

Medicare Benefit Policy Manual

Chapter 11 - End Stage Renal Disease (ESRD)

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10 - Definitions Relating to ESRD

(Rev. 1, 10-01-03)

A3-3165, A3-3166.1, B3-2230.1, PR 1-2703, RDF-245.1, B3-2230.1, B3-2230.2, A3-3171, HO-238, B3-2231, RDF-240

End Stage Renal Disease (ESRD) occurs from the destruction of normal kidney tissues over a long period of time. Often there are no symptoms until the kidney has lost more than half its function. The loss of kidney function in ESRD is usually irreversible and permanent.

Some services are listed in the definitions shown below. Medicare covers these services unless otherwise noted.

Note that services furnished to hospital inpatients are covered under Part A and paid in accordance with the applicable payment rules for the type of provider. Other dialysis services are payable under Part B.

A. Dialysis

Dialysis is a process by which waste products are removed from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. There are two types of renal dialysis procedures in common clinical usage: hemodialysis and peritoneal dialysis. Both hemodialysis and peritoneal dialysis are acceptable modes of treatment for ESRD under Medicare.

1. Hemodialysis - Blood passes through an artificial kidney machine and the waste products diffuse across a manmade membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body. Hemodialysis is accomplished usually in three to four hour sessions, three times a week.

2. Peritoneal - Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically.

Peritoneal dialysis is particularly suited for:

- Patients without family members to assist in self-dialysis;
- Children;
- Patients with no peripheral sites available for fistula or cannula placement;
- Patients who have difficulty learning the more complex hemodialysis technique; and

- Elderly patients with cardiovascular disease who are unable to tolerate intravascular fluid shifts associated with hemodialysis.

The three types of peritoneal dialysis are listed below:

a. Continuous Ambulatory Peritoneal Dialysis (CAPD) - In CAPD, the patient's peritoneal membrane is used as a dialyzer. The patient connects a 2-liter plastic bag of dialysate to a surgically implanted indwelling catheter that allows the dialysate to pour into the beneficiary's peritoneal cavity.

Four to 6 hours later, the patient drains the fluid out into the same bag and replaces the old bag with a new bag of fresh dialysate. This is done three to five times a day, with the first exchange being made when the patient wakes up in the morning, and the last exchange being made at bedtime. Because no machine is used, CAPD frees patients from the confinement of a machine; and because it is continuous, CAPD frees patients from the dietary restrictions associated with intermittent hemodialysis or intermittent peritoneal dialysis. For more information, see §70.

b. Continuous Cycling Peritoneal Dialysis (CCPD) - CCPD is a treatment modality that combines the advantages of the long dwell, continuous steady state dialysis of CAPD, with the advantages of automation inherent in intermittent peritoneal dialysis (IPD). The major difference between CCPD and CAPD is that the solution exchanges, which are performed manually during the day by the patient on CAPD, are moved to nighttime with CCPD and are performed automatically with a peritoneal dialysis cyclor. The long nighttime dwell of CCPD is moved to the daytime with CAPD.

At night, the patient connects a surgically implanted catheter to the cyclor system, which has four 2-liter containers of dialysate suspended. The cyclor automatically empties the patient's peritoneal cavity of the all-day dwell. The cyclor then cycles the nocturnal exchanges automatically while the patient sleeps. The number of nocturnal exchanges with CCPD are prescribed by the physician; generally there are three nocturnal exchanges occurring at intervals of 2 1/2 to 3 hours, with the fourth exchange being instilled in the morning upon awakening. The patient then disconnects from the cyclor and leaves the last 2-liter fill inside the peritoneum to continue the daytime long dwell dialysis.

c. Intermittent Peritoneal Dialysis (IPD) - Waste products pass from the patient's body through the peritoneal membrane into the peritoneal cavity where the dialysate is introduced and removed periodically by machine. Peritoneal dialysis generally is required for approximately 30 hours a week, either as three 10-hour sessions or less frequent, but longer, sessions.

3. Hemofiltration - Hemofiltration is a safe and effective technique for the treatment of ESRD patients and an alternative to peritoneal dialysis and hemodialysis. Hemofiltration (which is also known as diafiltration) removes fluid, electrolytes, and other low molecular weight toxic substances from the blood by filtration through hollow artificial membranes and may be routinely performed in three weekly sessions. In

contrast to both hemodialysis and peritoneal dialysis treatments, which eliminate dissolved substances via diffusion across semipermeable membranes, hemofiltration mimics the filtration process of the normal kidney. The technique requires an arteriovenous access. Hemofiltration may be performed either in facility or at home. (See §100.)

4. Hemoperfusion - Hemoperfusion is a process that removes substances from the blood through the dialysis membrane by using a charcoal or resin artificial kidney. When used in the treatment of a life threatening drug overdose, hemoperfusion is a covered service for patients with or without renal failure. Hemoperfusion is also covered when used in conjunction with DFO to treat aluminum toxicity. (See §110.) However, hemoperfusion is not covered when used to improve the results of hemodialysis or when used in conjunction with deferoxamine (DFO) to remove iron overload.

One or two treatments are usually all that is necessary to remove the toxic compound; additional treatments should be documented. Hemoperfusion may be performed concurrently with dialysis, and in those cases payment for the hemoperfusion should reflect only the additional care rendered over and above the care, which would have been given during the dialysis.

Hemoperfusion generally requires a physician to be present to initiate treatment and to be present in the hospital or an adjacent medical office during the entire procedure, as changes may be sudden. Special staff training and equipment are required.

5. Therapeutic Pheresis (Apheresis) - Apheresis is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma or cells) from whole blood and return the remaining constituents to the person from whom the blood was taken.

See the Medicare National Coverage Determinations Manual, Chapter 1, for the national coverage determination for apheresis.

6. Ultrafiltration - A process of removing excess fluid from the blood through a dialysis membrane by exerting pressure. It is not a substitute for dialysis. Occasionally, medical complications may occur which require that ultrafiltration be performed separately from the dialysis treatment.

B. ESRD Facility

An ESRD facility is a facility which is approved to furnish at least one specific ESRD service. Such facilities are:

1. Renal Transplantation Center - A hospital unit, which is approved to furnish transplantation, and other medical and surgical specialty services required for the care of the ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement. A renal transplantation center may also be a renal dialysis center.

2. Renal Dialysis Center - A hospital unit, which is approved to furnish the full spectrum of diagnostic, therapeutic, and rehabilitative services required for the care of ESRD dialysis patients (including inpatient dialysis furnished directly or under arrangement). A hospital need not provide renal transplantation to qualify as a renal dialysis center.

3. Renal Dialysis Facility - An independent unit that is approved to furnish dialysis service(s) directly to ESRD patients.

4. Self-Dialysis Unit - A unit that is part of an approved renal transplantation center, renal dialysis center, or renal dialysis facility, and furnishes self-dialysis services.

5. Special Purpose Renal Dialysis Facility - A renal dialysis facility that is approved to furnish dialysis at special locations on a short-term basis to a group of dialysis patients otherwise unable to obtain treatment in the geographical area. The special locations must be either special rehabilitative (including vacation) locations serving ESRD patients temporarily residing there, or locations in need of ESRD facilities under emergency circumstances.

C. Dialysis Services

The types of care available are:

1. Transplantation Service - A process by which: (a) a kidney is excised from a live or cadaveric donor, (b) a kidney is implanted in an ESRD patient, and (c) supportive care is furnished to the living donor and to the recipient following implantation.

2. Dialysis Service

A. Acute Dialysis - Dialysis given to patients who are not ESRD patients, but who require dialysis because of temporary kidney failure due to a sudden trauma; e.g., traffic accident or ingestion of certain drugs.

B. Back-Up Dialysis - Dialysis given to patients under special circumstances. Examples are: dialysis of a home dialysis patient in a dialysis facility when the patient's equipment fails, inpatient dialysis when a patient's illness requires more comprehensive care on an inpatient basis, and preoperative and postoperative dialysis provided to transplant patients.

C. Institutional Dialysis Services - Institutional dialysis services include all services, supplies, items, equipment, and ESRD related laboratory tests covered under the composite rate necessary to perform dialysis in an approved renal dialysis facility or center.

D. Inpatient Dialysis - Dialysis, which, because of medical necessity, is furnished to an ESRD patient on a temporary inpatient basis in a hospital.

E. Outpatient Dialysis - Dialysis furnished on an outpatient basis at a renal dialysis center or facility. Outpatient dialysis includes:

- **Staff-assisted Dialysis** - Dialysis performed by the staff of the center or facility.
- **Self-Dialysis** - Dialysis performed by an ESRD patient with little or no professional assistance. The patient must have completed an appropriate course of training.
- **Home Dialysis** - Dialysis performed by an appropriately trained patient (and the patient's caregiver) and at home.
- **Infacility Dialysis** - Dialysis furnished on an outpatient basis at an approved renal dialysis facility.
- **Self-Dialysis and Home Dialysis Training** - A program that trains ESRD patients to perform self-dialysis or home dialysis with little or no professional assistance, and trains other individuals to assist patients in performing self-dialysis or home dialysis.

D. Home Dialysis - Supplies, Equipment, and Support Services

1. Home Dialysis Equipment - Home dialysis equipment includes all of the medically necessary equipment prescribed by the attending physician, including (but not limited to) artificial kidney, automated peritoneal dialysis machines, and support equipment. Home dialysis supplies and equipment may be covered if used by an ESRD beneficiary in a nursing home.

2. Installation - Installation includes (but is not limited to): the identification of any minor plumbing and electrical changes required to accommodate the equipment; the ordering and performing of these changes; delivery of the equipment and its actual installation (i.e., hookup), as well as any necessary testing to assure proper installation and function.

Minor plumbing and electrical changes include those parts and labor required to connect the dialysis equipment to plumbing and electrical lines that already exist in the room where the patient will dialyze. Medicare does not cover wiring or rewiring of the patient's home or installing any plumbing to the patient's home or to the room of the home where the patient will dialyze.

3. Maintenance - Maintenance includes (but is not limited to): travel to the patient's home or, if needed, transportation of the equipment to a repair site; the actual performance of the maintenance or repair; and all necessary parts. Water purification

equipment maintenance includes replacing the filter on a reverse osmosis device, regenerating the resin tanks on a deionization device, using chemicals in a water softener, and periodic water testing to assure proper performance. Routine maintenance customarily performed by a patient are not covered services except for the cost of parts involved in this maintenance furnished by the facility to a patient.

4. Supplies - Supplies include all durable and disposable items and medical supplies necessary for the effective performance of a patient's dialysis. Supplies include (but are not limited to): dialyzers, forceps, sphygmomanometer with cuff and stethoscope, scales, scissors, syringes, alcohol wipes, sterile drapes, needles, topical anesthetics, and rubber gloves.

5. Support Services - Support services include (but are not limited to):

1. Periodic monitoring of a patient's adaptation to home dialysis and performance of dialysis, including provisions for visits to the home or the facility;
2. Visits by trained personnel for the patient with a qualified social worker and a qualified dietitian, made in accordance with a plan prepared and periodically reviewed by a professional team which includes the physician;
3. Individual's unscheduled visits to a facility made on an as-needed basis; e.g., assistance with difficult access situations;
4. ESRD related laboratory tests covered under the composite rate;
5. Providing, installing, repairing, testing, and maintaining home dialysis equipment, including appropriate water testing and treatment;
6. Ordering of supplies on an ongoing basis; and
7. A record keeping system that assures continuity of care. (See §70.3 for CAPD support services.)

NOTE: The CMS requires that suppliers billing Medicare under Method II must have a written agreement with a certified dialysis facility to provide these services.

6. Support Equipment - Support equipment is equipment used in conjunction with the basic dialysate delivery system. Such equipment includes (but is not limited to) pumps, such as blood and heparin pumps, alarms, such as bubble detectors, water purification equipment used to improve the quality of the water used for dialysis, and adjustable dialysis chairs.

7. Method Selection – For home dialysis, a beneficiary selects one of two methods for payment and billing. Under Method I (composite rate), the facility with which the patient is associated assumes responsibility for providing all home dialysis equipment, supplies and support services. Under Method II (direct dealing) the beneficiary deals directly with a single home dialysis supplier to secure the necessary supplies and equipment to dialyze at home.

E. Hospital-Based ESRD Facility

Hospital-based ESRD facility is an integral and subordinate part of a hospital and is operated with other departments of the hospital under common licensure, governance, and professional supervision, with all services of the hospital and facility fully integrated. Specifically, the facility would be hospital-based only if all the following conditions are met:

- The facility and hospital are subject to the bylaws and operating decisions of a common governing board. All authority in management flows from this administrative body which approves all personnel actions, appoints medical staff, and carries out similar management functions;
- The ESRD facility's director or administrator is under the supervision of the hospital's chief executive officer and reports through that officer to the governing board;
- The facility personnel policies and practices conform to those of the hospital;
- The administrative functions of the facility (that is, records, billing, laundry, housekeeping, and purchasing) are integrated with those of the hospital; and
- The dialysis unit and hospital are financially integrated, as evidenced by the cost report, which must reflect allocation of hospital overhead to the facility through the required step-down methodology (see the Medicare Provider Reimbursement Manual (Pub 15-1), §2306). For example, where a single dialysis department in a hospital is responsible for inpatient and outpatient dialysis and the costs are subsequently split between inpatient and outpatient, the outpatient department will normally be classified as hospital-based. In determining compliance with this criterion, the key issue is whether Pub 15-1, §2306, would require the hospital to make this cost allocation, rather than whether the hospital has actually made the allocation. If no allocation is made because the hospital failed to follow Pub 15-1, §2306, the hospital must resubmit a corrected cost report, and the facility will normally be classified as hospital-based.

