



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Home Dialysis and Associated Technologies

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Table of Contents

Coverage Policy	1
General Background	2
Coding/Billing Information	5
References	6
Policy History	9

Hyperlink to Related Coverage Policies

Home Sphygmomanometers
Nutritional Support

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

Some services related to home dialysis may be subject to the terms, conditions and limitations of the Durable Medical Equipment (DME) or Home Health Services benefit. In addition, some home dialysis supplies and equipment may not be covered. Please refer to the applicable benefit plan document to determine benefit availability and the terms and conditions of coverage.

CIGNA covers home hemodialysis for end-stage renal disease (ESRD) as medically necessary when ALL of the following criteria are met:

- The individual is stable on hemodialysis.
- The individual is free of complications and significant concomitant disease that would render home hemodialysis unsuitable or unsafe.
- The individual or caregiver is capable of completing a home dialysis training program and adhering to a prescribed treatment regimen.
- The individual has an adequate caregiver and arrangements with a backup, facility-based dialysis center.

CIGNA covers home nocturnal intermittent peritoneal dialysis (NIPD) as medically necessary for ESRD.

CIGNA covers home continuous cycling peritoneal dialysis (CCPD), including tidal peritoneal dialysis (TPD), as medically necessary for ESRD when ANY of the following criteria is met:

- There are frequent episodes of peritonitis.
 - The individual is incapable of performing peritoneal dialysis without assistance.
 - The individual cannot be adequately dialyzed by continuous ambulatory peritoneal dialysis (CAPD).
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General Background

Dialysis is the process of removing specific small molecules (e.g., uric acid) from a solution (e.g., blood) by letting them diffuse across a semipermeable membrane into water. It is a mechanical process that performs part of the work that healthy kidneys normally do. The main functions of dialysis include clearing wastes from the blood, restoring proper balance of certain electrolytes in the blood, and eliminating extra fluid from the body. For people with chronic renal failure (CRF) or end-stage renal disease (ESRD), dialysis is the only way, other than a kidney transplant, to prolong life. CRF and ESRD are usually caused by an irreversible scarring process that results in kidney failure or shutdown. Dialysis can be performed by employing either an artificial membrane system using extracorporeal blood (i.e., hemodialysis) or the peritoneal membrane (i.e., peritoneal dialysis). The choice of type of dialysis treatment is usually dictated by the patient's needs and the nephrologist's clinical judgment of which treatment will be best tolerated.

Hemodialysis

In hemodialysis, a hemodialyzer acts as an artificial kidney to remove waste products from the blood and restore the body's chemical balance. Getting the patient's blood to the hemodialyzer requires access to the patient's blood vessels, accomplished by surgery on the patient's arm or leg. The surgical procedure connects an artery to a vein underneath the skin, creating an enlarged vessel known as a fistula. Once healing occurs, two needles are inserted, one in the artery side of the fistula and the other in the vein side. Plastic tubing connects the patient to the hemodialyzer. The time required for each hemodialysis treatment is determined by the amount of remaining kidney function, fluid weight gain between treatments and build-up of harmful chemicals between treatments. Hemodialysis is considered more efficient than peritoneal dialysis in clearing toxins, especially small molecules. This type of dialysis can be performed in various settings, including home, outpatient, in-center, or hospital.

Facility-based dialysis is generally performed three times per week for 3–5 hours at a hospital or dialysis center. A patient who cannot have a kidney transplant and who has a spouse or other family member willing and able to assist in the treatments may be a candidate for home hemodialysis. Hemodialysis can be performed in a patient's home with coordination of care by a nephrologist, dialysis nurse, dialysis technician, dietician, social worker and others. The home self-dialysis schedule is more intensive than the intermittent schedule for conventional, in-center hemodialysis. Home hemodialysis is intended to reduce the morbidity and mortality associated with conventional hemodialysis by shortening the interdialytic interval, thus decreasing fluctuations in fluid, solute, and electrolyte balance and more closely simulating physiological kidney function. For home hemodialysis, the patient and support person are trained to dialyze the patient during the daytime or overnight using a unit equipped with dialyzer modules, a reuse apparatus, and a water treatment appliance. Training can take from several weeks to several months. The patient and caregivers are responsible for maintaining the dialysis equipment. Vascular access is provided by an arteriovenous (AV) fistula, an AV graft, or a central vein catheter. The patient's home must have sufficient space to accommodate the dialysis module, which consists of the dialyzer, an arterial line with a blood pump, and a venous line with an air trap, as well as other equipment. An adequate number of electrical outlets, a source of purified water adjacent to the equipment, and back-up resources are also necessary. Most centers monitor the home sessions remotely through a telephone or Internet connection. A healthcare professional is available for consultation, and the patient is also monitored at regular intervals in a physician's office or outpatient center. Daily hemodialysis is performed at home 5–7 times per week for 1–4 hours each day, and nocturnal hemodialysis is performed overnight 5–7 times per week for 6–10 hours. Home hemodialysis affords the patient a degree of scheduling flexibility, which is not always possible in a center. Disadvantages of home hemodialysis include the fact that the family member or support person, who must train for 6–8 weeks along with the patient, will be tied to the same schedule as the patient and will also bear the psychological burden of feeling responsible for the patient's safety.

