Hemodialysis Treatment for ESRD

Description of Procedure or Service

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.

Dialysis is the process in which waste products, (e.g., uric acid) are removed from the body by diffusion from one fluid compartment to another through a semi-permeable 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 patients with very advanced CKD, adequate management of uremic symptoms may require dialysis or kidney transplantation. In many such cases, renal replacement can prolong life and reduce symptoms. CKD and ESRD are usually caused by an irreversible scarring process that results in kidney failure or shutdown. 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.

Dialysis can be performed by using extracorporeal blood (i.e. hemodialysis), or internally, using the membranes of the abdomen as the diffusion surface (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.

In hemodialysis, vascular access makes hemodialysis treatments possible by using a machine to move the patient’s blood through a filter, called a dialyzer. The dialyzer acts as an artificial kidney to remove waste products from the blood and help restore the body’s chemical balance. In hemodialysis, blood is drawn from a surgically created vein, or else from a central venous catheter. If a vein is used, then typically two needles are inserted through the skin for each treatment—one to take blood from the patient and the other to bring it back after it has been treated. Either way, blood flows through the tubing to an artificial kidney (the “dialyzer”). In the dialyzer, the blood flows through thin fibers that filter out wastes and extra fluid. Tubing then brings the cleansed blood back to the body. This vascular access allows large amounts of blood flow continuously during hemodialysis treatments to filter as much blood as possible per treatment. For hemodialysis, access to the blood is provided by a catheter, or else by an arteriovenous (AV) fistula or AV graft. An AV fistula is created by connecting a person’s artery and vein; an AV graft uses an artificial tube to connect the artery and vein. To determine the type of access most suitable for an ESRD patient, a history must be taken and a physical examination of the patient’s venous, arterial, and cardiopulmonary systems must be performed. The urgency by which dialysis need to be started may influence the choice of vascular access.

Many providers recommend a standard treatment time, such as 4 hours, based on population data suggesting this is beneficial. Hemodialysis can be performed in various settings, including home,
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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.

Hemodialysis is commonly used more than three times a week for hemodynamically fragile patients – e.g. with pulmonary hypertension or other cardiac dysfunction, where there is a narrow window between hypotension and volume overload.

**Related Policy:**
Documentation Requirements for Treatment of End Stage Renal Disease

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

**Policy**

BCBSNC will provide coverage for Hemodialysis treatment for ESRD when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

This policy does not address Peritoneal dialysis.

**Benefits Application**

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

**When Hemodialysis Treatment for ESRD is covered**

Hemodialysis treatment is considered medically necessary for ESRD in the following situations:

1. Freestanding outpatient dialysis facilities, including but not limited to:
   - All services rendered during dialysis treatment;
   - Disposable supplies;
   - Drugs and biologicals, related to dialysis treatment administered by dialysis clinicians;
   - Laboratory tests rendered by the dialysis facility;
   - Nutritional counseling;
   - Relevant facility fees;
   - Related solutions;
   - Related solutions;
   - Hemoperfusion and hemofiltration

2. Home dialysis, including but not limited to:
   - Adjustable dialysis chair;
   - Certain drugs and biologicals, related to dialysis treatment, when they cannot be self-administered and/or when DME is necessary for their administration;
   - Deionization or reverse osmosis water purification along with moisture detector systems for home dialysis use. Include activated carbon filters when prescribed by a physician;
   - Disposable supplies;
   - Installation charges (up to the member’s lifetime limit), maintenance and reconditioning of home dialysis equipment is available to members at no cost;
   - Supplies necessary to perform all modalities of home dialysis;
   - Support services furnished by an approved ESRD facility;
   - Ultrafiltration monitor as a component of hemodialysis
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3. Inpatient dialysis for inpatient dialysis care