The existence of an agreement or an arrangement between a facility and a hospital for referral of patients, a shared service arrangement between a facility and a hospital (a common practice recognized by both Medicare and Medicaid), or the physical location of

a dialysis unit on the premises of a hospital, does not mean that a facility is hospital-based.

Any facility that does not meet all of the above criteria would be considered an independent facility.

20 - Coverage of Outpatient Maintenance Dialysis (Rev. 1, 10-01-03)

A3-3167, B3-2230.2, RDF-202, SOM-2272, RDF-317.1, PM AB-03-001

Medicare covers maintenance dialysis treatments when they are provided to ESRD patients by an approved hospital-based dialysis facility, an independent dialysis facility, or a special purpose dialysis facility. Outpatient dialysis treatments are covered in various settings: hospital outpatient facility, independent dialysis facility, or the patient's home. Dialysis treatments at dialysis facilities differ according to the types of patients being treated, the types of equipment and supplies used, the preferences of the treating physician, and the capability and makeup of the staff. Although not all facilities provide an identical range of services, the most common elements of a dialysis treatment are:

- a. Personnel services;
- b. Equipment and supplies - dialysis machine and its maintenance;
- c. Administrative services;
- d. Overhead costs;
- e. Monitoring access and related declotting the access or referring the patient;
- f. ESRD related laboratory tests; and
- g. Biologicals.

Direct nursing services include registered nurses, licensed practical nurses, technicians, social workers, and dietitians.

Facilities with self-dialysis units must meet specific health and safety requirements. Certain standards applicable to staff assisted dialysis have been adjusted for self-dialysis units in consideration of the differences in the two modalities. Before participating in self-dialysis, patients must have completed an appropriate training program in emergency procedures and have a safe storage area for their supplies. Access to the self-dialysis unit is limited to patients for whom the facility maintains patient care plans in order to exclude transient patients who might not be familiar with the facility's equipment or emergency procedures. The self-dialysis unit need not be physically separate from the rest of the facility nor operate on a separate shift.

20.1 - Noninvasive Vascular Studies for End Stage Renal Disease (ESRD) Patients
(Rev. 1, 10-01-03)

PM AB-03-01, PM-AB-01-129

For dialysis to take place there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for monitoring access, and when occlusions occur, must either declot the access or refer the patient for appropriate treatment.

Procedures associated with monitoring access include taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are covered under the composite rate.

Non-invasive vascular studies such as duplex and Doppler flow scans are not covered as a separately billable service if used to monitor a patient's vascular access site. Medicare pays for the technical component of the procedure in the composite payment rate.

An ESRD facility must furnish all necessary services, equipment, and supplies associated with a dialysis treatment, either directly or under arrangements that make the facility financially responsible for the service. If an ESRD facility or a renal physician decides to monitor the patient's access site with a non-invasive vascular study and does not have the equipment to perform the procedure, the facility or physician may arrange for the service to be furnished by another source. The alternative source, such as an independent diagnostic testing facility must look to the ESRD facility for payment.

Doppler flow studies may be considered appropriate in the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining the clinical course of the treatment for the patient. Routine monitoring by noninvasive Doppler flow studies is not covered outside the composite rate; however, if there are signs and symptoms of medical problems, these procedures are separately payable.

When a dialysis patient exhibits signs and symptoms of compromise to the vascular access site, Doppler flow studies may provide diagnostic information that will determine the appropriate medical intervention. Medicare considers a Doppler flow study appropriate when the beneficiary's dialysis access site manifests signs or symptoms associated with vascular compromise, and when the results of this test are necessary to determine the clinical course of treatment.

Examples supporting the medical necessity for Doppler flow studies include:

- a. Elevated dynamic venous pressure >200mm HG when measured during dialysis with the blood pump set on a 200cc/min.,

- b. Access recirculation of 12 percent or greater,
- c. An otherwise unexplained urea reduction ratio <60 percent, and
- d. An access with a palpable “water hammer” pulse on examination, (which implies venous outflow obstruction).

Unless the documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both.

An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates:

Reduced flow (blood flow rate less than 800cc/min or

A decreased flow of 25 percent or greater from previous study) and

The physician requires an arteriogram to further define the extent of the problem.

The patient’s medical record(s) must provide documentation supporting the need for more than one imaging study.

This policy is applicable to claims from ESRD facilities and all other sources, such as independent diagnostic testing facilities, and hospital outpatient departments.

The professional component of the procedure is included in the monthly capitation payment (MCP). The professional component is denied if billed by the MCP physician. Medically necessary services that are included or bundled into the MCP (e.g., test interpretations) are separately payable when furnished by physicians other than the MCP physician. The MCP physician is identified by the performing provider number that billed MCP services identified by the HCPCS code 90995.

30 - Composite Rate for Outpatient Maintenance Dialysis (Rev. 136, Issued: 01-28-11, Effective: 01-01-11, Implementation: 02-25-11)

The composite payment rate system is a prospective system for the payment of outpatient maintenance dialysis services furnished to Medicare beneficiaries. All maintenance dialysis treatments furnished to Medicare beneficiaries in an approved ESRD facility are covered by this system. Further, the composite rate system is one of two methods by which Medicare pays for maintenance dialysis performed in a beneficiary’s home. (For a description of the other method, see [§50](#))

The facility’s composite payment rate is a comprehensive payment for all modes of infacility and Method I home dialysis. Most items and services related to the treatment of

the patient's end-stage renal disease are covered under the composite rate payment. The cost of an item or service is included under the composite rate unless specifically excluded. Therefore, the determination as to whether an item or service is covered under the composite rate payment does not depend on the frequency that dialysis patients require the item or service or the number of patients who require it. The composite rate is payment for the complete dialysis treatment except for physicians' professional services, separately billable laboratory services, and separately billable drugs. This payment is subject to the normal Part B deductible and coinsurance requirements.

Under the composite rate, a dialysis facility must furnish all of the necessary dialysis services, equipment, and supplies. If it fails to furnish (either directly under arrangement or under an agreement with another approved ESRD facility) any part of the items and services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that the facility does furnish.

A certified hospital-based outpatient dialysis facility that is not the patient's usual facility can provide and must bill Medicare directly for routine maintenance services. The certified hospital-based dialysis facility cannot bill the patient's usual facility for payment and have the patient's usual facility bill Medicare.

Other ESRD Items and Services

Items and services included under the composite rate must be furnished by the facility, either directly or under arrangements to all of its dialysis patients. Examples of such items and services are:

- Bicarbonate dialysate;
- Cardiac monitoring;
- Catheter changes (Ideal Loop);
- Suture removal;
- Dressing changes (all dressings or protective access coverings, including catheter coverings, used to conceal a dialysis patient's access site, for any purpose, including allowing dialysis patients to bathe or shower as well as perform other day-to-day activities, are included in the composite rate);
- Crash cart usage for cardiac arrest;
- Dec clotting of shunt performed by facility staff in the dialysis unit;
- All oxygen and its administration furnished in the dialysis unit;
- Staff time to administer blood;

- Staff time used to administer separately billable parenteral items; and
- Staff time used to collect specimens for all laboratory tests.

Sometimes outpatient dialysis related services (e.g., dec clotting of shunts, suture removal, injecting separately billable ESRD related drugs) are furnished in a department of the hospital other than the dialysis unit (e.g., the emergency room (ER)). These services may be paid in addition to the composite payment rate only if the services could not be furnished in a dialysis facility or the dialysis unit of the hospital, due to the absence of specialized equipment or staff found only in the other department. In the case of emergency services furnished in the hospital ER, the services are paid separately subject to the additional requirement that there is a sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention in the ER could reasonably be expected to result in either:

- Placing the patient's health in serious jeopardy;
- Serious impairment to bodily functions; or
- Serious dysfunction of any bodily organ or part.

Since the above noted situations rarely occur, they require clinical documentation to validate they were met; otherwise, they would be denied services.

30.1 - Frequency of Dialysis Sessions (Rev. 1, 10-01-03)

A3-3112.6, A3-3166.2

Hemodialysis and peritoneal dialysis are covered at the frequencies shown below under the composite rate. Additional composite rate payments may be made when they are medically justified.

A. Hemodialysis

The usual pattern of hemodialysis consists of three sessions weekly, and these may be covered routinely. If the ESRD facility bills for any sessions in excess of this frequency, the intermediary shall consider requiring medical justification.

B. Peritoneal Dialysis

Peritoneal dialysis sessions are covered routinely at the same frequency as hemodialysis. If the ESRD facility bills for any sessions in excess of this frequency, the bills must be accompanied by medical justification acceptable to the intermediary. However, the

pattern of peritoneal dialysis may vary, in which case an equivalence is established between peritoneal and hemodialysis as described in the Medicare Claims Processing Manual, Chapter 1, “Inpatient Hospital Services,” §§40.

Maintenance **Intermittent Peritoneal Dialysis (IPD)** is usually accomplished in sessions of 10 to 12 hours in duration. Sometimes it is accomplished in fewer weekly sessions of longer duration. The payment screens applicable to maintenance IPD, as well as the facility’s actual payment for maintenance IPD, depends on the length of the dialysis session and the number of sessions furnished per week. If additional dialysis beyond the usual weekly maintenance dialysis is required because of special circumstances, the facility’s claim for these extra services must be accompanied by a medical justification. Under these circumstances, additional payment may be made. In all cases, the Part B deductible and coinsurance apply.

30.2 - Laboratory Services Included Under Composite Rate (Rev. 1, 10-01-03)

A3-3167.1, RDF-207.1, PR 1-2710.1

The costs of certain ESRD laboratory services performed by either the facility’s staff, or an independent laboratory, are included in the composite rate calculations. These laboratory tests are listed in §§30.2.1 and 70.2.A. (See §§50.1, 60.1, and 80 of the Medicare Claims Processing Manual, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” for payment instructions.) Therefore, payment for all of the tests is included in the facility’s composite rate, and the tests may not be billed separately to the Medicare program. Laboratory tests are performed either by the facility, in which case payment is included in the composite rate, or by an outside laboratory for the facility, in which case the laboratory bills the facility and is paid under the composite rate. (See the Medicare Claims Processing Manual, Chapter 1, “Inpatient Hospital Services,” §§40.)

30.2.1 - Laboratory Tests for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration (Rev. 1, 10-01-03)

A3-3167.3, RDF-207.3

A. Routinely Covered Tests Paid Under Composite Rate

The tests listed below are usually performed for dialysis patients and are routinely covered at the frequency specified in the absence of indications to the contrary, i.e., no documentation of medical necessity is required other than knowledge of the patient’s status as an ESRD beneficiary. When any of these tests is performed at a frequency greater than that specified, the additional tests are separately billable and are covered only if they are medically justified by accompanying documentation. A diagnosis of ESRD

alone is not sufficient medical evidence to warrant coverage of the additional tests. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using the ICD-9-CM coding system.

- **Per Treatment** - All hematocrit, hemoglobin, and clotting time tests furnished incident to dialysis treatments;
- **Weekly** - (1) Prothrombin time for patients on anticoagulant therapy, and (2) Serum Creatinine;
- **Weekly or Thirteen Per Quarter** - BUN;
- **Monthly** - Serum Calcium, Serum Potassium, Serum Chloride, CBC, Serum Bicarbonate, Serum Phosphorous, Total Protein, Serum Albumin, Alkaline Phosphatase, aspartate amino transferase (AST) (SGOT) and LDH; and
- **Automated Battery of Tests** - If an automated battery of tests, such as the SMA-12, is performed and contains most of the tests listed in one of the weekly or monthly categories, it is not necessary to **separately** identify any tests in the battery that are not listed. Further information concerning automated tests and the “50 percent rule” can be found in the Medicare Claims Processing Manual, Chapter 16, “Laboratory Services,” §160.

B. Separately Billable Tests

The following list identifies certain separately billable laboratory tests that are covered routinely, i.e., without documentation of medical necessity other than knowledge of the patient’s status as an ESRD beneficiary, when furnished at the specified frequencies. If they are performed at a frequency greater than that specified, they are covered only if accompanied by medical documentation. A diagnosis of ESRD alone is not sufficient documentation. The medical necessity of the test(s), the nature of the illness or injury (diagnosis, complaint or symptom) requiring the performance of the test(s) must be present on the claim. Such information must be furnished using the ICD-9-CM coding system.

Guidelines for Separately Billable Tests for Hemodialysis, IPD, CCPD, and Hemofiltration

Serum Aluminum - one every three months

Serum Ferritin - one every three months

(See §70.2 Item 1 for laboratory tests rendered to CAPD patients.)

30.2.2- Automated Multi-Channel Chemistry (AMCC) Tests

(Rev. 83; Issued: 02-15-08; Effective: 07-01-08; Implementation: 07-07-08)

Clinical diagnostic laboratory tests included under the composite rate payment are paid through the composite rate paid by the intermediary. To determine if separate payment is allowed for non-composite rate tests for a particular date of service, 50 percent or more of the covered tests must be non-composite rate tests.

