen
84540	Assay of urine/urea-n
84545	Urea-N clearance test
85014	Hematocrit
85018	Hemoglobin
85025	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count) and automated differential WBC count.
85027	Complete (cbc), automated (HgB, Hct, RBC, WBC, and Platelet count)
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
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

DRUGS SUBJECT TO ESRD CONSOLIDATED BILLING

Category	HCPCS	Title
Access Management	J1642	INJ HEPARIN SODIUM PER 10 U
	J1644	INJ HEPARIN SODIUM PER 1000U
	J1945	LEPIRIDUN
	J2993	RETEPLASE INJECTION
	J2997	ALTEPLASE RECOMBINANT
	J3364	UROKINASE 5000 IU INJECTION
	J3365	UROKINASE 250,000 IU INJ
	J0884	INJ ARGATROBAN
Anemia Management	J0882	DARBEPOETIN
	J0887	INJ. EPOETIN BETA (FOR ESRD ON DIALYSIS), 1 MCG
	J1439	INJ FERRIC CARBOXYMALTOSE, 1MG
	J1750	IRON DEXTRAN
	J1443	INJ. FERRIC PYROPHOSPHATE CIT
	J1756	IRON SUCROSE INJECTION
	J2916	NA FERRIC GLUCONATE COMPLEX
	J3420	VITAMIN B12 INJECTION
	Q0139	FERUMOXYTOL
	Q4081	EPO
	Q5105	INJECTION, EPOETIN ALFA, BIOSIMILAR
Bone and Mineral Metabolism	J0604	CINACALCET, ORAL, 1 MG, (FOR ESRD ON DIALYSIS)
	J0606	INJECTION, ETELCALCETIDE, 0.1 MG
	J0610	CALCIUM GLUCONATE INJECTION
	J0620	CALCIUM GLYCER & LACT/10 ML
	J0630	CALCITONIN SALMON INJECTION
	J0636	INJ CALCITRIOL PER 0.1 MCG
	J0895	DEFEROXAMINE MESYLATE INJ
	J1270	INJECTION, DOXERCALCIFEROL
	J1740	IBANDRONATE SODIUM
	J2430	PAMIDRONATE DISODIUM /30 MG
	J2501	PARICALCITOL
	J3489	ZOLEDRONIC ACID
Cellular Management	J1955	INJ LEVOCARNITINE PER 1 GM
Anti-Infectives	J0878	DAPTOMYCIN
	J3370	VANCOMYCIN HCL INJECTION
Composite Rate Drugs and Biologicals	A4802	INJ PROTAMINE SULFATE
	J0670	INJ MEPIVACAINE HYDROCHLORIDE
	J0945	BROMPHENIRAMINE MALEATE
	J1200	INJ DIPHENHYDRAMINE HCL

	J1205	INJ CHLOROTHIAZIDE SODIUM
	J1240	INJ DIMENHYDRINATE
	J1940	INJ FUROSEMIDE
	J2001	INJ LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
	J2150	INJ MANNITOL
	J2360	INJECTION, ORPHENADRINE CITRATE, UP TO 60 MG
	J2720	INJ PROTAMINE SULFATE
	J2795	INJ ROPIVACAINE HYDROCHLORIDE
	J3265	INJ TORSEMIDE
	J3410	INJ HYDROXYZINE HCL
	J3480	INJ. POTASSIUM CHLORIDE, PER 2 MEQ.
	J7030	INFUSION, NORMAL SALINE SOLUTION , 1000 CC
	J7040	INFUSION, NORMAL SALINE SOLUTION, STERILE (500 ML = 1 UNIT)
	J7042	5% DEXTROSE/NORMAL SALINE (500 ML = 1 UNIT)
	J7050	INFUSION, NORMAL SALINE SOLUTION, 250 CC
	J7060	5% DEXTROSE/WATER (500 ML = 1 UNIT)
	J7070	INFUSION, D5W, 1000 CC
	J7120	RINGERS LACTATE INFUSION, UP TO 1000 CC
	J7131	HYPERTONIC SALINE SOL
	Q0163	DIPHENHYDRAMINE HYDROCHLORIDE