

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 150	Date: NOVEMBER 16, 2011
	Change Request 7617

Transmittal 149, dated November 4, 2011, is being rescinded and replaced by Transmittal 150 to modify previous language in the Recurring Update Notification, Section B.-Policy, Calendar Year 2012 Rate Updates, item 8, and Outlier Policy Changes, items 1 and 2, MAP amounts per treatment and to remove business requirement 7617.6 to conform to the final rule. Additionally, a change was made to the pre-implementation contacts. All other information remains the same.

SUBJECT: Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2012

I. SUMMARY OF CHANGES: This Change Request implements; (1) the second year of the ESRD PPS 4-year transition, (2) the calendar year 2012 rate updates for the basic case-mix adjusted composite payment system portion of the blended payment amount and the ESRD PPS, and (3) changes to the outlier policy and consolidated billing requirements under the ESRD PPS. This recurring update notification applies to chapter 11, section 30.5.

EFFECTIVE DATE: January 1, 2012

IMPLEMENTATION DATE: January 3, 2012

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

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

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

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

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

Attachment – Recurring Update Notification

Pub. 100-02	Transmittal: 150	Date: November 16, 2011	Change Request: 7617
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SUBJECT: Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2012

Effective Date: January 1, 2012

Implementation Date: January 3, 2012

I. GENERAL INFORMATION

A. Background: Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) requires the implementation of an ESRD bundled Prospective Payment System (PPS) effective January 1, 2011. The calendar year (CY) 2011 ESRD PPS final rule, published on August 12, 2010, (75 FR 49030 through 49214) and Change Request (CR) 7064, Transmittal 2134, entitled “End Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Consolidated Billing for Limited Part B Services” implemented the ESRD PPS which included consolidated billing requirements.

For CY 2012, in addition to updating the ESRD PPS payment amount, CMS must continue to update the basic case-mix adjusted composite payment system for purposes of determining the composite rate portion of the blended payment amount during the ESRD PPS 4-year transition (CYs 2011 - 2013). CY 2012 implements the second year of the transition where the ESRD facilities that are receiving a blended payment under the transition will be paid a blended amount that will be based on 50 percent of the basic case-mix adjusted composite payment amount and 50 percent of the ESRD PPS payment amount. ESRD facilities that elected to be reimbursed 100 percent based on the ESRD PPS will continue to be reimbursed 100 percent based on the ESRD PPS payment amount.

Section 153(b) was amended by section 3401(h) of Public Law 111-148, the Affordable Care Act, that for 2012 and each subsequent year the Secretary shall reduce the ESRD bundled (ESRDB) market basket increase factor by a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Social Security Act (the Act). The ESRDB market basket increase factor minus the productivity adjustment will update the composite rate portion of the blended rate and the ESRD PPS payment rate portion of the blended rate under the transition and under the full ESRD PPS.

Transition Budget Neutrality Adjustment

Section 1881(b)(14)(E)(iii) of the Act requires that an adjustment to payments be made for renal dialysis services provided by ESRD facilities during the transition so that the estimated total payments under the ESRD PPS, including payments under the transition, equal the estimated total of payments that would otherwise occur under the ESRD PPS without such transition. Subsequent to the CY ESRD PPS final rule, CMS published an Interim Final Rule on April 6, 2011, (76 FR 18930) entitled, “Changes in the End-Stage Renal Disease Prospective Payment System Transition Budget Neutrality Adjustment” which revised the ESRD transition budget neutrality adjustment from a 3.1 percent reduction to zero percent for renal dialysis services furnished on April 1, 2011 through December 31, 2011. For CY 2012, CMS will continue to apply a zero percent reduction

to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS for renal dialysis services furnished January 1, 2012 through December 31, 2012.

Body Surface Area (BSA) Payment Adjustment

Under the ESRD PPS, CMS retained the BSA case-mix adjustment factor for adult patients from the basic case-mix adjusted composite payment system. For CY 2011, CMS used a national average of 1.84 to compute the BSA for the composite rate portion of the blended payment and a national average of 1.87 for the ESRD PPS. For CY 2012 and in subsequent years, CMS will use one national average of 1.87 for computing the BSA under the basic case-mix adjusted composite payment system portion of the blended payment during the transition and under the ESRD PPS.