Medicare will apply the following to AMCC tests for ESRD beneficiaries:

1. Payment is the lowest rate for services performed by the same provider, for the same beneficiary, for the same date of service.
2. The intermediary must identify for a particular date of service the AMCC tests ordered that are included in the composite rate and those that are not included. The composite rate tests are defined for Hemodialysis, Intermittent Peritoneal Dialysis (IPD), Continuous Cycling Peritoneal Dialysis (CCPD), and Hemofiltration (Attachment 1) and for Continuous Ambulatory Peritoneal Dialysis (CAPD) (Attachment 2).
3. If 50 percent or more of the covered tests are included under the composite rate payment, then all submitted tests are included within the composite payment. In this case, no separate payment in addition to the composite rate is made for any of the separately billable tests.
4. If less than 50 percent of the covered tests are composite rate tests, all AMCC tests submitted for that Date of Service (DOS) are separately payable.
5. A non-composite rate test is defined as any test separately payable outside of the composite rate or beyond the normal frequency covered under the composite rate that is reasonable and necessary.

Three pricing modifiers discretely identify the different payment situations for ESRD AMCC tests. The physician that orders the tests is responsible for identifying the appropriate modifier when ordering the tests.

- CD - AMCC test has been ordered by an ESRD facility or MCP physician that is part of the composite rate and is not separately billable
- CE - AMCC test has been ordered by an ESRD facility or MCP physician that is a composite rate test but is beyond the normal frequency covered under the rate and is separately reimbursable based on medical necessity

CF – AMCC test has been ordered by an ESRD facility or MCP physician that is not part of the composite rate and is separately billable

The ESRD clinical diagnostic laboratory tests identified with modifiers “CD”, “CE” or “CF” may not be billed as organ or disease panels. Effective October 1, 2003, all ESRD clinical diagnostic laboratory tests must be billed individually. See Pub. 100-04, Medicare Claims Processing Manual, Chapter 8, for additional billing and payment instructions as well as examples of the 50/50 rule.

For ESRD dialysis patients, CPT code 82330 Calcium; ionized shall be included in the calculation for the 50/50 rule (Pub 100-04, Chapter 16, § 40.6). When CPT code 82330 is billed as a substitute for CPT code 82310, Calcium; total, it shall be billed with modifier CD or CE. When CPT code 82330 is billed in addition to CPT 82310, it shall be billed with CF modifier.

Composite Rate Tests for Hemodialysis, IPD, CCPD, and Hemofiltration (Items in bold are non composite rate test)

Chemistry	CPT Code	Monthly	Weekly	13 x Quarter
Albumin	82040	X		
Alkaline Phosphatase	84075	X		
ALT (SGPT)	84460			
AST (SGOT)	84450	X		
Bilirubin, total	82247			
Bilirubin, direct	82248			
Calcium	82310	X		
Calcium ionized (billed with modifier CD or CE)	82330	X		
Calcium ionized (billed with modifier CF)	82330	X		
Chloride	82435	X		
Cholesterol	82465			
CK, CPK	82550			
CO2 (bicarbonate)	82374	X		
Creatinine	82565		X	
GGT	82977			
Glucose	82947			
LDH	83615	X		
Phosphorus	84100	X		
Potassium	84132	X		
Protein, total	84155	X		
Sodium	84295			
Triglycerides	84478			
Urea nitrogen (BUN)	84520			X
Uric Acid	84550			

Composite Rate Tests for CAPD (Items in bold are non composite rate test)

Chemistry	CPT Code	Monthly	Weekly	13 x Quarter
Albumin	82040	X		
Alkaline Phosphatase	84075	X		
ALT (SGPT)	84460			
AST (SGOT)	84450	X		
Bilirubin, total	82247			
Bilirubin, direct	82248			
Calcium	82310	X		
Calcium ionized (billed with modifier CD or CE)	82330	X		
Calcium ionized (billed with modifier CF)	82330	X		
Chloride	82435			
Cholesterol	82465			
CK, CPK	82550			
CO2 (bicarbonate)	82374	X		
Creatinine	82565	X		
GGT	82977			
Glucose	82947			
LDH	83615	X		
Phosphorus	84100	X		
Potassium	84132	X		
Protein, total	84155	X		
Sodium	84295	X		
Triglycerides	84478			
Urea nitrogen (BUN)	84520	X		
Uric Acid	84550			

30.3 - Requests for Composite Rate Exception **(Rev. 7, 02-20-04)**

See the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §40.

30.4 - Drugs and Biologicals **(Rev. 1, 10-01-03)**

A3-3168, B3-2231.3

Drugs and biologicals are covered under Medicare in accordance with the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.

Medicare covers blood furnished by a hospital-based or an independent dialysis facility.

Drugs and biologicals, such as blood, generally are not covered in the home dialysis setting unless they are provided under the direct personal supervision of a physician. When this condition is met, the physician must bill the carrier. Certain drugs and biologicals, however, may be considered home dialysis supplies and may be covered as such. This exception is limited to heparin, the heparin antidote, local anesthetics such as xylocaine, and antibiotics for peritoneal dialysis patients when used to treat infections of the catheter site or peritonitis.

Generally, except for those categories of drugs and biologicals for which coverage is specifically provided by the statute, e.g., EPO and drugs used as immunosuppressive therapy, drugs and biologicals are covered only if all of the following requirements are met:

- a. They meet the definition of drugs or biologicals;
- b. They are of the type that cannot be self-administered (see the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §50.B);
- c. They are not excluded as immunizations;
- d. They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice;
- e. They meet all the general requirements for coverage of items as incident to a physician's service; and
- f. They have not been determined by the FDA to be less than effective.

There are multiple hepatitis B vaccines available. Frequency, dosage and hepatitis associated antigen tests are determined by the patient's physician based on the drug labeling requirements for the specific vaccine provided.

30.4.1 - Drugs Covered Under the Composite Rate (Rev. 1, 10-01-03)

A3-3168.A, PR 1-2710.2, RDF-319.1

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 covered under the composite rate. For home patients under Method II (see §50), these items may be covered without documentation for medical necessity and may be billed by an ESRD supplier regardless of where they are furnished.

Following is a list of these items:

Heparin	Mannitol	Glucose
Antiarrhythmics	Saline	Antihypertensives
Protamine	Pressor drugs	Antihistamines
Local anesthetics	Heparin antidotes	Dextrose
Apresoline (hydralazine)	Benadryl	Inderal
Dopamine	Hydralazine	Levophed
Insulin	Lanoxin	Verapamil
Lidocaine	Solu-cortef	Antibiotics (when used at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis)

The administration of these items (both the staff time and the supplies) is covered under the composite rate and may not be billed separately.

30.4.2 - Separately Billable Drugs (Rev. 1, 10-01-03)

A3-3168.B, RDF-319.4, A3-3644.E, PR 1-2711.2

There are other drugs that are not covered under the composite rate, but that may be medically necessary for some patients receiving dialysis. When furnished in the dialysis facility, these items must be billed separately and be accompanied by medical

justification either through information on the claims form or as requested by the intermediary. They include: Antibiotics, Hematinics, Anabolics, Muscle relaxants, Analgesics, Sedatives, Tranquilizers, and Thrombolytics used to declot central venous catheters.

These separately billable drugs may 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. (See the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §§40.)

NOTE: Albumin may be reasonable and medically necessary for the treatment of certain medical complications in renal dialysis patients. In such cases, facilities must document medical need to the satisfaction of the intermediary's medical staff. If the intermediary determines that the drug is medically necessary, then separate payment in addition to the facility's composite rate may be made. However, if albumin is used as a substitute for any drug covered under the composite rate or used to accomplish the same effect, for example, as a volume expander, then payment for it must be included in the facility's composite rate payment for maintenance dialysis.

30.4.2.1 - Intravenous Iron Therapy **(Rev. 1, 10-01-03)**

B3-4461, A3-3644.E, RDF-319.4

Iron deficiency is a common condition in ESRD patients undergoing hemodialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs), which transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBC (hematocrit) levels. Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis.

For claims with dates of service on or after December 1, 2000, Medicare covers sodium ferric gluconate complex in sucrose injection for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy. In hospital outpatient departments, payment is made under the outpatient prospective payment system. Payment is made on a reasonable cost basis in critical access hospitals (CAHs). For claims with dates of service on or after December 1, 2000, payment is made on a reasonable cost basis in renal dialysis centers (freestanding facilities). For claims with dates of service on or after January 1, 2001, payment is made pursuant to 42 CFR 405.517 for renal dialysis centers (freestanding facilities).

Medicare covers iron sucrose injection as a first line treatment of iron deficiency anemia, when furnished intravenously to patients undergoing chronic hemodialysis who are

receiving supplemental erythropoietin therapy, for claims with dates of service on or after October 1, 2001. In hospital outpatient departments, payment is made under the outpatient prospective payment system. Payment is made on a reasonable cost basis in CAHs and in renal dialysis centers (freestanding facilities). Deductible and coinsurance apply.

30.4.2.2 - Levocarnitine for Treatment of Carnitine Deficiency in ESRD Patients (Rev. 1, 10-01-03)

PM AB-02-165

Carnitine is a naturally occurring substance that functions in the transport of long-chain fatty acids for energy production by the body. Deficiency can occur due to a congenital defect in synthesis or utilization, or from dialysis. The causes of carnitine deficiency in hemodialysis patients include dialytic loss, reduced renal synthesis and reduced dietary intake.

Intravenous levocarnitine is covered for those ESRD patients who have been on dialysis for a minimum of three months for one of the following indications.

Patients must have documented carnitine deficiency, defined as a plasma free carnitine level <40 micromol/L (determined by a professionally accepted method as recognized in current literature), along with signs and symptoms of:

Erythropoietin-resistant anemia (persistent hematocrit <30 percent with treatment) that has not responded to standard erythropoietin dosage (that which is considered clinically appropriate to treat the particular patient) with iron replacement, and for which other causes have been investigated and adequately treated, or

Hypotension on hemodialysis that interferes with delivery of the intended dialysis despite application of usual measures deemed appropriate (e.g., fluid management). Such episodes of hypotension must have occurred during at least 2 dialysis treatments in a 30-day period.

Continued use of levocarnitine is not covered if improvement has not been demonstrated within six months of initiation of treatment. All other indications for levocarnitine are non-covered in the ESRD population.

30.5 - ESRD Composite Payment Rates (Rev. 98, Issued: 12-12-08, Effective: 01-01-09, Implementation: 01-05-09)

Effective January 1, 2005, section 623 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) amended section 1881(b)(7) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. The MMA also required a drug add-on adjustment to the composite payment rate to account for the difference

between pre-MMA payments for separately billable drugs and payments based on revised drug pricing for 2005 which used average acquisition costs. For CY 2005, CMS computed a drug add-on adjustment of 8.7 percent.

Effective January 1, 2006, section 5106 of the Deficit Reduction Act of 2005 amended section 1881(b)(12) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. In addition, because the drug add-on adjustment is determined as a percentage of the composite payment rate, CMS must adjust the drug add-on adjustment to account for the 1.6 percent increase to the composite payment rate in order to ensure that the total dollars allocated from the drug add-on adjustment remains constant. The growth update to the drug add-on adjustment of 1.4 percent was unchanged, therefore the total drug add-on adjustment to the composite payment rate for 2006 was 14.5 percent.

For dialysis services furnished on or after January 1, 2007 through March 31, 2007, the growth update to the drug add-on adjustment to the composite payment rate was 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for 2007 increased from 14.5 percent to 15.1 percent.

For dialysis services furnished on or after April 1, 2007, section 103 of the Tax Relief and Health Care Act of 2006 amended section 1881(b)(12) of the Act to require a 1.6 percent increase to the ESRD composite payment rate. The effect of the 1.6 percent increase to the composite payment rate was a reduction in the drug add-on adjustment from 15.1 percent to 14.9 percent.

Effective January 1, 2008, there was no increase to the composite payment rate however, the drug add-on adjustment to the composite payment rate was increased by a growth update of 0.5 percent. As a result, the drug add-on adjustment to the composite payment rate for CY 2008 increased from 14.9 percent to 15.5 percent.

Effective January 1, 2009, section 153 of the Medicare Improvements for Patients and Providers Act of 2008 amended section 1881(b)(12) of the Social Security Act to require a 1 percent increase to the ESRD composite payment rate and that hospital-based dialysis facilities are paid the same composite payment rate as independent dialysis facilities. The effect of the 1 percent increase in the composite payment rate is a reduction in the drug add-on adjustment from 15.5 percent to 15.2 percent.

Future updates will be issued via Recurring Update Notifications.

40 - Beneficiary Selection Form CMS-382 for Home Dialysis Patients (Rev. 1, 10-01-03)

A3-3169.2, RDF-318, PR 1-2740.2

Each Medicare home dialysis beneficiary must choose the method by which Medicare pays for his or her dialysis services. To do this, each beneficiary must complete the Beneficiary Selection Form CMS-382, sign it and return it to the facility that supervises

his or her care. See the Medicare Claims Processing Manual, Chapter 8, “ Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §70.1, for further information. See §40.1, below for a discussion of the two methods available, Composite Rate (Method I), and Dealing Direct (Method II).

