

Dialysis Information Fact Sheet

What is dialysis?

Dialysis is a form of medical treatment that removes the body's wastes directly from the blood of people who have lost kidney function. Dialysis replaces some of the functions that the kidneys can no longer perform. There are two forms of dialysis: hemodialysis (also called artificial kidney treatment) and peritoneal dialysis.

ESRD

End Stage Renal Disease has the same meaning as the term irreversible chronic kidney failure, or that stage of kidney damage requiring dialysis or kidney transplantation to sustain life. Diabetic nephropathy, glomerulonephritis, and severe hypertension which leads to arteriolar nephrosclerosis are the disorders that cause three fourths of the ESRD in the United States.

Hemodialysis

Hemodialysis is a form of dialysis that uses an artificial kidney machine to remove excess fluids and waste products from the bloodstream. A vascular access, also called a dialysis shunt or fistula, is surgically implanted in the arm or leg, and blood is taken from the access usually through a needle inserted into the artery end of the access. A tube is attached to the needle and carries blood to the dialysis machine. With the assistance of a blood pump, the heart pumps blood through the tube to the machine, where it is cleansed by a dialyzer (artificial kidney). It then returns to the body through a tube attached to a needle which has been inserted into the vein end of the access. The blood is continuously circulated; only about a pint is outside the body at any time. Most hemodialysis treatments are performed in an outpatient dialysis clinic, but dialysis patients and/or partners can be trained to perform home hemodialysis under the supervision of the outpatient dialysis clinic.

Peritoneal Dialysis

Peritoneal dialysis is another method of removing waste, extra salt and fluid from the body. However, instead of using an artificial kidney, as in hemodialysis, the lining of the abdominal cavity is used. A peritoneal dialysis catheter is surgically implanted in the abdomen. A specially prepared solution called peritoneal dialysate is dripped into the abdomen through the catheter. After a specified length of time, the used dialysate is allowed to flow out of the abdominal cavity through the catheter. After it has drained, fresh dialysate is sent back in and the process is repeated several times per day. Each cycle of solution in and out is called an exchange. This is called continuous ambulatory peritoneal dialysis (CAPD). Peritoneal dialysis is a self care modality performed at home or the office by the patient.

Automated Peritoneal Dialysis (APD, CCPD, IPD) is performed with a cyclor, usually at night while the patient sleeps.

Transplantation

A kidney transplant is an alternative treatment for kidney failure. In transplantation, a kidney from a living relative, friend or from an unrelated person who has just died is removed and surgically placed into the body. A successful transplant provides a quality of life closer to that of a healthy person, unless there are complications from the medications that must be taken to prevent the body from rejecting the kidney. A referral is made by the nephrologist, nursing team or patient to a transplant center where a team of doctors evaluates their candidacy.

Industry Regulations

Dialysis facilities are subject to rules of several federal agencies including the Health Care Financing Administration (HCFA), the Occupational Safety and Health Administration (OSHA), and the Centers for Disease Control and Prevention (CDC), and a number of specific federal laws including the Americans With Disabilities Act (ADA), the Clinical Laboratory Improvement Amendments of 1990 (CLIA), and water quality and dialyzer reuse standards developed by the Association for the Advancement of Medical Instrumentation (AAMI). Dialysis facilities are also subject to state laws governing clinic regulations including the disposal of wastes. All of these laws and regulations are designed specifically to protect patients and assure quality of care.

In addition, Medicare is the major payor for dialysis services and has hundreds of pages of rules and regulations dialysis facilities must comply with in order to participate in the Medicare program. As a condition of participating in Medicare, dialysis facilities must meet rules concerning patient safety, the adequacy of their dialysis machines, water treatment systems, dialyzer reuse, emergency preparedness and all personnel must meet certain professional standards.

DIALYSIS SERVICES

Treatment

Generally, hemodialysis patients require treatments three times per week. A few patients will require treatments two times per week, while others require treatments four times per week. Usual treatment lengths vary from 3 to 5 hours.

Peritoneal dialysis patients perform 4-6 exchanges at home or work every day either by a manual method (CAPD) or an automated method (CCPD or APD.) Patients and/or their family members are trained by the dialysis facility staff to safely perform this at home. A few patients use the automated method every other day or three (3) days per week (IPD) either at home or in the dialysis facility.

Health Care Team

A team of health care professionals is necessary (and required by Medicare) to care for the many and various needs of people with ESRD. At a minimum the health care team consists of the following services:

Physician Services: The nephrologist (physician with advanced training in treating kidney disease) prescribes the treatment orders and evaluates the patients' responses to treatment, making prescription changes when necessary. The physician participates in the development and ongoing monitoring of the patients' short and long-term care plans. The physicians are responsible for seeing their patients at least monthly for an evaluation.