ESRD PPS Outlier Policy

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high cost outliers due to unusual variations in the type or amount of medically necessary care. Medicare regulation at 42CFR413.237(a)(1) provides that ESRD outlier services are those ESRD-related services that were or would have been considered separately paid under Medicare Part B, or would have been separately payable drugs under Medicare Part D (excluding ESRD-related oral-only drugs), prior to January 1, 2011. A listing of the ESRD PPS Outlier Services can be found on the CMS Website at:

http://www.cms.gov/ESRDPayment/30_Outlier_Services.asp#TopOfPage.

For CY 2012, CMS is making the following policy changes to the ESRD PPS outlier policy:

- Because of the number of Part B drugs and biologicals that may be considered ESRD-related eligible outlier service drugs, effective January 1, 2012, CMS is eliminating the issuance of a list of former separately billable Part B drugs and biologicals that would be eligible for outlier payments.

- For CY 2012, CMS is making two modifications to the computation of the separately billable Medicare Allowable Payment (MAP) amounts used to calculate outlier payments.

1. Subsequent to the publication of the CY 2011 ESRD PPS final rule, CMS' clinical review of the 2007 ESRD claims used to develop the ESRD PPS revealed that ESRD facilities routinely used alteplase and other thrombolytic drugs for access management purposes. Drugs and biologicals that are used as a substitute for any composite rate drug or are used to accomplish the same effect, are covered under the composite rate. Because outlier payments are restricted under 42CFR413.237(a) to those items or services that were or would have been considered separately billable prior to January 1, 2011, CMS has recalculated the average outlier services MAP amounts to exclude these composite rate drugs.

2. Subsequent to the publication of the CY 2011 ESRD PPS final rule, CMS learned that testosterone and anabolic steroids may be used for anemia management. Because drugs used for anemia management in ESRD patients were or would have been considered separately billable under Medicare Part B, these drugs would be outlier eligible drugs under 42CFR413.237(a)(1). Consequently, CMS has recomputed the outlier service MAP amounts to include these drugs.

- In order to compute the outlier payment for laboratory tests, the 50 percent rule is required for the tests that comprise the Automated Multi-Channel Chemistry (AMCC). The AMCC panel tests are identified in Pub. 100-02, chapter 11, section 30.2.2 and an explanation of the 50 percent rule can be found in Pub. 100-04, chapter 16, section 40.6. In the interest of administrative simplification, CMS is excluding the AMCC laboratory tests from the definition of eligible outlier services and from the computation of outlier payments. The 50 percent rule would continue to apply to AMCC laboratory tests for classification as either composite rate or separately billable for the purpose of computing the composite

rate portion of the ESRD PPS blended payment for ESRD facilities that are receiving payments under the ESRD PPS transition.

- Prior to the ESRD PPS, antibiotics when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis were considered to be composite rate drugs and when used for in-facility patients they were considered to be separately payable. Therefore, for CY 2011, antibiotics used by home patients were not eligible for outlier payment. CMS does not believe that it is appropriate to have this distinction between how antibiotics are classified as composite rate drugs versus drugs that are separately payable. Therefore, CMS is allowing antibiotics when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis to be separately billable under the composite rate portion of the ESRD blended payment amount and eligible for outlier payment for claims with dates of service on or after January 1, 2012.

CR 7471, Transmittal 2266, entitled “Implementation of Changes to the End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Outlier Payment Policy and Changes to the ESRD PPS Consolidated Billing Requirements for Laboratory Services Furnished in a Hospital Emergency Room or Department” implemented the system changes that were necessary for the policy changes to the ESRD PPS outlier policy for CY2012.

ESRD-Related Laboratory Tests

In the CY 2011 ESRD PPS final rule, CMS finalized a specific list of routine ESRD-related laboratory tests included as part of consolidated billing (Table F: ESRD-Related Laboratory Tests of the Appendix). CR 7497, Transmittal 939, entitled, “Independent Laboratory Billing of Automated Multi-Channel Chemistry (AMCC) Organ Disease Panel Laboratory Tests for Beneficiaries who are not Receiving Dialysis for Treatment of End Stage Renal Disease (ESRD)” sunset the requirement for independent laboratories to bill separately for each individual AMCC laboratory test included in organ disease panel codes for ESRD eligible beneficiaries. Because organ disease panels consist of AMCC laboratory tests that are ESRD-related laboratory services, it is important for CMS to ensure that these laboratory tests remain in the ESRD PPS bundle.