40.1 - Method I and Method II Reimbursement for Patients Dialyzing at Home

(Rev. 1, 10-01-03)

A3-3169, PR 1, 2740, RDF-245

Medicare beneficiaries, dialyzing at home, may choose between two methods of payment. This choice is recorded on the Beneficiary Selection Form, Form CMS-382.

Method I - The Composite Rate

If the Medicare home dialysis patient chooses Method I (Composite Payment Rate), the dialysis facility with which the patient is associated must assume responsibility for providing all home dialysis equipment and supplies, and home support services. For these services, the facility receives the same Medicare dialysis payment rate as it would receive for an infacility patient under the composite rate system. (See the Medicare Claims Processing Manual, Chapter 8, “Coverage of Extended Care (SNF) Services Under Hospital Insurance,” §30.5, for record keeping responsibilities. See §30 above and the Medicare Claims Processing Manual, Chapter 8, “Coverage of Extended Care (SNF) Services Under Hospital Insurance,” §10.1, for a description of services included in the Composite rate.) Under this arrangement, the facility bills the intermediary, and the beneficiary is responsible for paying the Part B deductible and the 20 percent coinsurance on the Medicare rate to the facility.

Method II - Dealing Direct

If a beneficiary elects Method II, the beneficiary will deal directly with a single Medicare supplier to secure the necessary supplies and equipment to dialyze at home. The selected supplier (not a dialysis facility) must take assignment and bill the Durable Medical Equipment Regional Carrier (DMERC.) The beneficiary is responsible to his or her supplier for unmet Part B deductible and for the 20 percent Medicare Part B coinsurance requirement.

For each beneficiary it serves, each supplier is required to maintain a written agreement with a support dialysis facility to provide backup and support services. A facility that has a written agreement to supply backup and support services bills the intermediary for services provided under the agreement. See §50.6 below for coverage of home dialysis support services.

Under Method II, a dialysis facility may be paid for home dialysis support services, but may **not** be paid for home dialysis equipment or supplies.

40.2 - Items and Services Included Under the Composite Rate for Method I Home Dialysis Patients (Rev. 1, 10-01-03)

A3-3169.1

All items and services described in this section are covered and included under the composite rate and must be furnished by the facility, either directly or under arrangements, to all of its Method I home dialysis patients who elect this method of reimbursement. If it fails to furnish (either directly or under arrangements) any part of the items and services covered under the rate, then its intermediary cannot pay the facility any amount for the part of the items and services that the facility does furnish. These items and services include:

- Medically necessary home dialysis equipment;
- Home dialysis support services, which include the delivery, installation, maintenance, repair and testing of home dialysis equipment and support equipment;
- Purchase and delivery of all necessary home dialysis supplies;
- ESRD related laboratory tests listed as covered under the composite rate; and
- All dialysis services furnished by the facility's staff.

Some examples (but not an all-inclusive list) of items and services that are covered and included in the composite rate and may **not** be billed separately when furnished by a dialysis facility are:

- Staff time used to administer blood;
- Dec clotting of shunts and any supplies used to declot shunts;
- Oxygen and the administration of oxygen; and
- Staff time used to administer separately billable parenteral items.

50 - Home Dialysis (Rev. 1, 10-01-03)

A3-3170, PR 1-2740.1, RDF-208

Home dialysis equipment and other medically necessary items for home dialysis prescribed by a physician are covered under Part B.

There are two methods by which a patient can be reimbursed for his or her dialysis equipment - the composite rate method (Method I) and the direct dealing method (Method II). Under Method I (composite rate), the facility with which the patient is associated assumes responsibility for providing all home dialysis equipment, supplies and support services. Under Method II (direct dealing) the beneficiary deals directly with a single home dialysis supplier to secure the necessary supplies and equipment to dialyze at home. (See §40.1.)

The direct dealing (Method II) patient has the choice of buying or renting (leasing) the equipment. With the exception of purchased items costing \$120 or less, which may be reimbursed in a single payment, Medicare pays the supplier for both rented and purchased equipment in monthly installments. Installment payments are made regardless of whether the patient pays for purchased equipment in a lump sum or in installments. Medicare makes monthly payments at a rate which approximates the reasonable monthly rental charge for similar equipment until either its share of the reasonable purchase price is paid, or until the equipment is no longer medically necessary, whichever comes first. Likewise, when covered home dialysis equipment is rented or leased, Medicare will pay 80 percent of the reasonable rental (lease) charge as long as the equipment is medically necessary.

The patient, for the leasing or purchase of home dialysis equipment or supplies, may enter into a variety of contractual agreements as follows:

- Manufacturers or suppliers may deal directly with a paying patient;
- Facilities may furnish equipment and supplies on a sale or rental basis to a patient; and,
- Equipment or supplies may be furnished to a patient by a manufacturer or supplier through a facility (i.e., items may be shipped directly to a patient but billed to a facility).

When payments stop because the beneficiary's condition has changed and the equipment is no longer necessary, the beneficiary is responsible for the remaining charges. Similarly, when payments stop because the beneficiary dies, the beneficiary's estate is responsible for the remaining charges. A beneficiary may sell or otherwise dispose of purchased equipment for which the beneficiary has no further use. If, after disposal of such equipment, there is again medical need for similar equipment, Medicare can pay for the rental or purchase of that equipment. Under Part B, payment can also be made for the installation, delivery, repair, maintenance, or replacement of home dialysis equipment. This payment also includes the costs of necessary supply items needed to effectively perform the dialysis. These items are covered only under the specified conditions discussed in the following sections. When covered, these items are reimbursed in a lump sum.

50.1 - Installation and Delivery of Home Dialysis Equipment (Rev. 1, 10-01-03)

A3-3170.1, RDF-60.1

Medicare will cover all reasonable and necessary expenses incurred in the original installation of home dialysis equipment. This coverage is not extended to expenses attributable to home improvement (e.g., plumbing or electrical work beyond that necessary to tie in with existing plumbing and power lines). Testing and assurance of equipment performance, which may be billed for as part of the basic delivery charge, are also covered. Medicare does not cover maintenance contracts on equipment, since Medicare pays only for costs that are actually incurred. The delivery and installation charge should be itemized, either on the face of the bill or an attached invoice.

50.2 - Current Use of Equipment

(Rev. 1, 10-01-03)

A3-3170.2, RDF-210

Monthly rental or installment payments for purchased items may be made only if the item was actually used during the month for which payment is claimed. Exceptions are allowed only under the circumstances outlined below and apply only to items of dialysis equipment necessary for home dialysis. Monthly rental charges or payments for purchased items may be continued for a period of up to three months after the month the equipment is last used because high installation charges could be paid a number of times for the same equipment if it is removed for temporary periods of nonuse. Nonuse is covered under the following circumstances:

- Beneficiary requires infacility treatment either for re-stabilization or as a result of some acute condition, but is expected to return to home dialysis;
- Beneficiary is temporarily without a suitable home dialysis assistant;
- Beneficiary is temporarily away from home but expects to return; (However, when a beneficiary consistently spends periods exceeding three months away from his or her home, this section does not apply)
- Beneficiary is a transplant candidate and is taken off home dialysis preparatory to transplant. (If the transplant cannot occur, or if the transplant is not successful, the patient will probably resume home dialysis and an evaluation can be made whether it will be within the immediate or foreseeable future.)

50.3 - Other Requirements for Coverage of Home Dialysis Equipment (Rev. 1, 10-01-03)

A3-3170.3, RDF-209, RDF-216.1

In addition to meeting the specific requirements of home dialysis equipment, the equipment must also meet the requirements outlined in the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §§110:

- The device is required because the patient has ESRD; and
- The equipment is appropriate for home use and is of the type prescribed by recognized specialists at approved home dialysis training centers.

Payment can also be made under the home dialysis equipment provision for supportive equipment that is used in conjunction with the basic dialysate delivery system. This includes blood and heparin pumps, air bubble detectors, blood leak detectors, unipuncture devices, water purification systems, and adjustable dialysis chairs.

Adjustable chairs, such as recliners, are covered when required as a component of a home hemodialysis delivery station. These chairs serve to preserve patients' health by allowing rapid manipulation in body position when medical circumstances warrant such changes during dialysis (e.g., when acute hypotension occurs and the patient is in danger of going into shock).

Reasonable costs of recliner chairs may not include a premium for style or for the capacity to rock, swivel, heat, or vibrate. Contractors may consider reviewing claims for recliner chairs to ensure that payment is consistent with what is reasonable and medically necessary to serve the intended therapeutic purpose. Since the adjustable chair is desirable in the absence of illness or injury, instructions in the National Coverage Determinations should be reviewed closely when replacement is claimed.

50.4 - Home Dialysis Equipment Provided to Home Hemodialysis and Peritoneal Dialysis Patients (Rev. 1, 10-01-03)

A3-3170.4

Coverage of any item of home dialysis equipment used for home dialysis depends on its medical necessity. Medical necessity is established by the physician's prescription, and by the equipment meeting Medicare guidelines that define home dialysis equipment. The beneficiary has the option of having the facility provide the equipment under the composite rate or of renting or purchasing such equipment directly from a supplier. (See [§40.1](#) for a description of these two methods of payment.)

50.5 - Coverage of Home Dialysis Supplies (Rev. 1, 10-01-03)

A3-3170.5, RDF-215, RDF-216.2

Supplies necessary to perform all modalities of home dialysis are covered, including such items as alcohol wipes, sterile drapes, gloves, telfa pads, bandages, etc.

Instruments and nonmedical supplies, such as scales, stopwatches, and blood pressure apparatus (this does not include automatic blood pressure monitoring devices such as those mentioned in the Medicare National Coverage Determinations Manual, Chapter 3, §410) are covered, regardless of whether provided separately or as part of a start-up kit. The beneficiary has the option of having the facility provide the supplies under the composite rate or of purchasing them directly from a supplier. (See §40.1 for a description of these two methods of payment.)

50.6 - Coverage of Home Dialysis Support Services (Rev. 1, 10-01-03)

A3-3170.6, PR 1-2740.1.B

If a beneficiary chooses Method II (direct dealing), all home dialysis support services required to perform dialysis at home are covered on an itemized basis.

Home dialysis support services must be furnished by a dialysis facility that is approved under 42 CFR Part 405.2100-2184 (Subpart U) to furnish home dialysis training and support services, and that has the written backup agreement with the supplier for that beneficiary. Covered support services include:

- Periodic monitoring of the patient's home adaptation (including visits to the home in accordance with a written plan prepared and periodically reviewed by a team that includes the patient's physician and other professionals familiar with the patient's condition);
- Emergency visits by qualified ESRD facility personnel;
- Maintaining a record keeping system that assures continuity of care;
- Maintaining and submitting all required documentation to the ESRD network;
- ESRD related laboratory tests included in the composite rate or in the Method II payment cap (See list in §30.2.1 and §70.2.A);
- Testing and appropriate treatment of water; and
- Monitoring the functioning of the dialysis equipment.

Some covered support services may involve indirect patient contact. The patient, for example, may need to consult with a nurse regarding dietary restrictions or with a social worker if the patient is having problems adjusting.

50.6.1 - Home Health and Hospice Benefits Available for ESRD Beneficiaries (Rev. 1, 10-01-03)

PASS Merritt004 memo

Medicare patients can receive care under both the ESRD benefit and the home health or hospice benefits. The key is whether or not the services are related to ESRD. Surgical dressing changes that are related to an ESRD condition are to be provided by the dialysis facility, but dressing changes for non-ESRD conditions may be provided under the home health benefit provided all eligibility criteria have been met.

50.6.1.1 - Coverage Under the Home Health Benefit for ESRD Patients (Rev. 1, 10-01-03)

Services that are covered under the composite rate are excluded from coverage under the Medicare home health benefit.

However, services can be provided to dialysis patients under the home health benefit as long as the condition that necessitates home health care is not included in the composite rate. A beneficiary, entitled to Medicare under the ESRD program, is eligible for home health benefits as is any other Medicare beneficiary if coverage conditions are met provided the patient's condition is not covered by the composite rate. This is true even where the primary condition is related to kidney failure.

A beneficiary may receive covered services under both the home health benefit and the ESRD benefit. Therefore, when ESRD patients meet all the eligibility criteria for coverage of home health services, Medicare will pay for home health care, such as decubitus care or for severe hypotension that is not included in the composite rate. See 42 CFR 409.49(e).

50.6.1.2 - Coverage for Surgical Dressings (Rev. 1, 10-01-03)

Medicare covers primary and secondary surgical dressings required for the treatment of a wound caused by, or treated by, a surgical procedure, or required after the debridement of a wound, regardless of the type of debridement. A health care professional, to the extent permissible, must perform the surgical procedure or debridement under State law. Surgical dressings are covered for as long as medically necessary.

Primary dressings are therapeutic or protective coverings applied directly to wounds or lesions either on the skin or caused by an opening to the skin. Secondary dressing materials that serve a therapeutic or protective function and that are needed to secure a primary dressing are also covered. Items such as adhesive tape, roll gauze, bandages, and disposable compression material are examples of secondary dressings. Elastic stockings, support hose, foot coverings, leotards, knee supports, surgical leggings, gauntlets, and

pressure garments for the arms and hands are examples of items that are not ordinarily covered as surgical dressings. Some items, such as transparent film, may be used as a primary or secondary dressing.

