

CMS Final Rules for the Prospective Payment of Dialysis

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On July 26, 2010, CMS released the final rules for the prospective payment of dialysis (the “bundle”), which will take effect on January 1, 2011. These rules are final and not subject to judicial or other review. The key components of the final rules are outlined below. This document focuses only on adult dialysis patients; there will be a separate document for pediatric dialysis.

It is important to note that there are areas where the rules are ‘black and white’ and precisely define the implementation of the bundle. There are also grey areas, where CMS has indicated that supplemental guidances will be issued providing additional details. These are noted where relevant.

How much is the bundled payment and what’s included in it?

CMS used Medicare payments made in 2007 to establish the bundled payment amount. They then increased those payments to account for projected costs in 2011. This base rate was then reduced to offset outlier payments, case mix adjusters, and a congressionally mandated 2% decrease in ESRD spending. The bundle components and estimated associated reimbursements are shown in Table 1. Note: An incremental 3.1% transition adjuster reduction is applied later in the calculation of the final payment amount (discussed in further detail later in this document).

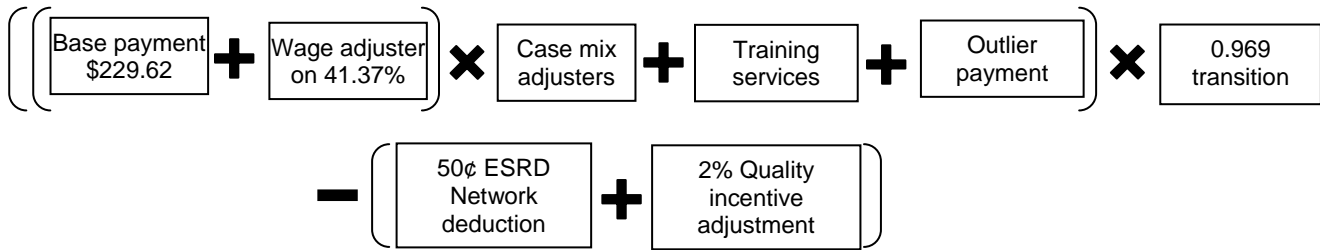
Table 1. Components of the bundle and associated reimbursement amount

<i>Composite rate services</i>	\$165.02
<i>Part B*</i>	
EPO	\$53.60
Darbepoetin	\$3.86
Calcitriol	\$0.06
Doxercalciferol	\$2.60
Paricalcitol	\$8.24
Iron sucrose	\$4.68
Sodium ferric gluconate	\$1.79
Levocarnitine	\$0.10
Alteplase	\$0.81
Vancomycin	\$0.09
Daptomycin	\$0.05
Other injectables	\$0.14
<i>Laboratory tests</i>	\$8.46
Dialysis facility supplies and IV fluids	\$1.04
DME and supplies	\$0.49
Ultrafiltration	\$0.07
Dialysis support services	\$0.04
<i>Part D</i>	
Oral Calcitriol	\$0.12
Oral Doxercalciferol	\$0.22
Oral Paricalcitol	\$0.14
Oral Levocarnitine	\$0.01
<i>Reductions</i>	
Congressionally mandated	-2%
Outlier	-1%
Case mix offset	-5.9%
Total	\$229.62

* Note that the amounts for injectable drugs are approximations based upon the calculations outlined in the final rules.

How do I calculate the new bundled payment?

The new bundled payment will be calculated on a per-treatment basis according to the diagram below. Note that this does not include the 20% reduction for patient co-pay



In brief, the base payment is \$229.62. The area wage adjuster is applied to 41.37% of this amount (or \$94.99), either increasing or decreasing the base payment. There is floor on the area wage adjuster, so that it cannot fall below 0.60. The wage adjusted base payment is then multiplied by the case mix adjusters, explained in detail below. Added to this are payments for training services and outlier payments, if they apply. This whole amount is then reduced by 3.1% to offset the costs of transition (the purpose of the transition adjuster is explained later).

There are two additional adjustments. First, the total payment is reduced by \$0.50 per treatment, which goes to support the ESRD networks. Second, starting in 2012, there will be up to a 2% reduction in payment for clinics that fail to meet Quality Incentive Program (QIP) measures for anemia and dialysis adequacy. The QIP program is described in greater detail below.

What are the new case mix adjusters?

In the current composite rate system, there are 3 case mix adjusters (CMAs): age; body mass index (BMI) and body surface area (BSA). CMS has added 8 new case mix adjusters. Seven CMAs are patient-level characteristics: onset of dialysis (for patients in the first four months of dialysis); 3 acute comorbidities (pericarditis, bacterial pneumonia, GI bleed in with hemorrhage); and 3 chronic comorbidities (hereditary hemolytic or sickle cell anemias, myelodysplastic syndrome, monoclonal gammopathy). One CMA is a facility characteristic: facility size <4,000 treatments each year from 2006-2008.