CMS is adding the “Assay of protein by other source,” which is identified by the Current Procedural Terminology code 84157 to the listing of items and services subject to consolidated billing for the ESRD PPS. This listing can be found on the CMS Website at:

http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage The “Assay of protein by other source” was a composite rate service under the basic case-mix adjusted composite rate system and, consequently, is considered a renal dialysis service under the ESRD PPS.

B. Policy:

Calendar Year (CY) 2012 Rate Updates

For CY 2012, CMS will make the following **updates to the basic case-mix adjusted composite payment system portion of the blended payment amount** for the second year of the ESRD PPS 4-year transition:

1. The CY 2011 Part D per treatment add-on amount (that is, \$0.49) will be added to the CY 2011 composite rate in order to update the Part D amount for CY 2012 ($\$138.53 + \$0.49 = \$139.02$).
2. The composite rate (with the addition of the CY 2011 Part D per treatment add-on amount of \$0.49) will be updated by the ESRDB market basket minus a productivity adjustment which results in an increase of 2.1 percent ($\$139.02 \times 1.021 = \141.94). Therefore, the unadjusted composite rate for CY 2012 is \$141.94.
3. The drug add-on percentage will be reduced from 14.7 to 14.3 as a result of the increase to the composite rate for CY 2012.

4. The wage index adjustment will be updated to reflect the latest available wage data. The wage index is available on the CMS Website at: <https://www.cms.gov/ESRDPayment/>
5. The wage index floor will be reduced from 0.6000 to 0.5500, then after applying a budget neutrality adjustment of 1.002830, the wage index floor will be 0.5520.
6. CMS will use the latest national average (that is, 1.87) to calculate the body surface area (BSA) adjustment for CY 2012 and subsequent years. This indicates that the national average of 1.87 will be used for computing the BSA under the basic case-mix adjusted composite payment system portion of the blend during the transition and under the ESRD PPS.
7. CMS will allow an antibiotic when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis to be separately billable under the composite rate portion of the ESRD blended payment amount for claims with dates of service on or after January 1, 2012.
8. For the ESRD PPS outlier policy, CMS is including alteplase and other thrombolytic drugs and biologicals used for access management purposes as part of the composite rate drugs, however, these drugs will continue to be paid separately under the composite rate portion of the ESRD blended payment amount for claims with dates of service on or after January 1, 2012.

For CY 2012, CMS will make the following **updates to the ESRD PPS base rate and wage index**:

1. The ESRD PPS base rate will be updated by the ESRDB market basket minus a productivity adjustment which results in an increase of 2.1 percent ($\$229.63 \times 1.021 = \234.45). Therefore, the unadjusted ESRD PPS base rate for CY 2012 is \$234.45.
2. The wage index adjustment will be updated to reflect the latest available wage data.
3. The wage index floor will be reduced from 0.6000 to 0.5500. There will be no application of a budget neutrality adjustment to the wage index floor for full ESRD PPS payments nor the ESRD PPS portion of the blended payment under the transition.
4. The wage index budget neutrality adjustment factor will be applied to the ESRD PPS base rate subsequent to the application of the ESRDB market basket minus productivity adjustment ($\$234.45 \times 1.001520 = \234.81).

Transition Budget Neutrality Adjustment

For CY 2012, for the transition budget-neutrality adjustment, CMS will continue a zero percent reduction to all payments made to ESRD facilities, that is, the zero percent adjustment would be applied to both the blended payments made under the transition and payments made under the 100 percent ESRD PPS for renal dialysis services furnished January 1, 2012 through December 31, 2012.

Outlier Policy Changes

For CY 2012, CMS will make the following updates to the average outlier service MAP amount per treatment:

1. For adult patients, the adjusted average outlier service MAP amount per treatments is \$78.00.
2. For pediatric patients, average outlier service MAP amount per treatment is \$45.44.

For CY 2012, CMS will make the following updates to the fixed dollar loss amount that is added to the predicted MAP to determine the outlier threshold:

1. The fixed dollar loss amount is \$141.21 for adult patients.
2. The fixed dollar loss amount is \$71.64 for pediatric patients.