If a physician, certified nurse midwife, physician assistant, nurse practitioner, or clinical nurse specialist applies surgical dressings as part of a professional service that is billed to Medicare, the surgical dressings are considered incident to the professional services of the health care practitioner. When surgical dressings are not covered incident to the services of a health care practitioner and are obtained by the patient from a supplier (e.g., a drugstore, physician, or other health care practitioner that qualifies as a supplier) on an order from a physician or other health care professional authorized under State law or regulation to make such an order, the surgical dressings are covered separately under Part B.

Abandoned, dysfunctional, or multiple access sites are not necessary for dialysis, so wound care of such sites is not the responsibility of the dialysis facility. Access sites that have been placed in a patient who has not yet started dialysis are also not the responsibility of the dialysis facility. Therefore, dressing changes of this nature are not included in the composite rate. Since the surgical wounds are not related to ESRD, the patient could be eligible for care under the home health benefit. The Home Health Agency would be able to provide the home care services in this instance because the patient is not yet affiliated with a dialysis facility, so the facility cannot provide home support services.

For home health aide services to be covered for surgical dressing changes, a beneficiary must meet the qualifying criteria as specified in the Medicare Benefit Policy Manual, Chapter 7, §20. The services provided by the home health aide must be part-time or intermittent as discussed in the Medicare Benefit Policy Manual, Chapter 7, §40.7. The services must meet the definition of home health aide services as defined in the Medicare Benefit Policy Manual, Chapter 7, “Home Health Services,” §40.2. Also, the services must be reasonable and necessary to the treatment of the patient’s illness or injury. Under the home health benefit, surgical dressings can be provided as a nonroutine medical supply subject to the requirements in the Medicare Benefit Policy Manual, Chapter 7, “Home Health Services,” §40.

In situations in which a new access has been surgically placed in a patient to enable a dialysis facility to provide dialysis treatment and the patient has started dialysis, Medicare would consider this a renal-related service. In this case the patient’s surgical wound is relevant to the patient’s ongoing dialysis treatment, and the patient is affiliated with a dialysis facility. Therefore, the dressing changes would be part of the home support services provided by the dialysis facility.

50.6.1.3 - Distinction Between Dialysis Related and Renal Related Services

(Rev. 1, 10-01-03)

All services, supplies, items, equipment and laboratory services that are related to the dialysis treatment are considered services that are directly related to dialysis. Examples of dialysis-related services include treatment of an infected shunt site, injecting drugs, or routine venipunctures that are necessary to monitor a dialysis patient's condition (e.g. blood urea nitrogen and creatinine test). Nondialysis services that are renal-related are services that are either necessary to provide the dialysis treatment or to ensure a desired outcome of the treatment but is not directly related to dialysis itself. An example of a non-dialysis service that is renal-related would be the procedure and supplies related to the insertion of a subclavian or femoral catheter.

50.6.1.4 - Coverage Under the Hospice Benefit (Rev. 1, 10-01-03)

If the patient's terminal condition is not related to ESRD, the patient may receive covered services under both the ESRD benefit and the hospice benefit. A patient does not need to stop dialysis treatment to receive care under the hospice benefit. Consequently, hospice agencies can provide hospice services to patients who wish to continue dialysis treatment.

50.7 - Water Purification and Softening Systems and Ultrafiltration Monitor (Rev. 1, 10-01-03)

See the Medicare National Coverage Determinations Manual, Chapter 3, §560, for the national coverage determination for water purification and softening systems.

See the Medicare National Coverage Determinations Manual, Chapter 3, §580, for the national coverage determination for ultrafiltration monitor.

50.8 - Coverage of Infacility Dialysis Sessions Furnished to Home Patients Who Are Traveling (Rev. 1, 10-01-03)

A3-3169.3, PR 1-2713.2

Patients who are normally home dialysis patients may be dialyzed by a certified facility on an infacility basis when traveling away from home. Patients who normally dialyze in a facility may wish to dialyze temporarily in another facility or as home dialysis patients while they travel or vacation. (See Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §100, for billing services when traveling.)

50.9 - Antibiotics Furnished to Method II Patients (Rev. 1, 10-01-03) A3-3168.C

If facility staff, in a dialysis facility, administers an antibiotic directly into the patient, the antibiotic may be billed by and paid to the dialysis facility. However, because antibiotics use at home by a patient to treat an infection of the catheter site or peritonitis associated with peritoneal dialysis are covered as home dialysis supplies, they are included in the Method II (Direct Dealing) payment cap for home dialysis supplies administered by the DMERC. As with any supply included in the Method II cap, the patient's Method II sole supplier must furnish these antibiotics either directly or under arrangements.

60 - Training

PR 2725.5 (General)

(Rev. 1, 10-01-03)

Self-dialysis and home dialysis training are programs that train ESRD patients to perform self-dialysis in the facility or home dialysis (including CAPD and CCPD) with little or no professional assistance. They also train other individuals to assist patients in performing self-dialysis or home dialysis. Dialysis training services are reimbursed in accordance with the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §50.8. A facility that has training costs greater than its composite training rate may apply for an exception to its training rate. However, the ESRD facility is responsible for demonstrating that its per treatment costs are reasonable and allowable. The burden of proof is on the facility to establish this fact.

60.1 - Hemodialysis Training

(Rev. 1, 10-01-03)

A3-3172.1, PR 1-2707, PR 1-2725.5.6.6

The average training time for hemodialysis patients is approximately 2 months, based upon 5-hour sessions given 3 times per week. In some dialysis programs, the dialysis partner is trained to perform the dialysis treatment in its entirety. The patient plays a secondary role. In other programs, the patient performs most of the treatment and is only aided by a helper.

Hemodialysis training services and supplies include personnel services; dialysis supplies parenteral items used in dialysis, written training manuals and materials, and laboratory tests covered under the composite rate. See §30.2.1 for these laboratory tests, which are covered during training.

60.2 - Intermittent Peritoneal Dialysis Training (IPD)

(Rev. 1, 10-01-03)

A3-3172.2, A3-3112.6.D

The IPD patients can be trained in approximately four weeks. IPD is usually accomplished in sessions of 10-12 hours. It is sometimes accomplished in fewer sessions

of longer duration. (See the Medicare Claims Processing Manual, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §50.5.) In the IPD program, the patient’s partner is usually trained to carry out the dialytic care. The patient plays a secondary or minimal role, as most are unable to perform self-care dialysis. IPD patients are usually unable to perform self-care dialysis because of other debilitating conditions. Training services and supplies include personnel services, dialysis supplies, parenteral items routinely used in dialysis, written manuals and materials, and laboratory tests covered under the composite rate. These laboratory tests are covered during training. (See §30.2.1).

60.3 - Continuous Ambulatory Peritoneal Dialysis (CAPD) Training
(Rev. 1, 10-01-03)
A3-3172.3, HO-238, B3-2231.2

The CAPD training is furnished in sessions that can last up to 8 hours (one session per day) 5 - 6 days per week. Typically, 6 - 8 CAPD exchanges can be performed per day for the purpose of teaching the patient the CAPD technique; however, no specific number of exchanges is required. Normally patients are trained within 2 weeks (5 - 6 training sessions per week); however, up to 15 sessions (i.e., 15 training days) may be covered routinely. Additional CAPD training sessions are covered only when documented for medical necessity. Extra training sessions raise questions about either the adequacy of CAPD for the patient or the patient’s capacity to learn or perform the CAPD technique. The patient’s physician should address these questions in the explanation of the need for extra training sessions. The intermediary will make a determination whether or not to permit training sessions in excess of 15.

The CAPD training services and supplies include personnel services, dialysis supplies, parenteral items routinely used in dialysis, training manuals and materials, and CAPD laboratory tests included under the composite rate.

The CAPD laboratory tests included under the composite rate are those monthly tests listed in §70.2.A and they are covered during training. The coverage frequency screens for these laboratory tests do not apply during training, as these tests are commonly given during each training session. All of these tests are included in the training screen, regardless of how frequently they are given, and may not be billed separately. However, separately billable laboratory tests must be documented for medical necessity.

A. CAPD Training Furnished to Inpatients

Normally, CAPD training is covered only on an outpatient basis. While CAPD training itself does not justify inpatient status, CAPD training is covered under Part A when furnished during a medically necessary inpatient stay. However, it is not paid separately if it is under a PPS stay. If Part A payment is not made for the stay, the CAPD training sessions would be reimbursed under Part B and be subject to the normal Part B deductible and coinsurance requirements.

B. CAPD Training for Patients Already Trained in Another Mode of Self-Dialysis

Services furnished in training a patient who is already trained in some other form of self-dialysis are covered. Fewer sessions should be required because of the transferability of certain basic skills.

C. Supplemental Dialysis During CAPD Training

It may be necessary to supplement the patient's dialysis during CAPD training with intermittent peritoneal dialysis because the patient has not yet mastered the CAPD technique. Generally, no more than three supplemental intermittent peritoneal dialysis sessions are required during the course of CAPD training, and these may be covered routinely. If more than three sessions are billed during training, the claims must be documented for medical necessity. Under certain circumstances, the form of supplemental dialysis may be hemodialysis.

60.4 - Continuous Cycling Peritoneal Dialysis (CCPD) Training (Rev. 1, 10-01-03)

A3-3172.4

Continuous cycling peritoneal dialysis training is furnished in sessions of eight hours per day five days per week. Typically, five exchanges can be performed per day to teach the patient the technique; however, no specific number of exchanges is required. Most patients are trained within two weeks; however, up to 15 sessions may be covered routinely. The intermediary will determine whether or not training sessions over 15 are medically necessary.

All training services and supplies are covered. These include personnel services, dialysis supplies, parenteral items routinely used in dialysis, training manuals and materials, and CCPD laboratory tests covered under the composite rate and listed in §30.2.1.

70 - Continuous Ambulatory Peritoneal Dialysis (Rev. 1, 10-01-03)

Refer to §10.A.2.a.

70.1 - Certification of Facilities Furnishing CAPD Services (Rev. 1, 10-01-03)

A3-3171.1, B3-2231.1, RDF-240.1

In order to furnish covered CAPD services, a facility must be a Medicare approved ESRD facility and must meet additional standards established by CMS. The CMS requires certification to furnish CAPD training and the CAPD support services described in §70.3.A. Certification is given for both training and support services at the same time;

a facility cannot be certified to provide one and not the other. The survey and certification agency for each state performs the necessary inspections and certifies a facility meets the standards applicable for CAPD.

70.2 - Institutional Dialysis Services Furnished to CAPD Patients (Rev. 1, 10-01-03)

A3-3171.2, B3-2231.2, HO-238.2, RDF-240.2

Once the patient is trained, CAPD is primarily a home service, as the patient performs CAPD 24 hours a day. Therefore (added), institutional dialysis services that are specifically CAPD services are training services and include associated services that are furnished in the facility during training. Persons who are primarily treated by CAPD may also require in facility dialysis, either intermittent peritoneal (IPD) or hemodialysis, occasionally.

A. Laboratory Tests

The following laboratory tests are covered routinely at the frequencies specified below if furnished to a CAPD patient in a certified setting. Any test furnished in excess of this frequency, or any test furnished that is not listed here is covered only if there is documentation of its medical necessity. A diagnosis of ESRD alone is not sufficient medical documentation. The nature of the illness or injury (diagnosis, complaint or symptom) requiring the test(s) must be present on the claims form. Such information must be furnished using the ICD-9-CM coding system. The nature of the illness or injury (diagnosis, complaint, or symptom) requiring the performance of any test not listed here must also be present on the form.

1. Laboratory Tests for CAPD Covered Routinely and Included Under the Composite Rate

Monthly

BUN	Total Protein
Creatinine	Albumin
Sodium	Alkaline Phosphatase
Potassium	LDH
CO2	AST, SGOT
Calcium	HCT
Magnesium	Hgb

Phosphate

Dialysate Protein

2. Laboratory Tests for CAPD Covered Routinely and Separately Billable

Every 3 months

WBC

RBC

Platelet count

Every 6 months

Residual renal Functions

24 hour urine volume

B. Equipment and Water Testing

CAPD does not require the use of any equipment or testing of water because the dialysate is prepared and delivered by the manufacturer. Therefore, neither a dialysis machine nor water testing or water treatment are covered for CAPD patients. Patients changing from another form of home dialysis to CAPD may have their claims for rental or lease-purchase of home dialysis equipment reimbursed up to three months after completing the CAPD training course, in accordance with the coverage tolerance rule in §60.3.

70.3 - Support Services and Supplies Furnished to Home CAPD Patients (Rev. 1, 10-01-03)

A3-3171.3, B3-2231.3, CIM-55-2, HO-238.3, RDF-240.3

The CAPD certification requires facilities furnishing CAPD services to provide directly, or via an agreement or arrangement with another renal dialysis facility (approved to furnish staff-assisted peritoneal dialysis or peritoneal self-dialysis training), the home dialysis services required to support home patients. For beneficiaries choosing Method II (direct dealing), the facility must have a written agreement with the supplier for that beneficiary. Home dialysis support services may be furnished in the home or in the facility. Support services may be provided directly or via an agreement or arrangement with another approved renal dialysis facility (approved to furnish staff-assisted peritoneal dialysis or peritoneal self-dialysis training) or by a physician's direct personal supervision.