Nursing Services: Licensed, registered nurses with specialized training in the care of people with ESRD coordinate all aspects of patient care with other members of the health care team. The nurses are qualified to perform and monitor the entire dialysis procedure and must be available to perform nursing assessments before and after each treatment. Nurses also evaluate patients' responses to treatment, initiate emergency measures as needed, provide patient education and training, particularly in the development and monitoring of patient care plans, and make recommendations for changes to the treatment. Nursing service may also include trained technicians who may perform the dialysis procedure and monitor patients under the supervision of a registered nurse.

Social Services: Medicare requires that social workers be available to perform psychosocial assessments of the patients. Social workers also provide supportive counseling to the patients and their families, participate in the development and ongoing assessment of the short and long-term care plans, act as a patient advocate, provide referral to community resources as needed, and act as a resource for issues related to employment, finances, insurance, transportation, travel, etc. These services are an important aspect of ESRD patient care as they help patients achieve their highest levels of functionality.

Nutritional Services: Medicare requires that dietitians be available to perform nutritional needs assessments for ESRD patients, to recommend dietary changes, to teach patients and families about the prescribed renal diet, and to monitor patients' compliance with dietary prescriptions by analyzing monthly laboratory results. Dietitians also participate in the development and ongoing assessment of the short and long-term care plans. Malnutrition is not an uncommon problem for either hemodialysis or peritoneal dialysis patients. The dietitians are instrumental in assessing the need for, determining the amount of, and evaluating the effectiveness of nutritional supplementation using intradialytic parenteral nutrition (IDPN) or intraperitoneal nutrition (IPN). Studies have shown that malnourished patients have higher morbidity and mortality.

Laboratory Services

Dialysis facilities collect blood for analysis monthly to determine whether the patients' treatment prescription is meeting the patients' needs. This is an important aspect of the ESRD patients' care as laboratory results are a primary indicator of therapy adequacy which, in turn, impacts morbidity and mortality.

HCFA and other payors require that dialysis facilities compare their patient outcomes to local, state and national standards. This requires that all the methods used to analyze the facility's samples be adjusted for ESRD and correlated so that the results can be averaged together. It also means that all lab results in each facility be able to be compiled into one database in order to analyze the data as required by HCFA or other payors.

Allowing a dialysis provider to send all patients samples to one laboratory specializing in ESRD is the most cost-effective and reliable way to ensure that quality services are being provided. A list detailing the minimum requirements for a laboratory used to perform ESRD lab services is available upon request from the dialysis facility.

Diagnostic Testing

Nerve Conduction Testing: As neurological and psychological problems can often result from End Stage Renal Disease. A routine nerve testing program can be of great assistance in the assessment of this very distressing condition, as well as serving as an indicator of adequacy of dialysis and thus assisting in determining the correct amount of therapy.

Bone Densitometry: Periodically patients may have the density of their bones measured to determine the existence or severity of renal osteodystrophy. This measurement is useful in implementing a plan to treat the osteodystrophy.

Doppler Flow Studies: One of the major causes of morbidity of the hemodialysis patient is vascular access failures. Periodic studies are very useful in assessing the blood flow through the access. If problems are noted, early intervention may prevent more costly access replacement surgeries, usually requiring an inpatient hospital admission.

Dialysis Services Reimbursement

Traditionally, outpatient dialysis facilities are reimbursed by Medicare, Medi-Cal or commercial insurance on a per-treatment basis (Medicare model). That is fixed amount is paid for the basic or "routine" treatment. Medicare defines the ESRD routine covered services in general terms in Chapter 27 of the Medicare Provider Reimbursement Manual (CFR 410.50 & CFR 410.52). Other renal related items or services not included in a routine treatment are considered separately billable.

Since the inception of this payment method in 1983, some services and items have been rolled into the composite rate, while new technologies have added services and items to the separately billable category. A current list of routine and separately billable services and items is available from the dialysis facility. One of the item that was approved by Medicare for ESRD patients in 1989 was the incenter administration of Erythropoietin (EPO). This is currently reimbursed as "an addition to the composite rate" based on the number of units administered.

Laboratory testing for most freestanding outpatient dialysis facilities is provided under contract with an ESRD clinical diagnostic testing laboratory. Typically, the dialysis facility will pay the ESRD lab for the routine testing as defined by Medicare and the ESRD lab will bill directly for any separately billable tests that are required. The dialysis facility can provide a list of routine and separately billable dialysis laboratory tests.