For CY 2012, CMS will make the following changes to the list of outlier services:

1. All ESRD-related Part B drugs and biologicals will be removed from the outlier list. Therefore, all ESRD-related non-composite rate Part B drugs and biologicals with an Average Sales Price rate will be included in the outlier calculation. This includes antibiotics when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis.
2. The ESRD-related Part D drugs which are based on the most recent prices retrieved from the Medicare Prescription Drug Plan Finder will be updated to reflect the most recent mean unit cost. The list of ESRD-related Part D drugs will also be updated to reflect the most recent list of ESRD-related Part D drugs that are eligible for outlier payment.
3. The mean dispensing fee of the National Drug Codes (NDC) qualifying for outlier consideration is revised to \$1.59 per NDC per month for claims with dates of service on or after January 1, 2012.
4. The AMCC laboratory tests are excluded from the definition of eligible outlier services and will therefore be removed.

Consolidated Billing Changes:

CMS is adding the following organ disease panels to the list of laboratory items and services subject to consolidated billing for the ESRD PPS for dates of service on or after January 1, 2012: 80047, 80048, 80051, 80053, 80061, 80069, and 80076. CMS is also adding the “Assay of protein by other source,” which is identified by the Current Procedural Terminology code 84157 to the list of items and services subject to consolidated billing for the ESRD PPS effective for dates of service on or after January 1, 2012.

II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)								
		A / B M A C	D M A C	F I	C A R R I E R	R H R I	Shared-System Maintainers			
						F I S S	M C S	V M S	C W F	
7617.1	Medicare contractors shall load the 2012 ESRD PPS PRICER.						X			

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	R H H I	Shared-System Maintainers			
					F I S S	M C S	V M S	C W F		
7617.2	Medicare contractors shall update the provider file for ESRD facilities to include newly attested low volume facilities and update any revised CBSA codes if applicable.	X		X						
7617.3	Medicare contractors shall update the new revised outlier services list. See Attachment A.						X			
7617.4	Medicare contractors shall update the new consolidated billing lists. See attachment B.								X	
7617.5	Contractors shall be aware of the change in policy allowing antibiotics when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis as separately billable for transitional payments and outlier consideration effective for claims with dates of service on or after January 1, 2012.	X		X						
7617.6	Requirement deleted.									
7617.7	Contractors shall revise the mean dispensing fee from \$1.73 per NDC per claim to \$1.59 per NDC per claim for claims with dates of service on or after January 1, 2012.						X			

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)								
		A / B M A C	D M E M A C	F I I E R	C A R R I E R	R H H I	Shared-System Maintainers			
					F I S S	M C S	V M S	C W F		
7617.8	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.	X		X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R I E R	R H H I S S	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
	Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
7617.1	For claims with dates of service in 2012, Medicare contractors shall pay ESRD facilities transitioning into the PPS 50% under the composite rate system and 50% under the PPS system as required in CR 7064, Transmittal 2134.
7617.1	Medicare contractors shall send the low volume amount from the PRICER to the claim value code 19 as required by CR 7388 Transmittal 2195.
7617.1	Medicare contractors shall apply the QIP reduction as required by CR 7460, Transmittal 2311.

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): For ESRD Policy, Michelle.Cruse@cms.hhs.gov (410)786-7540 or Terri.Deutsch@cms.hhs.gov (410)786-9462; for Claims Processing, Wendy.Tucker@cms.hhs.gov (410)786-3004.

Post-Implementation Contact(s):
Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For *Medicare Administrative Contractors (MACs)*, include the following statement:

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.