A. Home Dialysis Support Services

The full range of home dialysis support services required by home CAPD patients is covered. In addition to the general support services furnished to home hemodialysis patients, support services specifically applicable to CAPD patients include but are not limited to:

1. Changing the connecting tube (also referred to as an administration set);
2. Watching the patient perform CAPD and assuring that it is done correctly, and reviewing for the patient any aspects of the technique they may have forgotten, or informing the patient of modifications in apparatus or technique;
3. Documenting whether the patient has or has had peritonitis that requires physician intervention or hospitalization (unless there is evidence of peritonitis, a culture for peritonitis is not necessary); and
4. Inspection of the catheter site.

The CAPD support services must be furnished periodically (not less than once every 90 days) either directly by the sponsoring CAPD facility or through agreement or arrangement with a facility approved to furnish training in peritoneal self-dialysis or peritoneal staff assisted dialysis. These services will usually be furnished during a periodic follow-up visit, but they may be furnished at separate times. They may be furnished in the facility or in the home.

Normally, the changing of the connecting tube is performed in the facility, and all of the other CAPD support services can be performed at the same time. However, sometimes a member of the facility's staff may go to the patient's home to observe the patient's CAPD technique, take blood samples, etc. In any case, each of the CAPD support services may be covered routinely at a frequency of once per month.

Because these services must be furnished periodically, any claims under Method II for additional support services furnished more frequently than monthly (whether by the sponsoring CAPD facility or under an agreement or arrangement) must be documented to determine if they are reasonable and necessary.

B. Supplies

All supplies required to perform CAPD are covered. These include start-up durable supplies (whether or not they are part of a start-up kit) such as weight scales, sphygmomanometer, I.V. stand, and dialysate heaters; and consumable and disposable supplies such as dialysate, tubing, and gauze pads.

C. Peridex Filter Set

Peridex Filter Set is now located in the Medicare National Coverage Determinations Manual, Chapter 3, §570, as a national coverage determination.

80 - Physician's Services for Renal Dialysis Patients - General (Rev. 1, 10-01-03)

B3-2230.3

Payment for physician's services generally is subject to the guidelines in the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," §30. Medicare pays physician's services furnished in connection with dialysis sessions for outpatients who are on maintenance dialysis in a facility or at home by the monthly capitation payment method or the initial method. (See the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," for payment instructions.)

80.1 - Physicians' Services to an ESRD Inpatient (Rev. 1, 10-01-03)

B3-2230.4

Physicians' services furnished to ESRD patients, who require inpatient hospital care in connection with the renal condition or any other condition, are covered if the carrier determines the services to be reasonable and necessary. Inpatient physician's visits are covered in addition to the composite rate or MCP amount.

80.2 - Physicians' Services - Outpatient Maintenance Dialysis (Rev. 1, 10-01-03)

B3-2230.5, A3-3172.5, B3-2231.4

A physician's services, furnished to dialysis patients who are treated as outpatients, are divided into two major categories: direct patient care and administrative services. See [§80.4](#) for physician services to a kidney donor.

Medicare covers physician services furnished to beneficiaries on CAPD.

A. Direct Patient Care Services

These services are part of the medical treatment furnished to an individual patient that:

1. Are personally furnished by a physician to an individual patient;
2. Contribute directly to the diagnosis or treatment of an individual patient; and
3. A physician must ordinarily perform.

They include:

- Visits to the patient during dialysis, in conjunction with review of laboratory test results, nurses' notes, and any other medical documentation, as a basis for adjustment of the patient's medication or diet or the dialysis procedure, prescription of medical supplies, and evaluation of the patient's psychosocial status and the appropriateness of the treatment modality.
- Medical direction of staff in delivering services to a patient during a dialysis session;
- Pre- and post-dialysis examinations where medically appropriate;
- Insertions of a catheter for patients on maintenance peritoneal dialysis who are not provided an indwelling catheter;
- Services which must be furnished at a time other than during the dialysis procedure; e.g., monthly and semi-annual examinations to review health status and treatment; and
- Other services furnished during dialysis; e.g., declotting of shunts, needle insertions into fistulae, care during immediately life-threatening complications related to the dialysis procedure, and care of nonrenal conditions.

B. Administrative Services

A component of the facility's cost or charge for dialysis is for "administrative services" furnished by physicians. Administrative services are differentiated from physicians' direct patient care services because they constitute supervision of staff or are not directly related to the care of an individual patient, but benefit all patients and the facility as a whole. The administrative type of physician's service are services that are supportive of the facility as a whole and have benefit to patients in general. Examples of such services include participation in management of the facility, advice on and procurement of facility equipment and supplies, supervision of staff, staff training, and staff conferences. The carrier will disallow all claims for these services with an explanation that such services are paid as part of the dialysis services that are included in the facility charge for dialysis.

80.3 - Physicians' Services During Self-Dialysis Training (Rev. 1, 10-01-03)

B3-2230.6, A3-3172.5

A. Initial Training

All physicians' services required creating the capacity for self-dialysis are covered. For example:

1. Direction of, and participation in, training of dialysis patients;
2. Review of family and home status, environment, and counseling and training of family members; or
3. Review of training progress.

B. Subsequent Training

Occasionally, it is necessary to furnish additional training to an ESRD self-dialysis beneficiary after the initial training course is completed, e.g., because of a change from hemodialysis to peritoneal dialysis, a change in equipment. The amount of additional training required depends upon the transferability of the skills the patient has already learned. Subsequent training would normally be very limited. Physicians' training services furnished during subsequent training of an ESRD beneficiary are covered and reimbursed in addition to the initial training fee.

The payment for subsequent training sessions should be based on the amount of \$20 per training session. The total payment for a course of subsequent training may not be based on an amount that exceeds \$500.

Subsequent training sessions that are reimbursable under this rule must be distinguished from the ongoing services for which the original training fee is considered payment in full, e.g., answering the patient's questions arising after home dialysis has begun about the machine the patient has already been trained to use. No additional payment is made after the initial training course unless the subsequent training is required because of a change from the patient's treatment machine to a machine that the patient had not been trained to use in the initial training course, a change in the type of dialysis, or a change in setting or dialysis partner.

80.4 - Physicians' Services for Kidney Transplants

(Rev. 50, Issued: 06-02-06, Effective: 07-03-06, Implementation: 07-03-06)

Expenses for physicians' services to the donor are treated as though the recipient had incurred them. If the recipient dies, donor expenses actually incurred after death of the recipient will be treated as incurred before the death of the recipient.

Immunosuppressive therapy is not included in the 90-day global fee and is paid separately.

A comprehensive payment is also made when the surgeon performs other surgical procedures, e.g., splenectomy and/or nephrectomy at the time of the transplant. The

Medicare Part B carrier revises the payments, subject to the deductible and coinsurance requirements and the participating/nonparticipating physician rules, annually.

Payment for physician services to a live donor provided in connection with a kidney donation to an entitled beneficiary is made at 100 percent of the allowed amount. These services include the donor's preoperative surgical care, kidney excision inpatient stay and any subsequent related postoperative period. There is no deductible or coinsurance charged for services furnished to live donors. The Part B claim includes the name, address, and health insurance number of the recipient as well as the name and address of the live donor.

90 - Epoetin (EPO) **(Rev 8, 03-19-04)**

A3-3168.D, PR 1-2710.3, RDF-207.5, B3-4273

Erythropoietin produced primarily in the kidney, is the principal factor regulating red blood cell production. Epoetin alfa (EPO) and darbepoetin alfa (Aranesp) are biologicals that work in the same way as endogenous erythropoietin. EPO and Aranesp are covered under the Part B benefit for the treatment of anemia associated with ESRD patients who are on dialysis.

Epoetin is a biologically engineered protein that stimulates the bone marrow to make new red blood cells. Epogen and Aranesp are both FDA approved for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis. EPO/Aranesp is covered for this indication when it is furnished incident to a physician's service. Generally, ESRD patients with symptomatic anemia considered for initiation of EPO/Aranesp therapy should have a hematocrit less than 30 or hemoglobin less than 10; ESRD patients who have been receiving EPO/Aranesp therapy should have a hematocrit between 30 and 36.

In addition to coverage incident to a physician service, EPO/Aranesp is covered for the treatment of anemia for ESRD patients who are on maintenance dialysis when:

- It is administered in the renal dialysis facility; or
- It is self-administered in the home by any dialysis patient (or patient caregiver) who is determined competent to administer the drug and meets the other conditions detailed below;
- Both Method I (Composite Rate) and Method II (direct dealing) beneficiaries may obtain coverage for self-administered EPO/Aranesp. For Method II home patients, their single supplier of home dialysis equipment and supplies would furnish the EPO/Aranesp and bill Medicare through the DMERC. If an ESRD facility provides EPO/Aranesp, the facility would bill the intermediary.

NOTE: Payment may not be made for EPO/Aranesp under the incident to provision when EPO/Aranesp is administered in the renal facility. Program payment may not be made for EPO/Aranesp furnished by a physician to a home patient for self-administration.

For payment of EPO/Aranesp, see the Medicare Claims Processing Manual, Chapter 8, "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," §60.4.

Medicare covers EPO/Aranesp including items related to its administration for dialysis patients who use EPO/Aranesp in the home when the following conditions are met:

A. Patient Care Plan

A dialysis patient who uses EPO/Aranesp in the home must have a care plan for monitoring home use of EPO/Aranesp that includes the following:

1. Review of diet and fluid intake for aberrations as indicated by hyperkalemia and elevated blood pressure secondary to volume overload;
2. Review of medications to ensure adequate provision of supplemental iron;
3. Ongoing evaluations of hematocrit and iron stores;
4. Reevaluation of the dialysis prescription taking into account the patient's increased appetite and red blood cell volume;
5. Method for physician follow-up on blood tests and a mechanism (such as a patient log) for keeping the physician informed of the results;
6. Training of the patient to identify the signs and symptoms of hypotension and hypertension; and
7. The decrease or discontinuance of EPO/Aranesp if hypertension is uncontrollable.

B. Patient Selection

The dialysis facility, or the physician responsible for all dialysis-related services furnished to the patient, must make a comprehensive assessment that includes the following:

1. Pre-selection monitoring - The patient's hematocrit (or hemoglobin), serum iron, transferrin saturation, serum ferritin, and blood pressure must be measured.
2. Conditions the patient must meet - The assessment must find that the patient meets the following conditions:

- a. Is a dialysis patient;
- b. Has a hematocrit (or comparable hemoglobin level) that is as follows:

For a patient whom is initiating EPO/Aranesp treatment, no higher than 30 percent unless there is medical documentation showing the need for EPO/Aranesp despite a hematocrit (or comparable hemoglobin level) higher than 30 percent. Patients with severe angina, severe pulmonary distress, or severe hypotension may require EPO/Aranesp to prevent adverse symptoms even if they have higher hematocrit or hemoglobin levels.

For a patient who has been receiving EPO/Aranesp from the facility or the physician, between 30 and 36 percent; and

- c. Is under the care of:

A physician who is responsible for all dialysis-related services and who prescribes the EPO/Aranesp and follows the drug labeling instructions when monitoring the EPO home therapy; and

A renal dialysis facility that establishes the plan of care and monitors the progress of the home EPO/Aranesp therapy.

3. The assessment must find that the patient or a caregiver meets the following conditions:
 - Is trained by the facility to inject EPO/Aranesp and is capable of carrying out the procedure;
 - Is capable of reading and understanding the drug labeling;
 - Is trained in, and capable of observing, aseptic techniques; and
 - Is capable of understanding and implementing a plan for the care and storage of a drug. The assessment must find that EPO/Aranesp can be stored in the patient's residence under refrigeration and that the patient is aware of the potential hazard of a child's having access to the drug and syringes.

C. Responsibilities of Physician or Dialysis Facility

The patient's physician or dialysis facility must:

- Develop a protocol that follows the drug label instructions;

- Make the protocol available to the patient to ensure safe and effective home use of EPO/Aranesp;
- Through the amounts prescribed, ensure that the drug on hand at any time does not exceed a 2-month supply;
- Maintain adequate records to allow quality assurance for review by the network and State survey agencies. For Method II patients, current records must be provided to and maintained by the designated back-up facility; and,
- Submit claims for EPO in accordance with the Medicare Claims Processing Manual, Chapter 8, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §60.4.1.
- Submit claims for Aranesp in accordance with the Medicare Claims Processing Manual, Chapter 17, “Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims,” §60.7.1.

100 - Hemofiltration

(Rev. 1, 10-01-03)

A3-3174

Hemofiltration is a covered procedure under the Medicare program. Payment for this procedure is at the composite rate. Hemofiltration is a safe and effective alternative treatment to hemodialysis and is performed in three weekly sessions. While the procedure may be used for any ESRD patient, it appears to be most advantageous when applied to high-risk unstable patients such as older patients with cardiovascular diseases or diabetes, since it is associated with fewer side effects such as hypotension, hypertension, or volume overload.

Hemofiltration is a new method of blood purification for the removal of toxic substances that accumulate in patients with renal insufficiency. In contrast to both hemodialysis and peritoneal dialysis treatments, which eliminate dissolved substances via diffusion across semipermeable membranes, hemofiltration mimics the filtration process of the normal kidney. Solutes are removed by the use of convective transport through semipermeable membranes in a manner similar to that of the glomerular membrane of the normal kidney. The technique requires an arteriovenous access. Hemofiltration is usually performed in a facility; since the technique is new to this country, it is unlikely that it will be performed in the home.

