CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2588	**Date: November 5, 2012**
	Change Request 7869

Transmittal 2504, issued August 9, 2012, is being rescinded and replaced by Transmittal 2588, dated November 5, 2012 to clarify the policy regarding how ESRD-related drugs and biologicals are reported on ESRD claims and to reissue as no longer sensitive. All other information remains the same.

SUBJECT: Implementation of Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Consolidated Billing Requirements and a Clarification of Outlier Services for Calendar Year 2013

I. SUMMARY OF CHANGES: This instruction provides an update to the billing requirements for Daptomycin and clarifies Outlier Services for Calendar Year 2013.

EFFECTIVE DATE: January 1, 2013
IMPLEMENTATION DATE: January 7, 2013

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	8/50.2/ Drugs and Biologicals Included in the Composite Rate
R	8/60.2.1/ Separately Billable ESRD Drugs

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractors activities are to be carried out with 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 obliged 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:

Business Requirements

Manual Instruction

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

Attachment – Business Requirements

Pub. 100-04	Transmittal: 2588	Date: November 5, 2012	Change Request: 7869

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SUBJECT: Implementation of Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) Consolidated Billing Requirements and a Clarification of Outlier Services for Calendar Year 2013

Effective Date: January 1, 2013

Implementation Date: January 7, 2013

I. GENERAL INFORMATION

A. Background: Section 153(b) of the Medicare Improvements for Patients and Providers Act (MIPPA) amends section 1881(b)(12) of the Act by requiring the implementation of an End Stage Renal Disease (ESRD) bundled prospective payment system (PPS) effective January 1, 2011. 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.

ESRD Claims Reporting ESRD-Related Drugs and Biologicals
The Medicare Benefit Policy Manual, Pub. 100-02, chapter 11, section 30.4.1 lists the drugs and fluids that were included under the composite payment system as heparin, antiarrythmics, protamine, local anesthetics, apresoline, dopamine, insulin, lidocaine, mannitol, saline, pressors, heparin antidotes, benadryl, hydralazine, lanoxin, solu-cortef, glucose, antihypertensives, antihistamines, dextrose, inderal, levophed, and verapamil. The manual also explicitly states, "… drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate." Data analysis of 2011 ESRD claims indicates that ESRD facilities are reporting composite rate drugs resulting in duplicate payment to those ESRD facilities that are receiving a blended payment under the transition period and inappropriate inclusion in the outlier calculation (discussed below).

In addition, in the calendar year (CY) 2012 ESRD PPS final rule and in CR 7617, Transmittal 150, entitled "Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2012" we discussed alteplase and other thrombolytic drugs. We indicated that a clinical review of the 2007 claims used to develop the ESRD PPS revealed that ESRD facilities routinely used alteplase and other thrombolytic drugs for access management purposes. We also indicated that because these drugs are used to accomplish the same effect (that is, vascular access management) as a composite rate drug, they are also considered to be composite rate drugs and, therefore, should not be reported on the ESRD claim. In CR 7617, we removed alteplase and other thrombolytic drugs from the outlier calculation but we did not implement edits to prevent separate payment to the ESRD facilities that are receiving a blended payment during the transition.

ESRD-Related Drugs and Biologicals that Qualify as Outlier Services
Medicare regulations at 42 CFR §413.237(a)(1)(i) provide that ESRD outlier services are those ESRD-related services that were or would have been considered separately billable under Medicare Part B for renal dialysis

services furnished prior to January 1, 2011. Therefore, items and services that would have been included under the composite rate do not qualify as an outlier services.

ESRD Claims Reporting Daptomycin
CR 7064 provided ESRD consolidated billing requirements for certain Part B services included in the ESRD PPS bundled payment. All drugs reported on the ESRD facility claim that do not have an AY modifier are considered included in the ESRD PPS. The list of drugs and biologicals for consolidated billing are designated as always ESRD-related and therefore separate payment is not made to ESRD facilities. Daptomycin is included on the consolidated billing list.