2 Attachments

Attachment A-Outlier Services

Injectable Drugs		
Category	HCPCS Code	Description
Anemia management	J0882 ¹	DARBEPOETIN
Anemia management	J1756 ¹	IRON SUCROSE INJECTION
Anemia management	J2916 ¹	NA FERRIC GLUCONATE COMPLEX
Anemia management	J3420 ¹	VITAMIN B12 INJECTION
Anemia management	Q4081 ¹	EPO
Antiemetic	J0780 ¹	PROCHLORPERAZINE INJECTION
Antiemetic	J1260 ¹	DOLASETRON MESYLATE
Antiemetic	J1626 ¹	GRANISETRON HCL INJECTION
Antiemetic	J2405 ¹	ONDANSETRON HCL INJECTION
Antiemetic	J2550 ¹	PROMETHAZINE HCL INJECTION
Antiemetic	J2765 ¹	METOCLOPRAMIDE HCL INJECTION
Antiemetic	J2950 ¹	PROMAZINE HCL INJECTION
Antiemetic	J3230 ¹	CHLORPROMAZINE HCL INJECTION
Antiemetic	J3250 ¹	TRIMETHOBENZAMIDE HCL INJ
Antiemetic	J3310 ¹	PERPHENAZINE INJECTION
Anxiolytic	J2060 ¹	LORAZEPAM INJECTION
Anxiolytic	J2250 ¹	INJ MIDAZOLAM HYDROCHLORIDE
Anxiolytic	J3360 ¹	DIAZEPAM INJECTION
Bone and mineral metabolism	J0610 ¹	CALCIUM GLUCONATE INJECTION
Bone and mineral metabolism	J0630 ¹	CALCITONIN SALMON INJECTION
Bone and mineral metabolism	J0636 ¹	INJ CALCITRIOL PER 0.1 MCG
Bone and mineral metabolism	J0895 ¹	DEFEROXAMINE MESYLATE INJ
Bone and mineral metabolism	J1270 ¹	INJECTION, DOXERCALCIFEROL
Bone and mineral metabolism	J1740 ¹	IBANDRONATE SODIUM
Bone and mineral metabolism	J2430 ¹	PAMIDRONATE DISODIUM /30 MG
Bone and mineral metabolism	J2501 ¹	PARICALCITOL
Cellular management	J1955 ¹	INJ LEVOCARNITINE PER 1 GM
Pain management	J1170 ¹	HYDROMORPHONE INJECTION
Pain management	J1885 ¹	KETOROLAC TROMETHAMINE INJ
Pain management	J2175 ¹	MEPERIDINE HYDROCHL /100 MG
Pain management	J2270 ¹	MORPHINE SULFATE INJECTION
Pain management	J2271 ¹	MORPHINE SO4 INJECTION 100MG
Pain management	J2275 ¹	MORPHINE SULFATE INJECTION
Pain management	J2300 ¹	INJ NALBUPHINE HYDROCHLORIDE
Pain management	J2310 ¹	INJ NALOXONE HYDROCHLORIDE
Pain management	J3010 ¹	FENTANYL CITRATE INJECTION
Pain management	J3070 ¹	PENTAZOCINE INJECTION
Anti-infective	J0278 ²	AMIKACIN SULFATE
Anti-infective	J0285 ²	AMPHOTERICIN B
Anti-infective	J0290 ²	AMPICILLIN 500 MG INJ