110 - Hemoperfusion

(Rev. 1, 10-01-03)

A3-3175

General

Hemoperfusion is covered under Medicare when furnished as described below for the types of covered conditions described in this instruction. Contractors should use the following as general guidelines of what may be considered covered. As with all items and services, the services must be reasonable and necessary for the diagnosis or treatment of the specific patient involved.

Hemoperfusion is an extracorporeal technique, which uses activated charcoal or ion-resins as an artificial kidney for the removal of toxic substances from the blood and for the treatment of acute and chronic renal failure.

A. Covered

Hemoperfusion is a covered service when it is used in the treatment of life-threatening drug overdose, for patients with or without renal failure effective for services performed on or after September 1, 1979. Hemoperfusion generally requires a physician to be present to initiate treatment and to be present in the hospital or an adjacent medical office during the entire procedure as changes may be sudden. Special staff training and equipment are required.

One or two treatments are usually all that is necessary to remove the toxic compound; additional treatments should be documented. Hemoperfusion may be performed concurrently with dialysis, and in those cases payment for the hemoperfusion should reflect only the additional care rendered over and above the care given for the dialysis.

In addition, the use of hemoperfusion in conjunction with deferoxamine (DFO) for the treatment of patients with aluminum toxicity has been demonstrated to be clinically efficacious and is therefore regarded as a covered service.

B. Noncovered

The effects of using hemoperfusion to improve the results of chronic hemodialysis are not known. Therefore, when used for this purpose, hemoperfusion is not covered because it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the law. In addition, it has not been demonstrated that the use of hemoperfusion in conjunction with deferoxamine (DFO), in treating symptomatic patients with iron overload, is efficacious. There is also a paucity of data regarding its efficacy in treating asymptomatic patients with iron overload. Therefore, hemoperfusion used in conjunction with DFO in treating patients with iron overload is not a covered service; i.e., it is not considered reasonable and necessary within the meaning of §1862(a)(1) of the law.

120 - Skilled Nursing Facility (SNF) Patients Needing Dialysis Services (Rev. 1, 10-01-03)

B3-4210.3, PM AB-01-129

Section 4432(b) of the Balanced Budget Act (BBA) requires consolidated billing for SNFs. Under the consolidated billing requirement, the SNF must submit Medicare claims to the fiscal intermediary (FI) for all the Part A and Part B services that its residents receive during the course of a covered Part A stay, except for certain excluded services. The consolidated billing requirement essentially confers on the SNF itself the Medicare billing responsibility for the entire package of care that its Part A residents receive, except for a limited number of specifically excluded services. Dialysis and certain dialysis-related services including covered ambulance transportation to obtain the dialysis services are excluded from consolidated billing and the services may be billed separately according to the chart below. Erythropoietin for certain dialysis patients is also excluded from SNF consolidated billing and may be billed by the rendering provider.

SNF Patients Needing Dialysis Services Billing Chart

	Scenario	Billing is done by the SNF	Billing is done by the Dialysis Facility	Billing is done by the DME Supplier
A	Part A covered stay in Medicare certified SNF. Dialysis services are furnished in SNF by a dialysis facility under arrangements with SNF. Patient has not elected home dialysis.	Dialysis services would be included in the global per diem payment that the SNF receives for the covered Part A stay under the Prospective Payment System (PPS).	NOT APPLICABLE. SNF made arrangements. Dialysis was not performed on the premises of the dialysis facility.	NOT APPLICABLE. Services were furnished under arrangement by the SNF.
B	Part A covered stay in Medicare certified SNF. Services furnished by SNF without any involvement from the dialysis facility. Patient has not elected home dialysis.	The dialysis services would be included in the global per diem payment that the SNF receives for the covered Part A Stay under the PPS.	NOT APPLICABLE. Services were furnished by SNF and not by the ESRD facility.	NOT APPLICABLE. Services were furnished by SNF and not by a DME supplier.
C	Part A covered stay in Medicare certified SNF. Services furnished on site at a Medicare certified ESRD facility.	NOT APPLICABLE. SNF must elect to unbundle dialysis services from SNF Consolidated Billing in order to have dialysis provided on site at a certified ESRD facility. The SNF would still receive the global per diem payment for the	Dialysis facility bills for services under Part B.	NOT APPLICABLE. Services were rendered by dialysis facility and not by supplier in connection with home dialysis.

	Scenario	Billing is done by the SNF	Billing is done by the Dialysis Facility	Billing is done by the DME Supplier
		covered Part A stay (excluding the dialysis services) under the PPS.		
D	Part A covered stay in SNF. Services furnished in SNF to patient who has elected home dialysis and who has received training.	NOT APPLICABLE. SNF must elect to unbundle dialysis services from SNF Consolidated Billing in order for a patient to elect home dialysis under Part B. The SNF would still receive the global per diem payment for the covered Part A stay (excluding the dialysis services) under the PPS.	If a beneficiary is a Method I patient, the dialysis facility bills Medicare Part B for the supplies, equipment and the support services. If a beneficiary is a Method II patient, the dialysis facility only bills Medicare Part B for support services.	If beneficiary is a Method II patient, supplier bills Medicare Part B for the supplies and equipment.
E	Part B covered patient in Medicare certified SNF. No part A covered stay. Services furnished in SNF by dialysis facility under arrangements with SNF. Patient has not elected home dialysis.	NOT APPLICABLE. Since the patients Part A coverage has been exhausted, the SNF would not receive any Medicare reimbursement for providing the dialysis treatment.	NOT APPLICABLE.	NOT APPLICABLE.
F	Part B covered patient in Medicare certified SNF. No Part A covered stay. Services furnished by SNF	NOT APPLICABLE. Since the patient's Part A coverage has been exhausted, the SNF would not receive any Medicare	NOT APPLICABLE.	NOT APPLICABLE.

	Scenario	Billing is done by the SNF	Billing is done by the Dialysis Facility	Billing is done by the DME Supplier
	without any involvement from the facility. Patient has not elected home dialysis.	reimbursement for providing the dialysis treatment.		
G	Part B covered patient in Medicare certified SNF. No Part A stay. Services are furnished on site at certified ESRD facility.	NOT APPLICABLE.	Dialysis facility bills for outpatient dialysis services under Part B.	NOT APPLICABLE.
H	Part B-covered patient in Medicare certified SNF. No Part A covered stay. Services furnished in SNF. Patient has elected home dialysis and has received training.	NOT APPLICABLE.	If beneficiary is Method I home patient, dialysis facility bills Part B for providing the dialysis equipment, supplies and support services to the home dialysis patient in the SNF. If Method II, the dialysis facility bills Part B for support services provided to the home dialysis patient in the SNF.	If a Method II home dialysis patient, DME supplier bills Part B for providing dialysis equipment and supplies to the home dialysis patient in the SNF.
I	Part B covered patient in non-Medicare certified SNF.	NOT APPLICABLE. Non-Medicare certified SNF is not eligible to bill under the consolidated billing.	If the patient receives outpatient dialysis, the dialysis facility would bill for outpatient dialysis services under Part B. If the patient elects home dialysis under Method I home, the dialysis facility bills Part B for providing the dialysis	If a Method II home dialysis patient, DME supplier bills Part B for providing dialysis equipment and supplies to the home dialysis patient

	Scenario	Billing is done by the SNF	Billing is done by the Dialysis Facility	Billing is done by the DME Supplier
			equipment, supplies and support services to the home dialysis patient in the SNF. If Method II, the dialysis facility bills Part B for support services provided to the home dialysis patient in the SNF.	in the SNF.

130 - Inpatient Hospital Dialysis (Rev. 1, 10-01-03)

A3-3173, A3-3173.1, A3-3173.2

Dialysis services provided by any participating Medicare hospital are covered if the inpatient stay is medically necessary and the primary reason for the admission is not maintenance dialysis. Reimbursement for the maintenance dialysis is included in the PPS reimbursement for the DRG that represents care for the actual reason for admission.

In many cases, ESRD patients who require inpatient care are experiencing complications that affect the nature of the dialysis services. Payment for medically necessary inpatient dialysis is not subject to the composite rate.

A hospital may decide not to provide dialysis services directly to an inpatient. In this situation, the hospital must make arrangements with a certified ESRD facility to provide the dialysis services.

Inpatient dialysis services are also covered if an ESRD emergency occurs. However, when the emergency is over, outpatient maintenance dialysis must be performed in an ESRD certified facility or coverage will be denied. The intermediary should examine all claims for inpatient dialysis services, from hospitals that are not certified under the ESRD conditions for coverage, to ensure that one or more of these special situations exist.

130.1 - Inpatient Dialysis in Nonparticipating Hospitals (Rev. 1, 10-01-03)

A3-3173.3

Emergency inpatient dialysis services provided by a nonparticipating U.S. hospital are covered if the requirements in §130 above are met.

130.2 - Extended Intermittent Peritoneal Dialysis (Rev. 1, 10-01-03)

A3-3173.4

Extended intermittent peritoneal dialysis (EIPD) is performed once a week, usually for 30 hours or more, and is provided in the hospital due to the duration of treatment. Although the services are provided in the hospital, they are billed as outpatient maintenance dialysis services and reimbursed under Part B as long as the patient is not admitted as an inpatient for another reason. EIPD is an acceptable, but not optimal mode of treatment, appropriate only when the patient cannot attend a facility two or three times a week, for geographic or other reasons, and is not suited for home dialysis. (See §30.1.)

130.3 - Services Provided Under an Agreement

(Rev. 1, 10-01-03)

A3-3173.5

An approved ESRD facility may make a written **agreement** with a second facility under which the second facility furnishes certain covered outpatient dialysis items or services to patients. When services are provided under an agreement, the first facility is discharged from professional responsibility for the services furnished. The second facility is responsible for obtaining reimbursement directly from the Medicare program and the beneficiary, but may not bill the beneficiary for amounts in excess of the normal coinsurance and any applicable deductible.

130.4 - Services Provided Under an Arrangement **(Rev. 1, 10-01-03)**

A3-3173.6

An approved ESRD facility may make written **arrangements** with a second facility to provide certain covered outpatient dialysis items or services to patients. When services are provided under an arrangement, the first facility retains professional responsibility for those services and also for obtaining reimbursement for them. The first facility may bill the patient any applicable coinsurance and deductible amounts. The second facility is permitted to seek payment only from the first facility, and may not bill the patient or the Medicare program.

130.5 - Dialysis Services Provided Under Arrangements to Hospital Inpatients **(Rev. 1, 10-01-03)**

A3-3173.7

Any nonphysician service provided to a hospital inpatient must either be provided directly by the hospital or be arranged for by the hospital. (See the Medicare Claims Processing Manual, Chapter 1, “General Billing Requirements.”) Therefore, a hospital may not contract an agreement as described in §130.3 above, for care (except for physician’s care) provided to its inpatients.

140 - Transplantation **(Rev. 1, 10-01-03)**

A3-3178, PR 1-2770, RDF-230

Introduction

Renal transplantation is a principal form of treatment for patients with ESRD. Medicare has developed a method of reimbursement for the variety of medical services required to

support a transplant program, including payment for Medicare's share of the costs of organ procurement.

In addition, Medicare has developed coverage and reimbursement criteria for necessary medical services provided to potential donors and recipients. In some situations, these services are provided before the effective date of Medicare entitlement for the potential transplant recipient.

Medicare pays for the covered services provided a Medicare patient who receives a living or cadaveric transplant. A certified transplant center's (CTC) or organ procurement organization's (OPO) expenses in providing kidneys are included in the transplant provider's living or cadaveric kidney acquisition cost center. To participate in the Medicare program, any CTC or OPO must be a member of the Organ Procurement and Transplantation Network (OPTN). The CTC is required to notify the OPO designated for its service area of potential donors. (See the Medicare Provider Reimbursement Manual, Part 1, §§2771, for rules in developing a living and cadaveric acquisition charge.)

See the OPTN Web site at <http://www.optn.org/members/search.asp> or a search facility for various transplant centers, including kidney transplant centers.

140.1 - Identifying Candidates for Transplantation (Rev. 1, 10-01-03)

A3-3178.1, RDF-231

After a patient is diagnosed as having ESRD, the physician should determine if the patient is suitable for transplantation. If the patient is a suitable transplant candidate, a live donor transplant is considered first because of the high success rate in comparison to a cadaveric transplant. Whether one or multiple potential donors are available, the following sections provide a general description of the usual course of events in preparation for a live-donor transplant.

140.2 - Identifying Suitable Live Donors (Rev. 1, 10-01-03)

A3-3178.2, RDF-231

Those who are willing and medically able to donate a kidney are tested to determine whether they are of the same blood type as the recipient. After blood typing, the recipient and the donors are tissue typed. Only those candidates with blood and tissue types similar to the recipient are considered further.

After tissue typing, those medically suitable donors are evaluated on physical, psychological, and social factors. Potential donors who remain after the above testing may be hospitalized for about two days for further evaluation using procedures not

appropriately performed on outpatients. These procedures may include intravenous urography and renal arteriography.

If the results of the above tests identify several suitable donors, the most suitable donor is selected, and arrangements are made for the transplant. At such time, the donor and recipient will enter the hospital to undergo the excision and transplantation, respectively.