4. ESRD facilities providing dialysis treatment either in-facility or in the home are limited to three treatments per week, unless it is determined that the frequency of treatments should be extended beyond the limitation, as follows.
   a. An extra session may be necessary for persons with a potassium level greater than 6 meq per liter, a rapidly rising potassium, or evidence of significant muscle damage such as elevated creatine phosphokinase.
   b. Extra dialysis sessions may be necessary when there is evidence of significant volume overload such as:
      - Marked daily weight gain in excess of five pounds per day;
      - New onset or worsening signs and symptoms of congestive heart failure;
      - Marked generalized edema;
      - Pulmonary edema (demonstrated by abnormal blood gases (hypoxemia), chest x-ray findings or physical examination) which responds positively to fluid removal (improves with dialysis); OR
      - Evidence that volume loads cannot be reduced by other alternative means such as ultrafiltration.
   c. A severe catabolic state in which the creatinine has risen rapidly, for example faster than 3-4mg/dl per day and may be associated with hyperkalemia. In addition, muscle enzymes may also be elevated.
   d. Extra dialysis sessions may be necessary when there is documentation showing patients are clinically benefitted by more treatments because they are hemodynamically unstable (e.g. with pulmonary hypertension or other cardiac dysfunction, where there is a narrow window between hypotension and volume overload), or have recurring episodes of hypotension or cramping, despite appropriate adjustment of target weight.

5. Hemodialysis services and all medically necessary equipment and supplies used to furnish dialysis in a dialysis center, member’s home or inpatient hospital facility are considered medically necessary.

When Hemodialysis Treatment for ESRD is not covered

Hemodialysis treatment for ESRD is considered not medically necessary when the above criteria are not met.

Policy Guidelines

Chronic kidney disease is a progressive condition, which is defined as kidney damage persisting for ≥3 months demonstrated by abnormalities in blood or urine markers or on renal imaging and/or an estimated or measured glomerular filtration rate (GFR) < 60 mL/min/1.73m² for ≥3 months. Kidney failure is defined as either a GFR of < 15 mL/min/1.73 m² or as the need for renal replacement therapy, e.g., dialysis or renal transplantation. Some causes of kidney failure are diabetes, hypertension, glomerulonephritis, cystic kidney disease, nephrotoxic agents, and infection. Some patients may choose to forego renal replacement, understanding that this choice may cause shortened survival. End-stage renal disease (ESRD) is manifested by signs and symptoms of uremia and the need for chronic dialysis or transplantation. Treatment of ESRD involves the management of uremia, maintenance of nutritional status, optimization of hemoglobin and serum phosphate, and prevention of comorbidities through dialysis or transplantation. Treatment of advanced CKD involves the management of uremic symptoms, addressing nutritional status, metabolic derangements, anemia and volume status. For patients with very advanced CKD, dialysis or kidney transplantation will often provide the most satisfactory way to address these issues.
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Dialysis is the process of removing solutes that accumulate as a result of diminished renal function. This process removes waste products from the body by diffusion from one fluid compartment to another across a semi-permeable membrane. Dialysis is normally indicated in the management of patients with end stage renal disease (ESRD). Dialysis may be required for other reasons, including septic shock, severe metabolic derangements (eg hyperkalemia, tumor lysis syndrome).

When 90% or more of usual kidney function is lost, either kidney transplantation or dialysis is required to sustain life. Nearly 400,000 persons in the United States and 2 million worldwide are dependent on dialysis; of these, approximately 90% in the United States and 70% in Canada undergo hemodialysis, which is typically delivered three times a week. The rationale for thrice-weekly hemodialysis was derived from a combination of physiological experiments, assessments of patient acceptance, feasibility, logistics, and costs. Mortality remains high (approximately 18 to 20% per year) despite improvements in the technology for dialysis, the development of new pharmaceutical agents, and experience over the course of more than 40 years since maintenance dialysis became available. Moreover, although dialysis can sustain life, it rarely restores health; patients undergoing dialysis have considerable complications (including frequent and extended hospitalizations) and relatively poor functional status and health-related quality of life.

The optimal “dose” of hemodialysis remains uncertain. Anchored to a thrice-weekly regimen and typically expressed as a metric of small-solute (urea) clearance, dialysis dosing has been informed by numerous observational studies and a few carefully conducted, randomized clinical trials. Despite ample observational data suggesting that the dose of hemodialysis (expressed as the per-session Kt/V <sub>urea</sub>, which is the product of the urea clearance and the duration of the dialysis session normalized to the volume of distribution of urea) correlates directly with survival, the Hemodialysis (HEMO) Study showed that there was no benefit from more intensive hemodialysis (higher per-session Kt/V <sub>urea</sub>) when patients underwent hemodialysis three times a week. However, solute removal can be dramatically augmented by increasing the frequency of hemodialysis sessions. Several uncontrolled studies showed that there were significant improvements in patient-reported outcomes and results of laboratory tests when patients were treated with more frequent in-center or at-home hemodialysis. Because of ongoing uncertainty regarding the optimal dose of hemodialysis, the hypothesis was tested regarding frequent (six times per week) in-center hemodialysis, as compared with conventional thrice-weekly hemodialysis, would improve an array of objective and patient-reported outcomes.