Recently, smaller, portable hemodialysis machines have been developed intended to be used in facilities or at home. One of these is the NxStage System One™ (NxStage Medical, Inc., Lawrence, MA). This device received

U.S. Food and Drug Administration (FDA) 501(k) clearance for use in the home in 2005. According the FDA summary the indications for use include, “the System is designed to deliver hemofiltration, hemodialysis and/or ultrafiltration in an acute or chronic care facility and is also indicated for hemodialysis and/or ultrafiltration in the home.”

Literature Review: The medical literature includes a number of studies that evaluated the relative effects on survival of home hemodialysis compared to outpatient hemodialysis at a dialysis center. There are several observational studies that indicate that there are benefits obtained with the more frequent dialysis provided at home (Johnson, et al., 1984; Arkouche, et al., 1999; Chan, et al., 2002; and, Friedman, et al., 2002; Sands, et al., 2009). Culleton et al. (2007) reported on a randomized, controlled trial of 52 patients that compared conventional hemodialysis to frequent nocturnal hemodialysis performed at home. The results indicated that there was an improvement in ventricular mass, reduction in blood pressure medications, and improvement in selected measures of quality of life.

Professional Societies/Organizations: A review was performed by the National Institute for Clinical Excellence (NICE, 2002) (United Kingdom) to provide guidance on the location where hemodialysis is carried out. The recommendations note that patients suitable for home hemodialysis will include those who:

- have the ability and motivation to learn to carry out the process and the commitment to maintain treatment
- are stable on dialysis
- are free of complications and significant concomitant disease that would render home hemodialysis unsafe or unsuitable
- have a good functioning vascular access
- have a caregiver who has made an informed decision to assist
- have a suitable space that could be adapted within their home environment

Peritoneal Dialysis

Peritoneal dialysis uses the same filtering process as hemodialysis, but uses the body's peritoneal membrane, rather than a dialyzer, as the filter. The peritoneal membrane is a sac that lines the walls of the abdominal cavity and surrounds the abdominal organs. It contains many blood vessels, making it an effective membrane for dialysis. Before peritoneal dialysis can be performed, a catheter (i.e., a flexible, hollow tube) must be surgically inserted in the lower abdomen. Four or five inches of the catheter remain outside the body at all times. Catheter insertion is done in an operating room, usually with local anesthesia. After being thoroughly trained, patients perform their own peritoneal dialysis at home or in any clean area. The dialysis does not involve needles or removing blood from the body.

Modalities of peritoneal dialysis include:

- continuous ambulatory peritoneal dialysis (CAPD)
- continuous cycling peritoneal dialysis (CCPD)
- intermittent peritoneal dialysis (IPD)
- nocturnal intermittent peritoneal dialysis (NIPD)
- tidal peritoneal dialysis (TPD)

With peritoneal dialysis, patients are less restricted in their food and fluid intake than with hemodialysis; there is no need for vascular access; less fluid accumulates; and the removal of fluid is slow and continuous. Thus, there is less stress on the heart, and blood pressure is better controlled (Woredokal, 2002). A patient who has problematic vascular access or who prefers home dialysis but cannot perform hemodialysis because of lack of a partner or suitable home environment may be a candidate for peritoneal dialysis.

The National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF, 2001) clinical practice guidelines provide evidence-based recommendations for the provision of adequate peritoneal dialysis, specifically about when to initiate dialysis, how and when to measure the dialysis dose, and how strong a dose of dialysis to administer.

Peritonitis is the most common major problem associated with peritoneal dialysis. Symptoms of peritonitis may include abdominal pain, nausea, vomiting or diarrhea. Treatment consists of antibiotics, which may be added to

the dialysate or given intravenously. Other complications may include catheter obstruction or malposition, and pain associated with inflow or drain phases of dialysis exchange (Teitelbaum, 2003).