B. Policy:

Revision to ESRD Claims Reporting ESRD-Related Drugs and Biologicals, Effective January 1, 2013
Composite rate items and services should not be reported on the ESRD facility claim. Because ESRD facilities are continuing to inappropriately report composite rate drugs, we developed a list (attachment A) of certain drugs and biologicals based on the 2011 claims data that are considered to be composite rate drugs. ESRD facilities that are receiving reimbursement under the transition and have been inappropriately reporting drugs and biologicals considered to be in the composite rate will no longer be separately paid in the composite rate portion of the blended payment for these drugs effective January 1, 2013. In addition, because these ESRD-related drugs are considered to be in the composite rate they are also considered to be always ESRD-related. Therefore, we are updating the list of items and services that, effective January 1, 2013, are subject to consolidated billing requirements (attachment B) which can be found on the CMS website at the following link: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Consolidated_Billing.html
ESRD-related drugs and biologicals located on this list are not eligible to be paid separately with the AY modifier.

The list of ESRD-related drugs on attachment A is not an all-inclusive list and ESRD facilities should not be reporting any composite rate items and services on the ESRD claim. ESRD facilities should not change treatment behaviors to receive separate payment. For example drugs and biologicals used for the purpose of access management should not be reported on the claim because in accordance with the Medicare Benefit Policy Manual, Pub. 100-02, chapter 11, section 30.4.1, those drugs are considered to be composite rate drugs. We are continuing to monitor the claims data for drug utilization.

The list of ESRD-related drugs and biologicals on attachment B is not an all-inclusive list of the drugs and biologicals that are included in the ESRD PPS. For example, any anti-infective drugs that are used for access management are included in the ESRD PPS. Attachment B has been updated to reflect 2011 claims data. However, any drug or biological (even if not one of the categories in attachment B) that is used for the treatment of ESRD (that is, ESRD-related) is included in the ESRD PPS and is not separately paid.

Clarification of ESRD-Related Drugs and Biologicals that Qualify as Outlier Services, Effective January 1, 2013
Because ESRD facilities are continuing to inappropriately report composite rate drugs, composite rate drugs are incorrectly being included in the outlier calculation. Therefore, we developed a list of drugs and biologicals (attachment A) from the 2011 claims data that are considered to be composite rate drugs. This is not an all-inclusive list and ESRD facilities should not be reporting composite rate items and services on the ESRD claim. The ESRD-related drugs and biologicals listed on attachment A will not qualify as outlier services.

Revision to ESRD Claims Reporting Daptomycin, Effective January 1, 2013
ESRD facilities have the ability to receive separate payment for Healthcare Common Procedure Coding System (HCPCS) code J0878 *Injection, Daptomycin, 1 MG* furnished on or after January 1, 2013, by placing the AY modifier on the 72X claim when daptomycin is furnished to an ESRD patient that is not for the treatment of ESRD. The ESRD facility is required to indicate (in accordance with ICD-9 guidelines) the diagnosis code for which daptomycin is indicated.

Peginesatide, Effective January 1, 2013
Peginesatide, is a new ESA drug approved for the treatment of anemia in dialysis patients. Peginesatide has been assigned a permanent Healthcare Common Procedure Code System (HCPCS) code of J0890. This

permanent code replaces the temporary code issued Q2047. Peginesatide is subject to ESRD consolidated billing requirements. The drug description indicates use while on dialysis, therefore it would be inappropriate to bill J0890 with modifier AY. The consolidated billing requirement may not be overridden with the use of the AY modifier.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7869.1	Contractors shall allow separate payment consideration for code J0878 *Injection, Daptomycin, 1 MG* Short description: *Daptomycin* reported on type of bill 72x with a modifier AY.						X				
7869.2	For 72x bill type, contractors shall not include codes for drugs and biologicals included on the composite rate drug list (see Attachment A) in the computation of the value code 79 Medicare Allowable Payment (MAP) calculation for outlier payments.						X				
7869.3	For 72x bill type, contractors shall not allow payment for drugs and biologicals included on the composite rate drug list (see Attachment A) as separately payable under the composite rate portion of the ESRD blended payment.						X				
7869.4	Contractors shall update the consolidated billing code lists for ESRD Supply, Laboratory Tests, and Drugs Subject to ESRD Consolidated Billing. See attachment B. Contractors shall use the updated lists to determine the items that shall be payable separately.	X	X	X	X		X			X	
7869.5	Medicare contractors shall add J0890 Injection, Peginesatide, 0.1 MG (For ESRD on Dialysis) Short description: Peginesatide injection to the ESRD PPS drug consolidated billing list.	X	X	X	X		X			X	
7869.5.1	Medicare contractors shall not allow a bypass of the consolidated billing edit when the AY modifier is present on the line item J0890.	X	X	X	X		X			X	

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7869.6	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	X	X	X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	the article release via the established "MLN Matters" listserv. 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 1 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:
7869.1	Contractors shall apply deductible and coinsurance for J0878 when billed with the AY modifier when separate payment is made.