Attachment A-Outlier Services

<i>Anti-infective</i>	<i>J0295²</i>	<i>AMPICILLIN SODIUM PER 1.5 GM</i>
<i>Anti-infective</i>	<i>J0456²</i>	<i>AZITHROMYCIN</i>
<i>Anti-infective</i>	<i>J0530²</i>	<i>PENICILLIN G BENZATHINE INJ</i>
<i>Anti-infective</i>	<i>J0560²</i>	<i>PENICILLIN G BENZATHINE INJ</i>
<i>Anti-infective</i>	<i>J0580²</i>	<i>PENICILLIN G BENZATHINE INJ</i>
<i>Anti-infective</i>	<i>J0637²</i>	<i>CASPOFUNGIN ACETATE</i>
<i>Anti-infective</i>	<i>J0690²</i>	<i>CEFAZOLIN SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J0692²</i>	<i>CEFEPIME HCL FOR INJECTION</i>
<i>Anti-infective</i>	<i>J0694²</i>	<i>CEFOXITIN SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J0696²</i>	<i>CEFTRIAZONE SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J0697²</i>	<i>STERILE CEFUROXIME INJECTION</i>
<i>Anti-infective</i>	<i>J0698²</i>	<i>CEFOTAXIME SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J0713²</i>	<i>INJ CEFTAZIDIME PER 500 MG</i>
<i>Anti-infective</i>	<i>J0715²</i>	<i>CEFTIZOXIME SODIUM / 500 MG</i>
<i>Anti-infective</i>	<i>J0743²</i>	<i>CILASTATIN SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J0744²</i>	<i>CIPROFLOXACIN IV</i>
<i>Anti-infective</i>	<i>J0878²</i>	<i>DAPTOMYCIN</i>
<i>Anti-infective</i>	<i>J1335²</i>	<i>ERTAPENEM SODIUM</i>
<i>Anti-infective</i>	<i>J1364²</i>	<i>ERYTHRO LACTOBIONATE /500 MG</i>
<i>Anti-infective</i>	<i>J1450²</i>	<i>FLUCONAZOLE</i>
<i>Anti-infective</i>	<i>J1580²</i>	<i>GARAMYCIN GENTAMICIN INJ</i>
<i>Anti-infective</i>	<i>J1590²</i>	<i>GATIFLOXACIN INJECTION</i>
<i>Anti-infective</i>	<i>J1840²</i>	<i>KANAMYCIN SULFATE 500 MG INJ</i>
<i>Anti-infective</i>	<i>J1890²</i>	<i>CEPHALOTHIN SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J1956²</i>	<i>LEVOFLOXACIN INJECTION</i>
<i>Anti-infective</i>	<i>J2020²</i>	<i>LINEZOLID INJECTION</i>
<i>Anti-infective</i>	<i>J2185²</i>	<i>MEROPENEM</i>
<i>Anti-infective</i>	<i>J2280²</i>	<i>MOXIFLOXACIN</i>
<i>Anti-infective</i>	<i>J2510²</i>	<i>PENICILLIN G PROCAINE INJ</i>
<i>Anti-infective</i>	<i>J2540²</i>	<i>PENICILLIN G POTASSIUM INJ</i>
<i>Anti-infective</i>	<i>J2543²</i>	<i>PIPERACILLIN/TAZOBACTAM</i>
<i>Anti-infective</i>	<i>J2700²</i>	<i>OXACILLIN SODIUM INJECTION</i>
<i>Anti-infective</i>	<i>J3000²</i>	<i>STREPTOMYCIN INJECTION</i>
<i>Anti-infective</i>	<i>J3260²</i>	<i>TOBRAMYCIN SULFATE INJECTION</i>
<i>Anti-infective</i>	<i>J3370²</i>	<i>VANCOMYCIN HCL INJECTION</i>
Oral and Other Equivalent Forms of Injectable Drugs		
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 1/1/2014)		
NDC	Drug Product	Mean Unit

Attachment A-Outlier Services

		Cost
30698014301 30698014323 54868346100	Rocaltrol (calcitriol) 0.25 mcg capsules	\$1.45
30698014401	Rocaltrol (calcitriol) 0.5 mcg capsules	\$2.31
30698091115	Rocaltrol (calcitriol) 1 mcg/mL oral solution (15ml/bottle)	\$12.33
00054000725 00054000713 00093065701 <i>43353063381³</i> 00440721599 54868458400 63304023901 63304023930 67544103581	Calcitriol 0.25 mcg capsules	\$0.98
00093065801 54868458200 63304024001	Calcitriol 0.5 mcg capsules	\$1.60
00054312041 63304024159	Calcitriol 1 mcg/mL oral solution (15ml/bottle)	\$9.57
00074431730	Zemplar (paricalcitol) 1 mcg capsule	\$8.89
00074431430	Zemplar (paricalcitol) 2 mcg capsule	\$17.76
00074431530	Zemplar (paricalcitol) 4 mcg capsule	\$35.31
<i>58468012001³</i>	<i>Hectorol (doxercalciferol) 0.5 mcg capsule</i>	<i>\$6.49</i>
<i>58468012401³</i>	<i>Hectorol (doxercalciferol) 1 mcg capsule</i>	<i>\$12.96</i>
58468012101	Hectorol (doxercalciferol) 2.5 mcg capsule	\$22.52
54482014407	Carnitor (levocarnitine) 330 mg tablet	\$0.82
54482014508	Carnitor (levocarnitine) 1GM/10ML oral solution (118mL/bottle)	\$0.25
<i>54482014801⁴</i>	<i>Carnitor SF (levocarnitine) 1GM/10ML oral solution (118 mls)</i>	<i>\$0.25</i>
<i>54482014701³</i>	<i>Carnitor (levocarnitine) 1 g/5 mL injection</i>	<i>\$6.48</i>
64980050312 50383017104	Levocarnitine 1GM/10ML oral solution (118mL/bottle)	\$0.20
64980013009 50383017290	Levocarntin 330 mg tablet	\$0.67