Continuous Ambulatory Peritoneal Dialysis (CAPD): CAPD is the only type of peritoneal dialysis that does not involve machines. It can be done in any clean, well-lit place. Once the solution is warm, the patient allows the prescribed amount of sterile dialysate solution to flow into the abdominal catheter to fill the abdominal cavity. This catheter carries the dialysis solution into and out of the abdomen. The dialysate solution contains dextrose, which pulls wastes and extra fluid into the abdominal cavity. The peritoneum within the abdominal cavity allows the waste products and extra fluids to pass from the blood into the dialysate solution. Thus, the wastes and fluid leave the body when the dialysate solution is drained. The dialysate solution remains in the abdominal cavity for 4–5 hours, a period referred to as the dwell time. While the dialysate remains inside the peritoneal cavity, the patient can go about his/her daily activities. At the end of the dwell time, the patient drains the used dialysate from the abdomen and repeats the procedure using a new bag of dialysate. The process of filling and draining is called an exchange. A typical schedule calls for four exchanges per day, each with a dwell time of between four and six hours. CAPD is seen as simpler to deliver than hemodialysis. The benefit of CAPD is that it can easily be learned by the patient, allowing some independent control over therapy.

Continuous Cycling Peritoneal Dialysis (CCPD): CCPD is similar to CAPD, except that it utilizes a portable cyclor machine which connects to the catheter and automatically warms, fills, drains and weighs the dialysate solution during the night at timed intervals while the patient sleeps. Treatment usually includes 3–5 exchanges during the night over a 10- to 12-hour period. A patient undergoing CCPD typically programs the cyclor machine to deliver a dialysate exchange at the end of the nighttime cyclor dialysis. In the morning, the patient disconnects from the cyclor with a full abdomen and begins a single exchange with a dwell time that lasts the entire day. The patient carries the dialysate in the peritoneum for part or all of the day. In some cases, the patient performs one or more manual exchanges during the day in addition to the last bag fill exchange. These additional exchanges are usually performed so that the patient can receive an adequate dose of dialysis (Brenner, 2004). CCPD may be used independently or in conjunction with CAPD to achieve adequate response. Adding CCPD to CAPD enables the patient to add more exchanges with the hope of achieving better clearance (Brenner, 2004). In December 2001, the (FDA) approved the HomeChoice[®] Personal Cyclor Peritoneal Dialysis System (Baxter Healthcare Corp., McGaw Park, IL) to perform automated cycling peritoneal dialysis.

Intermittent Peritoneal Dialysis (IPD): IPD, the oldest form of dialysis, is usually performed in the hospital for 10 to 12 hours, three times per week. This treatment is often used in emergency situations or as a first dialysis treatment. The patient is hooked up to a machine during treatment, as in CCPD.

Nocturnal Intermittent Peritoneal Dialysis (NIPD): NIPD is similar to CCPD, but with more overnight exchanges (at least six) and without the patient performing an exchange during the day. The fluid is drained in the morning, and the abdomen remains empty of dialysis solution the entire day. NIPD patients may be more comfortable without the pressure of dialysate in their abdomens during the day, but they are getting less dialysis than they would with CCPD. For this reason, NIPD is usually reserved for patients whose peritoneums are able to transport waste products very rapidly or who still have substantial remaining kidney function.

Tidal Peritoneal Dialysis (TPD): TPD consists of the repeated instillation of small tidal volumes of dialysis fluid via a cyclor machine. The procedure is usually performed nightly. Variables to be set include reserve volume, tidal outflow volume, tidal replacement volume, flow rate, and frequency of exchanges. Theoretically, draining the peritoneal cavity incompletely after each dwell maintains an intraperitoneal reservoir, resulting in more continuous contact of the dialysate with the peritoneal membrane. In addition, the more rapid cycling of dialysis may increase mixing and prevent the formation of stagnant fluid films within the abdomen. In most, but not all, studies, however, TPD has not resulted in an increase in urea or creatinine clearance when compared to cyclor peritoneal dialysis (Juergensen, 2000). The differences in results among these studies stem from differences between the cyclor and TPD prescriptions chosen for analysis. It appears that the continual presence of some dialysate in the peritoneal cavity during the cycling procedure of TPD can decrease abdominal discomfort during inflow and outflow. A major disadvantage of TPD is the cost of the large volume of fluid needed. There is little evidence in the literature to suggest that TPD can provide clearance superior to that provided by cyclor dialysis (Brenner, 2004). TPD may be appropriate in a select group of patients.