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
For Claims Processing, Wendy.Tucker@cms.hhs.gov, Tracey.Mackey@cms.hhs.gov

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

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.

Attachment (2)

Attachment A

HCPC	Long Description
A4802	PROTAMINE SULFATE, FOR HEMODIALYSIS, PER 50 MG
C9121	INJECTION, ARGATROBAN, PER 5 MG
J0670	INJECTION, MEPIVACAINE HYDROCHLORIDE, PER 10 ML
J1200	INJECTION, DIPHENHYDRAMINE HCL, UP TO 50 MG
J1205	INJECTION, CHLOROTHIAZIDE SODIUM, PER 500 MG
J1240	INJECTION, DIMENHYDRINATE, UP TO 50 MG
J1642	INJECTION, HEPARIN SODIUM, (HEPARIN LOCK FLUSH), PER 10 UNITS
J1644	INJECTION, HEPARIN SODIUM, PER 1000 UNITS
J1940	INJECTION, FUROSEMIDE, UP TO 20 MG
J1945	INJECTION, LEPIRUDIN, 50 MG
J2001	INJECTION, LIDOCAINE HCL FOR INTRAVENOUS INFUSION, 10 MG
J2150	INJECTION, MANNITOL, 25% IN 50 ML
J2720	INJECTION, PROTAMINE SULFATE, PER 10 MG
J2795	INJECTION, ROPIVACAINE HYDROCHLORIDE, 1 MG
J2993	INJECTION, RETEPLASE, 18.1 MG
J2997	INJECTION, ALTEPLASE RECOMBINANT, 1 MG
J3364	INJECTION, UROKINASE, 5000 IU VIAL
J3365	INJECTION, IV, UROKINASE, 250,000 I.U. VIAL
J3410	INJECTION, HYDROXYZINE HCL, UP TO 25 MG
Q0163	DIPHENHYDRAMINE HYDROCHLORIDE, 50 MG, ORAL, FDA APPROVED PRESCRIPTION ANTI-EMETIC, FOR USE AS A COMPLETE THERAPEUTIC SUBSTITUTE FOR AN IV ANTI-EMETIC AT TIME OF CHEMOTHERAPY TREATMENT NOT TO EXCEED A 48 HOUR DOSAGE REGIMEN

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
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/ HCPCS	Short Description
80047	Basic Metabolic Panel (Calcium, ionized)
80048	Basic Metabolic Panel (Calcium, total)
80051	Electrolyte Panel
80053	Comprehensive Metabolic Panel
80061	Lipid 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
G0306	CBC/diff wbc w/o platelet
G0307	CBC without platelet

DRUGS SUBJECT TO ESRD CONSOLIDATED BILLING

Category	HCPCS	Title
Access Management	*C9121*[1]	*INJ ARGATROBAN*
	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
	J0886[1]	*EPO*
	J0890[1]	*PEGINESATIDE*
	J1750[1]	*IRON DEXTRAN*
	J1756	IRON SUCROSE INJECTION
	J2916	NA FERRIC GLUCONATE COMPLEX
	J3420	VITAMIN B12 INJECTION
	Q0139[1]	*FERUMOXYTOL*
	Q2047	PEGINESATIDE
	Q4081	EPO
	J2250[2]	*INJ MIDAZOLAM HYDROCHLORIDE*
	J3360[2]	*DIAZEPAM INJECTION*
Bone and Mineral Metabolism	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
	J3487[1]	*ZOLEDRONIC ACID*
	S0169[1]	*CALCITRIOL*
Cellular Management	J1955	INJ LEVOCARNITINE PER 1 GM
Anti-Infectives	J0878	DAPTOMYCIN
	J3370	VANCOMYCIN HCL INJECTION
Composite Rate Drugs and Biologicals	*A4802*[1]	*INJ PROTAMINE SULFATE*
	J0670[1]	*INJ MEPIVACAINE HYDROCHLORIDE*
	J1200[1]	*INJ DIPHENHYDRAMINE HCL*
	J1205[1]	*INJ CHLOROTHIAZIDE SODIUM*
	J1240[1]	*INJ DIMENHYDRINATE*
	J1940[1]	*INJ FUROSEMIDE*
	J2001[1]	*INJ LIDOCAINE HCL FOR INTRAVENOUS*

		INFUSION, 10 MG
	J2150[1]	*INJ MANNITOL*
	J2720[1]	*INJ PROTAMINE SULFATE*
	J2795[1]	*INJ ROPIVACAINE HYDROCHLORIDE*
	J3410[1]	*INJ HYDROXYZINE HCL*
	Q0163[1]	*DIPHENHYDRAMINE HYDROCHLORIDE*

[1] Effective January 1, 2013, this ESRD-related item or service is subject to ESRD PPS consolidated billing requirements.