The mean dispensing fee of the NDCs listed above is \$1.59. This amount will be applied to each NDC included on the monthly claim. We will limit 1 dispensing fee 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) and uses the full 15 ml bottle, the quantity is reported as 15, not 1. This allows for the most accurate calculation for

Attachment A-Outlier Services

the outlier.	
Laboratory Tests	
CPT/HCPCS	Short Description
<i>82040⁵</i>	<i>Assay of serum albumin</i>
82108	Assay of aluminum
<i>82247⁵</i>	<i>Bilirubin, total</i>
<i>82248⁵</i>	Bilirubin, direct
82306	Vitamin d, 25 hydroxy
<i>82310⁵</i>	<i>Assay of calcium</i>
<i>82330⁵</i>	<i>Assay of calcium, ionized</i>
<i>82374⁵</i>	<i>Assay, blood carbon dioxide</i>
82379	Assay of carnitine
<i>82435⁵</i>	<i>Assay of blood chloride</i>
<i>82465⁵</i>	<i>Assay, bld/serum cholesterol</i>
<i>82550⁵</i>	<i>Assay of ck (cpk)</i>
<i>82565⁵</i>	<i>Assay of creatinine</i>
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

Attachment A-Outlier Services

82947 ⁵	<i>Assay, glucose, blood quant</i>
82977 ⁵	<i>Assay of GGT</i>
83540	Assay of iron
83550	Iron binding test
83615 ⁵	<i>Lactate (LD) (LDH) enzyme</i>
83735	Assay of magnesium
83970	Assay of parathormone
84075 ⁵	<i>Assay alkaline phosphatase</i>
84100 ⁵	<i>Assay of phosphorus</i>
84132 ⁵	<i>Assay of serum potassium</i>
84134	Assay of prealbumin
84155 ⁵	<i>Assay of protein, serum</i>
84295 ⁵	<i>Assay of serum sodium</i>
84450 ⁵	<i>Transferase (AST) (SGOT)</i>
84460 ⁵	<i>Alanine amino (ALT) (SGPT)</i>
84466	Assay of transferrin
84478 ⁵	<i>Assay of triglycerides</i>
84520 ⁵	<i>Assay of urea nitrogen</i>
84540	Assay of urine/urea-n
84545	Urea-N clearance test
84550 ⁵	<i>Assay blood/uric acid</i>
85041	Automated rbc count
85044	Manual reticulocyte count

Attachment A-Outlier Services

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

¹ Effective January 1, 2012, all ESRD-related Part B drugs and biologicals reported with a HCPCS that is on the ASP list will be included for outlier payments (with the exception of composite rate drugs). Therefore, effective January 1, 2012, all ESRD-related Part B drugs and biologicals are being removed from the outlier list.

² Effective January 1, 2012, CMS is eliminating the inclusion of antibiotics when used in the home to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis as part of the composite rate drugs and allowing them to be separately paid under the composite rate portion of the ESRD blended payment amount and be eligible for inclusion under the outlier calculation. Also effective January 1, 2012, all ESRD-related Part B drugs and biologicals

Attachment A-Outlier Services

reported with a HCPCS that is on the ASP list will be included for outlier payments. Therefore, effective January 1, 2012, all antibiotics are being removed from the list of outlier services.

³ Effective January 1, 2012, this ESRD-related item or service is eligible for outlier payment and is therefore being added to the list of outlier services.

⁴ Effective January 1, 2012, this ESRD-related item or service is no longer eligible for outlier payment and is therefore being deleted from the list of outlier services.

⁵ Effective January 1, 2012, the AMCC laboratory tests are excluded from the definition of eligible outlier services and from the computation of outlier payments and are therefore being deleted from the list of outlier services.