Peridex Filter Sets

Peridex Filter Sets® (Millipore Co., Billerica, MA) are designed to provide sterile filtration during infusion of the dialysis solution in a CAPD patient's peritoneal cavity. The filter set contains a bacterial filter designed to block peritonitis-causing organisms and thus reduce the incidence of peritonitis. The published literature indicates that the Peridex Filter Set has not been shown to be safe and effective in preventing peritonitis.

Ultrafiltration Monitors

Ultrafiltration monitors are designed to reduce the clinical risks of over- and underfiltration during hemodialysis. Overfiltration is the removal of too much fluid from body tissues; underfiltration is the removal of too little fluid. Ultrafiltration and ultrafiltration monitoring as components of hemodialysis have an established and critical role in maintaining the well-being of ESRD patients. Ultrafiltration monitors are supported in the literature as safe and effective and are considered medically necessary when used to calculate fluid rates for those recipients who present difficult fluid management problems.

Crit-Line In-Line Monitor

The Crit-Line In-Line Monitor® (In-Line Diagnostics, Kaysville, UT) was approved by the U.S. Food and Drug Administration (FDA) in July 1999 as a class II device. It was approved through the 510(k) process for the intended use as a noninvasive device to measure hematocrit, oxygen saturation and access blood flow. The Crit-Line In-Line Monitor has been used in hemodialysis patients and other fluid-overloaded patients to measure hematocrit levels and oxygen saturation. The monitor measures hematocrit and oxygen saturation optically as blood passes through the dialysis tubing while the patient is undergoing dialysis treatment. The Crit-Line graphically displays and records the hematocrit, the percent blood-volume change (which is derived from the hematocrit) and the oxygen saturation. The hematocrit and oxygen saturation are measured by an optical sensor attached to a sterile, disposable blood chamber that is placed in-line between the arterial blood tubing set and the dialyzer. The Crit-Line determines the hematocrit according to both the absorption properties of hemoglobin and the scattering properties of red blood cells passing through the blood chamber. The efficacy of the Crit-Line In-Line Monitor in avoiding intradialytic morbid events, preventing ischemia due to intradialytic hypoxia, and determining access re-circulations has not been proven in the literature.

Intradialytic Parenteral Nutrition (IDPN)

Intradialytic parenteral nutrition (IDPN) is a form of parenteral nutrition infused during dialysis. IDPN has been proposed as a treatment option for malnutrition associated with patients undergoing dialysis. (Please refer to the CIGNA Coverage Policy on Nutritional Support for coverage details.)

Summary

Dialysis can be safely performed in the home utilizing either home hemodialysis or peritoneal dialysis. The choice of type of dialysis treatment is usually dictated by the individual's special needs and the nephrologist's clinical judgment of which treatment will be best tolerated.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT®*	Description
99512	Home visit for hemodialysis

HCPCS Codes	Description
C1881	Dialysis access system (implantable)
E1500	Centrifuge, for dialysis
E1510	Kidney, dialysate delivery system kidney machine, pump recirculating, air removal system, flowrate meter, power off, heater and temp control with alarm, IV poles, pressure gauge, concentrate container
E1520	Heparin infusion pump for hemodialysis

E1530	Air bubble detector for hemodialysis, each, replacement
E1540	Pressure alarm for hemodialysis, each, replacement
E1550	Bath conductivity meter for hemodialysis, each
E1560	Blood leak detector for hemodialysis, each, replacement
E1570	Adjustable chair, for ESRD patients
E1580	Unipuncture control system for hemodialysis
E1590	Hemodialysis machine
E1592	Automatic intermittent peritoneal dialysis system
E1594	Cycler dialysis machine for peritoneal dialysis
E1610	Reverse osmosis water purification system, for hemodialysis
E1615	Deionizer water purification system, for hemodialysis
E1620	Blood pump for hemodialysis, replacement
E1625	Water softening system, for hemodialysis
E1630	Reciprocating peritoneal dialysis system
E1634	Peritoneal dialysis clamps, each
E1636	Sorbent cartridges, for hemodialysis, per 10
S9335	Home therapy, hemodialysis; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing services coded separately), per diem
S9339	Home therapy; peritoneal dialysis, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately), per diem

ICD-9-CM Diagnosis Codes	Description
585.6	End stage renal disease
586	Renal failure, unspecified
V45.11	Renal dialysis status

***Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	11/15/2008	0229	Home Dialysis and Associated Technologies

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