2 Effective January 1, 2013, this item or service is no longer subject to ESRD PPS consolidated billing requirements.

50.2 - Drugs and Biologicals Included in the Composite Rate

(Rev. 2588, Issued: 11-05-12, Effective: 01-01-13, Implementation: 01-07-13)

Certain drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items or are used to accomplish the same effect are also included in the composite rate. The administration of these items (both staff time and supplies) is covered under the composite rate and may not be billed separately. Self-administered items are not covered under the Medicare program with the exception of EPO. For a list of the drugs included in the composite rate see the Medicare Benefit Policy Manual (Pub. 100-02, Chapter 11, Section 30.4.1).

A list of composite rate drugs used for Medicare standard system editing is available at the following link. The list is not considered an all-inclusive list, therefore, contractors may have additional requirements regarding composite drugs.

http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/index.html?redirect=/ESRDPayment/

60.2.1.1 – Separately Billable ESRD Drugs

(Rev. 2588, Issued: 11-05-12, Effective: 01-01-13, Implementation: 01-07-13)

The following categories of drugs (including but not limited to) are separately billable when used to treat the patient's renal condition:

- Antibiotics;
- Analgesics;
- Anabolics;
- Hematinics;
- Muscle relaxants;
- Sedatives;
- Tranquilizers; and
- Thrombolytics: used to declot central venous catheters.

NOTE: Erythropoietin replacement therapies are separately billable and paid at established rates through appropriate billing methodology: Epotein Alfa (EPO) §60.4 and Darbepoetin Alfa (Aranesp) §60.7.

These separately billable drugs may only be billed by an ESRD facility if they are actually administered in the facility by the facility staff. Staff time used to administer separately billable

drugs is covered under the composite rate and may not be billed separately. However, the supplies used to administer these drugs may be billed in addition to the composite rate.

Effective January 1, 2011, section 153b of the MIPPA requires that all ESRD-related drugs and biologicals be billed by the renal dialysis facility. When a drug or biological is billed by providers other than the ESRD facility and the drug or biological furnished is designated as a drug or biological that is included in the ESRD PPS (ESRD-related), the claim will be rejected or denied. In the event that an ESRD-related drug or biological was furnished to an ESRD beneficiary for reasons other than for the treatment of ESRD, the provider may submit a claim for separate payment using modifier AY.

All drugs reported on the renal dialysis facility claim are considered included in the ESRD PPS. The list of drugs and biologicals for consolidated billing are designated as always ESRD-related and therefore not allowing separate payment to be made to ESRD facilities. However, CMS has determined that some of these drugs may warrant separate payment.

Exceptions to "Always ESRD Related" Drugs:
The following drugs have been approved for separate payment consideration when billed with the AY modifier attesting to the drug not being used for the treatment of ESRD.
The ESRD facility is required to indicate (in accordance with ICD-9 guidelines) the diagnosis code for which the *drug* is indicated.

- *Vancomycin, effective January 1, 2012*
- *Daptomycin, effective January 1, 2013*

Items and services subject to the consolidated billing requirements for the ESRD PPS can be found on the CMS website at:
http://www.cms.gov/ESRDPayment/50_Consolidated_Billing.asp#TopOfPage.

Other drugs and biologicals may be considered separately payable to the dialysis facility if the drug was not for the treatment of ESRD. The facility must include the modifier AY to indicate it was not for the treatment of ESRD.

Drugs are assigned HCPCS codes. If no HCPCS code is listed for a drug (e.g., a new drug) the facility bills using HCPCS code J3490, "Unclassified Drugs," and submits documentation identifying the drug. To establish a code for the drug, the FI checks HCPCS to verify that there is no acceptable HCPCS code for billing and if a code is not found checks with the local carrier, which may have a code and price that is appropriate. If no code is found the drug is processed under HCPCS code J3490. See Chapter 17 for a complete description of drug pricing.