Attachment B

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
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

Attachment B

A4672 DRAINAGE EXTENSION LINE, STERILE, FOR DIALYSIS, EACH
A4673 EXTENSION LINE WITH EASY LOCK CONNECTORS, USED
WITH DIALYSIS
CHEMICALS/ANTISEPTICS SOLUTION USED TO
A4674 CLEAN/STERILIZE DIALYSIS EQUIPMENT, PER 8 OZ
A4680 ACTIVATED CARBON FILTER FOR HEMODIALYSIS, EACH
DIALYZER (ARTIFICIAL KIDNEYS), ALL TYPES, ALL SIZES,
A4690 FOR HEMODIALYSIS, EACH
BICARBONATE CONCENTRATE, SOLUTION, FOR
A4706 HEMODIALYSIS, PER GALLON
BICARBONATE CONCENTRATE, POWDER, FOR
A4707 HEMODIALYSIS, PER PACKET
ACETATE CONCENTRATE SOLUTION, FOR HEMODIALYSIS,
A4708 PER GALLON
ACID CONCENTRATE, SOLUTION, FOR HEMODIALYSIS, PER
A4709 GALLON
TREATED WATER (DEIONIZED, DISTILLED, OR REVERSE
A4714 OSMOSIS) FOR PERITONEAL DIALYSIS, PER GALLON
A4719 "Y SET" TUBING FOR PERITONEAL DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4720 DEXTROSE, FLUID VOLUME GREATER THAN 249CC, BUT
LESS THAN OR EQUAL TO 999CC, FOR PERITONEAL DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4721 DEXTROSE, FLUID VOLUME GREATER THAN 999CC BUT LESS
THAN OR EQUAL TO 1999CC, FOR PERITONEAL DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4722 DEXTROSE, FLUID VOLUME GREATER THAN 1999CC BUT
LESS THAN OR EQUAL TO 2999CC, FOR PERITONEAL
DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4723 DEXTROSE, FLUID VOLUME GREATER THAN 2999CC BUT
LESS THAN OR EQUAL TO 3999CC, FOR PERITONEAL
DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4724 DEXTROSE, FLUID VOLUME GREATER THAN 3999CC BUT
LESS THAN OR EQUAL TO 4999CC, FOR PERITONEAL
DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4725 DEXTROSE, FLUID VOLUME GREATER THAN 4999CC BUT
LESS THAN OR EQUAL TO 5999CC, FOR PERITONEAL
DIALYSIS
DIALYSATE SOLUTION, ANY CONCENTRATION OF
A4726 DEXTROSE, FLUID VOLUME GREATER THAN 5999CC, FOR
PERITONEAL DIALYSIS

Attachment B

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

Attachment B

E1510	KIDNEY, DIALYSATE DELIVERY SYST. KIDNEY MACHINE, PUMP RECIRCULATING, 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 PERITONEAL 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/ HCPCS	Short Description
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Attachment B

80047 ¹	<i>Basic Metabolic Panel (Calcium, ionized)</i>
80048 ¹	<i>Basic Metabolic Panel (Calcium, total)</i>
80051 ¹	<i>Electrolyte Panel</i>
80053 ¹	<i>Comprehensive Metabolic Panel</i>
80061 ¹	<i>Lipid Panel</i>
80069 ¹	<i>Renal Function Panel</i>
80076 ¹	<i>Hepatic Function Panel</i>
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 ¹	<i>Assay of protein by other source</i>
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

Attachment B

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
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
Anemia management	J0882	DARBEPOETIN
	J1756	IRON SUCROSE INJECTION
	J2916	NA FERRIC GLUCONATE COMPLEX

Attachment B

	J3420	VITAMIN B12 INJECTION
	Q4081	EPO
	J2250	INJ MIDAZOLAM HYDROCHLORIDE
	J3360	DIAZEPAM INJECTION
	J0610	CALCIUM GLUCONATE INJECTION
	J0630	CALCITONIN SALMON INJECTION
	J0635	CALCITRIOL
	J0636	INJ CALCITRIOL PER 0.1 MCG
	J0895	DEFEROXAMINE MESYLATE INJ
	J1270	INJECTION, DOXERCALCIFEROL
	J1740	IBANDRONATE SODIUM
	J2430	PAMIDRONATE DISODIUM /30 MG
	J2501	PARICALCITOL
Cellular management	J1955	INJ LEVOCARNITINE PER 1 GM
Anti-infectives	J0878	DAPTOMYCIN
	J3370	VANCOMYCIN HCL INJECTION

¹ Effective January 1, 2012, ESRD-related item or service is subject to ESRD PPS consolidated billing requirements.