When tests do not identify an acceptable living donor, the patient is considered for a cadaveric transplant and placed on hemo- or peritoneal dialysis, if this has not already proved necessary. If the ultimate goal is transplantation, the patient is registered with a kidney transplant registry.

140.3 - Pretransplant Outpatient Services (Rev. 1, 10-01-03)

A3-3178.3

All hospital outpatient services provided to live donors and recipients in anticipation of a transplant during the preentitlement period and after entitlement, but prior to admission to the hospital for transplantation, are covered. Such services would include kidney recipient registration fees, laboratory tests (including tissue typing of recipient and donors), and general medical evaluations of the recipient and the donor(s). Pretransplant physicians' services are also covered.

140.4 - Pretransplant Inpatient Services (Rev. 1, 10-01-03)

A3-3178.4

The following rules apply to kidney transplant inpatient medical evaluations when the kidney recipient has Medicare entitlement or is in the preentitlement period. The preentitlement period is that period prior to the patient's actual Medicare entitlement, during which services are furnished in anticipation of a transplant, after the patient has been diagnosed to have end stage renal disease. If the potential kidney recipient does not have entitlement, or is not in the preentitlement period, no services rendered to the kidney recipient or to the related living donor for kidney transplant the Medicare program will cover medical evaluations.

140.5 - Living Donor Evaluation, Patient Has Entitlement or is in Preentitlement Period (Rev. 1, 10-01-03)

A3-3178.5, RDF-233.1

When a living donor is admitted to a hospital (before admission for excising the donor kidney) for a medical evaluation in anticipation of a kidney donation, all hospital and

physicians' services costs applicable to medical evaluation are considered kidney acquisition service costs. As such, the hospital statistics (charges, patient days, etc.) and the physicians' charges should be treated in accordance with all other kidney acquisition service statistics and the related costs are included in Medicare costs.

When the live donor subsequently enters the hospital for the actual excision, the hospital costs of services rendered to the donor will continue to be treated as kidney acquisition service costs under Part A. However, at that point physician services are no longer considered kidney acquisition services and are not reimbursable under Part A. Instead, during the donor's inpatient stay for the excision surgery and during any subsequent donor inpatient stays resulting from a direct complication of the organ donation, physician services are billed under Part B. They are billed in the normal manner but on the account of the recipient at 100 percent of the fee schedule. Note that services furnished to kidney donors are covered under the account of the recipient.

Services listed in the following sections are also covered. However, they are not billed as such but become a part of the kidney acquisition costs.

140.6 - Kidney Recipient Admitted for Transplant Evaluation (Rev. 1, 10-01-03)

A3-3178.6, RDF-233, RDF-233.2

When a potential recipient is admitted to a hospital (before admission for the actual transplant) solely for a medical evaluation for an anticipated kidney transplant, all hospital and physicians' services costs applicable to the anticipated transplant are considered kidney acquisition service costs.

140.7 - Kidney Recipient Evaluated for Transplant During Inpatient Stay (Rev. 1, 10-01-03)

A3-3178.7, RDF-233.3

When a recipient is admitted to a hospital for a medical reason other than in anticipation of a transplant, but during the stay, a medical evaluation for an anticipated kidney transplant is performed, all hospital and physicians' services costs applicable to the medical evaluation are considered kidney acquisition service costs. Accordingly, those services will be treated the same as the services above. However, all hospital and physicians' services applicable to the nontransplant related services (i.e., related to the medical services for which the patient was actually admitted) must not be included with kidney acquisition services costs; instead such services must be billed in the same manner as any other inpatient service on the account of the recipient. These latter services may be billed to the Medicare program only if the recipient has actual Medicare entitlement.

140.8 - Kidney Recipient Admitted for Transplantation and Evaluation

(Rev. 1, 10-01-03)

A3-3178.8, RDF-233.4

When the medical evaluation for a transplant is performed on the recipient or the living donor during the same inpatient stay in which the actual transplant occurs, all such services will be billed, and the costs will be accumulated in the normal manner. For example, all hospital services rendered to the donor will be considered kidney acquisition services. However, all physicians' services rendered to the living donor and all hospital and physicians' services rendered to the recipient will be billed in the same manner as any other inpatient services on the account of the recipient.

140.9 – Post-transplant Services Provided to Live Donor

(Rev. 148, Issued: 10-28-11; Effective: Policy Effective date: November 28, 2011; Claims Processing Effective date: April 1, 2012; Implementation: April 2, 2012)

The donor *of an organ for a Medicare transplant beneficiary* is covered for an unlimited number of days of care in connection with the *organ* removal operation. Days of inpatient hospital care used by the donor *in connection with the organ removal operation shall* not be charged against either party's utilization record. However, the program's assumption of liability is limited to those donor expenses that are incurred directly in connection with the *organ* donation.

Coverage of *organ* donor services includes postoperative recovery services directly related to the *organ* donation. *For routine follow-up care* the period of postoperative recovery ceases when the donor no longer exhibits symptoms related to the kidney donation. Claims for services rendered more than 3 months after donation surgery will be reviewed. However, follow-up examinations may be covered up to 6 months after the donation to monitor for possible complications. The requirement that additional payment cannot be made for services included in the donor's *organ removal* charge still applies.

Regarding donor follow-up:

Expenses incurred by the transplant center for routine donor follow-up care are included in the transplant center's organ acquisition cost center.

Follow-up services performed by the operating physician are included in the 90-day global payment for the surgery. Beyond the 90-day global payment period, follow-up services are billed using the recipient's health insurance claim number.

Follow-up services billed by a physician other than the operating physician for up to 3 months following donation surgery should be billed under the recipient's health insurance claim number.

Regarding donor complications:

Expenses incurred for complications that arise with respect to the donor are covered only if they are directly attributable to the donation surgery. Complications that arise after the date of the donor's discharge will be billed under the recipient's health insurance claim number. This is true of both facility cost and physician services. Billings for donor complications will be reviewed.

In all of these situations, the donor is not responsible for co-insurance or deductible.

140.10 - Coverage After Recipient Has Exhausted Part A (Rev. 1, 10-01-03)

A3-3178.11

If the recipient has exhausted Part A benefits while the donor still requires and receives inpatient hospital care, the program continues to pay for such donor care under Part A at 100 percent reimbursement.

140.11 - Cadaver Kidneys (Rev. 1, 10-01-03)

A3-3178.12

Costs incurred by the provider in connection with the acquisition of a cadaver kidney are reimbursable by the program through the kidney acquisition cost center. Typical covered costs involved in excising the cadaver kidney include: surgeons' service, operating room, anesthetist, donor evaluation and support, preservation supplies (perfusion materials and equipment), preservation technician, telephone consultation charge, intensive care costs, pathology, central supply costs, organ transportation costs, and transportation costs for a technician. There is no provision in the law for coverage of charges by an agent transporting a kidney for transplant into an eligible beneficiary, if the agent bills the program or the patient directly. However, reimbursement may be made to hospitals and included in kidney acquisition costs.

140.12 - Services Involved (Rev. 1, 10-01-03)

A3-3178.13, RDF-232

When there is no suitable living donor, a patient with renal failure may be considered for a cadaveric transplant. In such cases, the services provided to recipients of "live donor" kidneys (i.e., tissue typing and other related tests) are also provided to potential recipients of cadaver kidneys. However, because a kidney may not be available for a long period of time, additional services may be provided in the form of direct physician care for the patient's renal condition, and certain tests may be performed on a regular basis to allow the physician to have current information regarding the status of the patient and his or her suitability for transplant. In addition, the number of mixed lymphocyte cultures which

are prepared whenever a kidney is procured that may suit the recipient depends on the number of kidneys which become available for transplant. The cost of registering a potential recipient with a kidney transplant registry is also covered, as well as the services furnished to maintain organ viability after excision, i.e., preservation, and transporting the kidney to the place of transplantation.

140.13 - Tissue Typing Services for Cadaver Kidney (Rev. 1, 10-01-03)

A3-3178.14

Tissue typing services for cadaveric kidney recipients are treated in a similar manner to the way in which such services are covered and reimbursed in live donor cases. Tissue typing of the cadaveric organ by the excising hospital becomes an organ acquisition cost that is included in the charges for organs, which are supplied by the hospital.

140.14 - Cadaver Excision Yielding Two Kidneys (Rev. 1, 10-01-03)

A3-3178.15

When two kidneys are obtained from a cadaver, and both kidneys are shipped to the same transplant hospital or organ procurement agency, the hospital should adjust its normal charges to reflect any increased perfusion, preservation, and shipping costs due to the additional kidney. On the other hand, when the kidneys are sent to separate organizations or transplant hospitals, the excising hospital should prorate its charges to the receiving organizations so that the total charges do not exceed the amount that would have been billed if one transplant hospital or agency had received both kidneys.

140.15 - Provider Costs Related to Cadaver Kidney Excisions (Rev. 1, 10-01-03)

A3-3178.16

Typical provider costs involved in excising a cadaver kidney whether or not it is eventually transplanted include:

- Intensive care costs;
- Surgeon's services - anesthetist services, operating room, preservation supplies (perfusion materials and equipment), preservation technician's services, donor evaluation and support, pathology, central exchange costs (transportation and packaging), and administration costs (overhead items).

140.16 - Noncovered Transplant Related Items and Services (Rev. 1, 10-01-03)

A3-3178.17

The following list represents some of the transplant related items and services which are not covered and for which no program payment can be made:

- Travel, room, and board expenses incurred by a live donor;
- Travel, room, and board expenses (to any transplant center) incurred by the recipient;
- Reimbursement for the kidney itself when the live donor or the cadaver donor's next of kin sells the kidney;
- Transportation of the potential cadaveric donor to the transplant hospital (only transportation of the organ is reimbursable as part of the organ procurement charge); or
- Pronouncement of death and burial expenses for the cadaveric donor.

140.17 - Other Covered Services (Rev. 1, 10-01-03)

A3-3178.18

A. Tissue Typing

Tissue typing of the recipient, as well as tissue typing and tests to determine the suitability of a living donor or a cadaveric kidney, are covered as medical expenses, necessary for the treatment of an eligible recipient. The costs of these services are covered under the hospital insurance or medical insurance programs (Part B coverage after recipient has exhausted Part A), and are reflected in the kidney acquisition costs.

B. Preservation Laboratories

The services performed by preservation laboratories are medically necessary for the treatment of a beneficiary's illness. A participating hospital is reimbursed for the reasonable cost of such services which its own laboratory performs or which the hospital purchases from a freestanding preservation laboratory or organ procurement agency.

C. Registration Fees

A participating hospital which expects to perform a kidney transplant will be reimbursed for the reasonable cost incurred in listing the patient and the patient's blood characteristics with a professionally recognized organization that maintains a registry of

potential transplant candidates, and which provides a regular listing of such patients to hospitals engaged in kidney procurement.

140.18 - Hospitals that Excise but Do Not Transplant Kidneys
(Rev. 1, 10-01-03)

A3-3178.19, PR 1-2772

The excising hospital plays an important part in the national organ procurement effort. Most of these hospitals are community hospitals and neither excise kidneys on a regular basis nor perform transplants. A hospital that excises but does not transplant kidneys must be certified to participate in the Medicare program. Where the hospital is not participating in the Medicare program, organs may be accepted from it only if they cannot be obtained from any other source.

A hospital that excises but does not transplant kidneys may perform excisions on cadavers or on live donors; however, regardless of the vital status of the donor, most of the hospital services utilized in the excision are the same.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R148BP</u>	01/28/2011	Billing for Donor Post-Kidney Transplant Complication Services	04/02/2012	7523
<u>R136BP</u>	01/28/2011	Clarification of Existing Policy Regarding Items and Services Included Under End Stage Renal Disease (ESRD) Composite Payment Rate	02/25/2011	7312
<u>R98BP</u>	12/12/2008	Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year 2009	01/05/2009	6216
<u>R83BP</u>	02/15/2008	Clinical Lab: New Automated Test for the AMCC Panel Payment Algorithm	07/07/2008	5874
<u>R67BP</u>	03/09/2007	2007 Update to the End Stage Renal Disease Composite Payment Rates	04/02/2007	5535
<u>R61BP</u>	11/24/2006	Implementation of Changes in End Stage Renal Disease (ESRD) Payment for Calendar Year (CY) 2007	01/02/2007	5407
<u>R50BP</u>	06/02/2006	Immunosuppressive Therapy For Kidney Transplant	07/03/2006	4143
<u>R44BP</u>	02/10/2006	Update to the ESRD Composite Payment Rate	02/13/2006	4291
<u>R35BP</u>	06/03/2005	Automated Multi-Channel Chemistry (AMCC) for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Non-CAPD Patients	07/05/2005	3802
<u>R27BP</u>	11/23/2004	New ESRD Composite Payment Rates Effective January 1, 2005	01/03/2005	3554
<u>R08BP</u>	03/05/2004	Policy Changes to Reflect Billing for Darbepoetin Alfa and Epoetin	04/05/2004	2984

<u>R07BP</u>	02/20/2004	Restoring Composite Rate Exceptions for Pediatric Facilities Under the ESRD Composite Rate System	04/01/2004	3119
<u>R01BP</u>	10/01/2003	Introduction to the Benefit Policy Manual	N/A	N/A

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