There are a number of caveats to the case mix adjusters:

- There are different CMA weights used to calculate the base rate and used to calculate the outlier payment
- CMAs are applied to all treatments in a month
- The first 4 CMAs (facility size, age, BMI, BSA) are applied in every month
- Of the last 7 CMAs (comorbidities and dialysis onset), only the one with the highest weight is applied in a month
- Chronic comorbidity CMAs are applied from the date of onset until transplant or death, but date of onset must occur on or after 1/1/2000
- Acute comorbidity CMAs are applied in the month of onset, and the following 3 months (thus, for a total of 4 months)

To clarify, let's examine a patient who was diagnosed with sickle cell anemia in 2001, started dialysis in January 2011, and was diagnosed with pericarditis in March 2011. The onset of dialysis adjuster of 1.51 would be applied in January, February, March and April. Though sickle cell and pericarditis were also diagnosed, both would be superseded by the onset of dialysis CMA. The pericarditis adjuster of 1.114 would only be applied in May and June. Assuming no other comorbidities occurred; the patient would have the sickle cell adjuster of 1.072 applied to each month after June.

Table 2. Base Rate and Outlier Payment Case Mix Adjusters

Patient and facility characteristic	Base Rate Adjuster	Outlier Payment Adjuster
Facility size: 4,000 treatments each year from 06-08	1.189	0.975
Age		
18-44	1.171	0.996
45-59	1.013	0.992
60-69	1.000	1.000
70-79	1.011	0.963
80+	1.016	0.915
Body surface area	1.020	1.014
BMI < 18.5	1.025	1.078
Onset of renal dialysis: ≤ 4 mo*	1.510	1.450
<i>Acute</i>		
Pericarditis	1.114	1.354
Bacterial pneumonia	1.135	1.422
GI bleed in with hemorrhage	1.183	1.571
<i>Chronic</i> †		
Hereditary hemolytic or sickle cell anemias	1.072	1.225
Myelodysplastic syndrome	1.099	1.309
Monoclonal gammopathy	1.024	1.074

* Based on 2728 Medical Evidence Form

† Based on claims since 2000

Shading indicates that only one of these CMAs can be applied in a month

There are additional administrative demands for the CMAs. First, CMS has specified a set of ICD-9 codes defining each comorbidity adjuster. That ICD-9 code must appear on the claim form in order for the CMA to be applied. Second, CMS specified:

“We will require ESRD facilities to provide documentation in the patient’s medical/clinical record to support any diagnosis recognized for a payment adjustment, utilizing specific criteria. We will address these documentation requirements in sub-regulatory guidance.” P. 354

CMS provided only one specific example for documentation, that “radiographic diagnosis” of bacterial pneumonia would be required in the medical chart.

Aren’t oral drugs, like phosphate binders and Sensipar, included in the bundle?

The only oral drugs included in the bundle in 2011 are oral versions of activated Vitamin D and Levocarnitine (see Part D in Table 1). However, CMS clearly stated that phosphate binders, Sensipar and other ESRD medications will be added to the bundle on January 1, 2014. Final rules on oral drugs will be issued in 2013.

There is an important caveat regarding oral medications. CMS stated:

“However, to the extent that any cardiac drug or biological (including anti-hypertensive drugs and biologicals) are furnished by an ESRD facility for ESRD-related conditions, the drug or biological would be considered a renal dialysis service and separate payment will not be made.” P. 117

It will be necessary to itemize all medications administered in the dialysis facility on the Medicare claim form. A special modifier will then be used to indicate which orals and biologics were administered for non-ESRD conditions. CMS expects that dialysis units will use the time before 2014 to make arrangements for the eventual inclusion of oral medications in the bundle.

Which Labs are included in the bundle?

A set of specified ESRD labs have been added to the composite rate. These are shown below. As with medications, it will be necessary to itemize all laboratory assays ordered by the MCP physician in the dialysis facility on the claim form. A special modifier will then be used to indicate which labs were administered for non-ESRD conditions.

Table 3. Laboratory Tests Included in the Bundle

Serum albumin	Erythropoietin	Transferrin	Hep b core antibody, Igm
Aluminum	Ferritin	Urea nitrogen	Hep b surface antibody
Calcium	Blood folic acid serum	Urine/urea-n	Blood culture for bacteria
Calcium, Ionized	Iron	Urea-N clearance	Culture, bacteria, other
Blood carbon dioxide	Iron binding	Hematocrit	Culture bacteria aerobic, other
Carnitine	Magnesium	Hemoglobin	Culture bacteria anaerobic
Blood chloride	Parathyroid hormone	Automated CBC w and w/o diff WBC	Culture bacteria, except blood
Creatinine	Alkaline phosphatase	Automated rbc count	Culture anaerobe ident, each
Urine creatinine	Phosphorus	Manual reticulocyte count	Culture aerobic identify
Creatinine clearance	Serum potassium	Automated reticulocyte count	Culture screen only
Vitamin B-12	Prealbumin	Reticyte/hgb concentrate	Hepatitis b surface ag, eia
Vitamin d, 25 hydroxy	Protein, serum	Automated leukocyte count	CBC/diff wbc w/o platelet
Vit d 1, 25-dihydroxy	Serum sodium	Hep b core antibody, total	CBC without platelet

Will I continue to receive payments for training services for home dialysis?