Peritoneal dialysis is a continuous treatment process and as such cannot be billed on a per treatment basis. Instead, the composite rate is used to calculate a weekly rate (3 x composite rate) and a daily rate (weekly rate / 7). The sum of the weekly rates and daily rates are used to compute the reimbursement for the month.

Medicare reimburses 80% of the composite rate and separately billable charges, the 20% balance being paid by Medi-Cal, commercial insurance or the patient.

Physician (Nephrologist) services are not included in the composite rate paid to the facility. These services are reimbursed on a Monthly Capitation Payment (MCP) system, where the basic renal related services are included in the fee and non covered services are separately billable.

Transportation

The frequency of chronic dialysis (3 x wk) creates significant transportation problems for dialysis patients and their families. This is a hardship not only in getting to and from the dialysis facility, but in getting to their other health care providers such as hospitals, laboratories, clinics, or physicians' offices. It is important to dialysis patients' quality of life that every effort is made to allow them access to the services nearest their residences and to provide financial assistance for transportation when needed. If such efforts are not made, the patients won't receive the services they require which is likely to result in increased morbidity and mortality and thus increased cost.

Hospitalization

Common complications that might occur with renal failure that require frequent hospitalization are congestive heart failure, vascular access problems and chronic infections.

Any medical complications warranting a patient to be hospitalized for a medical or surgical condition, requires dialysis while an inpatient at a hospital. Dialysis offered in this way is called inpatient dialysis. Congestive heart failure is a common occurrence in patients with renal failure. Causes are hypertension, fluid volume excess and anemia.

Vascular access is an internal fistula, internal graft or an external shunt or catheter. To be implanted, each device requires surgery and patients are instructed pre & post surgery on access care. A great deal of monitoring is required for the access to remain patent. If the access becomes clotted or non-functioning, then patency has to be restored. The patient is sent to the hospital and a vascular surgeon restores patency to resume dialysis treatments. The ability to be dialyzed and the adequacy of dialysis is dependent on a functioning access.

Infection is one of the leading causes of death in dialysis patients. The ability to adequately fight infection is affected by kidney failure, predisposing the patient to sepsis. Often antibiotic therapy and/or admittance to a hospital is required. An aseptic technique must be used when initiating and discontinuing dialysis.

Continuous Quality Improvement (CQI) - using HCFA data

The entire health care industry is being asked for evidence that patients receive quality care. In 1992, in conjunction with the renal community, HCFA developed the Health Care Quality Improvement Program (HCQIP) to assist dialysis providers to improve care in measurable ways, and to promote increased cooperation in the development of new quality assessment instruments. In July 1994, HCFA distributed its "strategic plan" to "guarantee equal access to the best health care". HCFA's mission states: "We are committed to excellence and continuous quality improvement". Their goal is: to provide information and feedback to health care providers for their use in improving the mainstream of care. The approach includes reviewing patterns of care and outcomes. Presently HCFA's medical record review topics or priorities are:

1. Anemia (Hematocrit)
Blood Pressure (hyper-hypotension)
Metabolic Control (URR; Kt/V; K+)
Nutrition (Albumin, Weights, IDPN)
Renal Osteodystrophy (Ca⁺⁺, P₀₄)
Transplantation
2. Patient/Staff Satisfaction Surveys
3. Water Treatment
4. Reuse (General Indicators, Dialyzer Labeling, Sterilants)
5. Pre & Post Dialysis Assessment
Multiple indicators
Critical Incidents/Patient Safety
Ultrafiltration
6. Infection Control
Universal Precautions
Peritonitis (Peritoneal Dialysis)
Hepatitis Screening
Pyrogenic reactions
7. Equipment Safety
8. Dialysis Access
Clotted grafts/access infections

ESRD Laboratory Requirements

The purpose of this document is to explain to you why patients with kidney failure that are treated at our dialysis unit must have their laboratory testing done by a ESRD Clinical Diagnostics Laboratory. The process of dialysis, as well as the administration of many of the drugs used to treat the patient is controlled through the use of lab results. Dialysis clinic staff use lab results often in the care of the patient--certain groups of results are used by different personnel in different ways. Lab results must be uniform from patient to patient--both in terms of format of reports and in types of procedures used (i.e. reference ranges must be the same). In addition, our laboratory supplies results in special formats tailored to dialysis unit staff needs. We have for instance hematocrit lists of all unit patients used for correct and efficient administration of Epogen. We also have specialized and specific cumulative trend reporting allowing staff to easily follow a patient's important dialysis parameters, over time. Some of these specialized reports include a Nutritional Assessment Report to help the patient understand their diet, also Bone Management and Anemia Management Reports are available to the unit staff including ALL patients from the unit.