The Frequent Hemodialysis Network (FHN) Daily Trial was a multicenter, prospective, randomized, parallel-group trial of frequent (six times per week), as compared with conventional (three times per week) in-center hemodialysis. The study was conducted between January 2006 and March 2010 at 11 university-based and 54 community-based hemodialysis facilities in North America. The FHN Daily Trial and a companion Nocturnal Trial (ClinicalTrials.gov number, NCT00271999) were sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases and the Centers for Medicare and Medicaid Services, with additional support from DaVita, Dialysis Clinics, Fresenius Medical Care, Renal Advantage, Renal Research Institute, and Satellite Healthcare. The dialysis companies donated several weekly dialysis sessions; they had no role in the design of the study or in the analysis of the data. Recruitment and data collection were performed by site investigators and study coordinators. An independent data and safety monitoring board reviewed the safety data and interim results. The study was approved by the institutional review board at each participating study site. The study population was diverse with respect to age, sex, race or ethnic group, the primary cause of kidney disease, coexisting conditions, income, and education; the median duration of end-stage renal disease was 3.6 years.

After randomization, prescriptions for dialysis were determined centrally and were transmitted to each clinical center. Patients who were assigned to thrice-weekly hemodialysis (120 patients) continued their usual dialysis prescriptions, which included a minimum target equilibrated Kt/
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$V_{\text{urea}}$ of 1.1 and a session length of 2.5 to 4.0 hours. The equilibrated $Kt/V_{\text{urea}}$ is the ratio of the equilibrated urea clearance during each dialysis session (Kt) to the patient's volume of urea distribution (V). The target equilibrated $Kt/V_n$, where $V_n=3.271 \times V^{2/3}$, in the group that underwent hemodialysis six times per week (125 patients) was 0.9 provided that the length of the session was between 1.5 and 2.75 hours. These prescriptions were factored by $V^{2/3}$ rather than V (similar to scaling surface area from body mass) to reduce the dependence of dialysis prescriptions on body mass and to avoid unfeasibly long dialysis treatments for patients with large body mass. Simulation studies indicated that these interventions would provide substantial differences in targeted weekly standard $Kt/V_{\text{urea}}$ between the treatment groups. Although frequent hemodialysis is far from perfect, it may more closely approximate the capacity of a native or transplanted kidney to regulate extracellular volume and solute composition. However, the benefits of hemodialysis performed six times per week were gained at the cost of more frequent interventions related to vascular access.

Frequent hemodialysis improved the control of hypertension and hyperphosphatemia but had no significant effects on cognitive performance, self-reported depression, serum albumin concentration, or use of erythropoiesis-stimulating agents. Patients who underwent frequent hemodialysis were significantly more likely to undergo interventions related to vascular access. Before major changes in practice can be recommended, the net effects of frequent hemodialysis will need to be balanced against the added burden for the patient and societal cost.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 90935, 90937, 90951, 90952, 90953, 90954, 90955, 90956, 90957, 90958, 90959, 90960, 90961, 90962, 90963, 90964, 90965, 90966, 90967, 90968, 90969, 90970, 90999, G8714, G8715

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources


National Kidney Foundation 2015; Hemodialysis and Hemodialysis Access, reviewed on August 23, 2016 from https://www.kidney.org/atoz/content/hemoaccess
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Policy Implementation/Update Information

10/25/16  New policy developed. BCBSNC will provide coverage for Hemodialysis treatment for ESRD when it is determined to be medically necessary because the medical criteria and guidelines outlined in the policy are met. Notification given 10/25/2016 for policy effective date 12/30/2016. (jd)


9/15/17  Revised “When Not Covered” statement to “Hemodialysis treatment for ESRD is considered not medically necessary when the above criteria are not met.” No change to policy intent. (jd)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.