Yes, there will be a home training add-on adjustment. For facilities that opt in 100% to the bundled payment system, training services will be covered as follows:

- The training must be administered by a Medicare-certified training facility
- Reimbursement will be \$33.44 per training session
- The \$33.44 will be multiplied by the area wage adjuster, and this amount will be reduced by 3.1% for the transition offset
- No training services will be paid during the first 4 months of dialysis
- 15 training sessions will be reimbursed for PD, 25 for home HD and CCPD

For facilities that choose to Phase in, training sessions will continue to be reimbursed at the current rate (\$12 for PD, \$20 for home HD and CCPD) for the phase in portion of the bundle.

How does the transition work?

Units will have the option of opting into the new bundled payment system 100% on January 1, 2011 or phasing in over 4 years. The phase in means that payments will be “blended” for the first three years, with 25% based on the new payment system in 2011, 50% in 2012, 75% in 2013, and 100% in 2014. By November 1, 2010, all dialysis units will need to notify CMS of their choice. If a dialysis unit does not notify CMS of its choice, it will be automatically phased in. Because CMS expects units to selectively opt in or phase in based on which provides optimal reimbursement, they reduced the bundled payment (base payment, training services, and outlier payment) by 3.1% to offset this incremental cost. The payments under the new payment system have been described in this document. The payments under the old system will be modified in several ways:

- The base composite rate in 2011 will be \$138.53
- The drug add-on will be 14.7%
- \$0.49 will be added to cover the costs of oral medications in the bundle

How does the outlier payment system work?

The outlier payment only applies to items that are currently separately billable (not included in the current composite rate). This includes all items listed under Part B and Part D in Table 1.

The \$229.62 base payment includes **\$82.78** for these items. CMS will base the outlier payment on the difference between the Medicare Allowable Payment (MAP) for these Part B and Part D items, and the \$82.78 plus a \$155.44 “donut hole.” The “donut hole” is an amount that is not reimbursed. CMS will publish supplemental guidance specifying the MAP for each of the outlier items.

The calculation of the outlier payment will take 9 steps:

1. Calculate the patient’s outlier case-mix adjuster for the month (see Table 2, column 3)
2. Multiply the monthly case mix adjuster by \$82.78 (the outlier eligible portion of the base payment)
3. Add the \$155.44 “donut hole” to the case mix adjusted outlier eligible portion. This is the patient’s outlier threshold.
4. For each item in the outlier payment, multiply the number of units used that month (e.g., 120,000 units of Epoetin alfa) by the MAP. Sum these.
5. Divide the summed MAP by the # of treatments that month. This is the per treatment outlier MAP.
6. Subtract the outlier threshold (#3) from the per treatment outlier MAP (#5). If the number is positive, that month qualifies for an outlier payment.
7. Multiply #6 by 0.969, which reduces the outlier payment 3.1% for the transition adjuster.
8. Multiply #7 by 0.80 (Medicare reimbursement is 80%). This is how much Medicare will reimburse you per session for the outlier payment that month. The remaining 20% is the patient’s co-pay.
9. Multiply #8 by the number of treatments that month. This is the total outlier payment for the month.

How does the Quality Incentive Program (QIP) work?

Beginning in 2012, CMS will review each dialysis facility’s performance on the following metrics:

- Percent of hemoglobin measures below 10 g/dL
- Percent of hemoglobin measures above 12 g/dL
- Percent of URRs >65%

In future guidance, thresholds will be set for each of these measures. Failure to meet these thresholds will result in a payment reduction of up to 2%. The rules specifying the actual reduction for missing these quality measures will be provided in future guidance.

CMS has indicated that in future years, URR will likely be replaced by Kt/V. CMS has proposed possible future QIP measures: vascular access, vascular access infections, hospitalization, measures of bone and mineral metabolism, patient satisfaction, and patient-reported quality of life.

What else do I need to know?

The CMS final rules are 932 pages long, with many more details than can be covered in this brief synopsis. Other key issues include:

1. In center & home hemodialysis (peritoneal, nocturnal, etc.) will be reimbursed at the same rate.
2. Incremental payments will be eliminated for pediatric facilities, isolated essential facilities, and atypical service intensity starting 1/1/14. There will be no incremental payment for Hawaii or Alaska. No new exceptions will be instituted after 1/1/2011.
3. There will be an annual update of the bundled market basket minus 1%. This update can be negative: if utilization of dialysis goods and services decreases, the base payment can be decreased in future years.
4. Goods and services not included in the current composite rate payments (Part B and Part D in Table 1, including injectable and oral medications, laboratory testing, etc.) will not be covered by the bad debt provision.
5. Home dialysis Method II DME suppliers, laboratories and Part D plans will no longer be able to direct bill Medicare after 1/1/2001, but must seek payment through a patient’s ESRD facility
6. Cost report forms will be updated to reflect the changes in the bundled payment system.