Our dialysis clinic has a unified Clinical Information System which allows unit staff on line access to laboratory results along with clinical histories, medications, and other types of care needed by the patient. Another aspect of this Clinical Information System is our ability to collect, analyze and react to CQI data. This enables our company to minimize morbidity and require fewer hospital admissions. The usefulness of this system and its ability to help our staff administer the best possible care to our patients is negated if we are not able to use a standard set of care options, including a single laboratory.

There is an analogy to be drawn between our patients and in-patients in the hospital. The process of dialysis is a form of artificial life support. Many of the treatments given to our patients to decrease morbidity and to increase their quality of life are monitored and set by laboratory results. It is not any more reasonable to expect dialysis unit staff to be able to care for patients using lab results from ASSORTED LABORATORIES, than it is to expect the same from ICU staff in the hospital. We, therefore, are using only one laboratory for ALL of our patients. In this way we can offer safe and effective patient care.

The following page details the list of minimum requirements of our dialysis clinic on the ESRD laboratory in order to provide adequate patient care.

MEMO

To: CDC Members
From: CDC Board of Directors
Subject: Dialysis HMO Information Document
Date: November 12, 2001

The enclosed documents have been developed by the California Dialysis Council to assist dialysis providers in educating Managed Care Organizations in the complicated process of providing care to End Stage Renal Disease patients

The full document is comprised of two individual documents and reference to Amgen's Reference Guide to Dialysis Medicare Reimbursement (or similar documentation) as detailed below:

- 1) Dialysis Information Fact Sheet (4 pages). This is the main document to be sent by a dialysis facility to a HMO to explain dialysis.
- 2) ESRD Laboratory Requirements (2 pages). This is a supplement to document #1, giving specific details of the ESRD Laboratory requirements. It is referred to in document #1 under Laboratories Services, last sentence on page two.
- 3) A Reference Guide to Dialysis Medicare Reimbursement - Amgen, Inc. This or similar documentation can be used to provide specific details of the complex reimbursement issues involved with dialysis services. It is referred to in document #1 under Dialysis Services Reimbursement, page 3, second paragraph, second sentence and third paragraph last sentence. Section II of the Amgen Reference Guide to Dialysis Reimbursement will provide most of the relevant information required. Amgen has made copies of this guide available to all dialysis providers. If you do not have a copy, contact your Amgen representative.

This document has been produced by the CDC as a member service and is suggested as a **guide**. Members are free to edit or customize the document as they wish. To facilitate this, a copy of the document is available on 3½" diskette in WordPerfect 6.0, Microsoft Word 7.0 and ASCII formats. To receive a copy, please send a check for \$10.00 (to cover the cost of materials and processing) to the CDC Administrative Office giving your facility name, address, telephone number and the contact person.

Minimum ESRD Laboratory Requirements

1. Printer in the clinic to receive lab results.
2. Computer terminal for on line ordering and on line result review.
3. Minimum blood requirements (these patients are all anemic and need extensive testing). "Monthly EPO panels" (chem 20, magnesium, pre-albumin, HBsAg, iron, transferrin, ferritin, CBC, retic) should take no more than 1-10ml SST and 1-2.5ml EDTA.
4. Critical list must be supplied to clinic over printer (not on the phone) and parameters must be customized to dialysis unit requirements.
5. Turn around time for all monthly + EPO panel tests must be before the patient returns for the next dialysis treatment (i.e.: Monday draws must be reported before 6:00 am Wednesday).
6. Results must be printed in the clinic and also transferred to the unit's main computer in specified configuration ASCII format for addition to our clinical information database.
7. Custom reference ranges must be available so that lab results can be compared regardless of what lab does the testing.
8. Cumulative reporting using only certain specified parameters, conforming to facility standards must be available.
9. Reports listing multiple patients with multiple parameters must be available (i.e. Anemia & Bone Management reports). These reports are used by nursing staff to assess medication requirements.
10. Albumin must be performed by BCP method, to correlate with the rest of our patients' results.
11. Iron testing must use a reagent free from interference by heparin.
12. For microbiology, a method for optimal recovery of organisms from peritoneal effluent must be used.
13. The following calculations must be available for routine reporting:
 - a. Calcium-phosphorus product
 - b. Calcium adjusted for low albumin; and adjusted calcium phosphorus product
 - c. Effective KT/V, for measuring dialysis efficiency
 - d. Creatinine and urea clearances corrected for surface area
 - e. P.E.T. testing for peritoneal dialysis patients including creatinine correction for high glucose
 - f. Vascular access recirculation testing

We invite you to contact our dialysis clinic at your earliest convenience so that we can answer any questions or elaborate on any of the above requirements .