

Corporate Medical Policy

Hemodialysis Treatment for ESRD

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Description of Procedure or Service

End Stage Renal Disease (ESRD) occurs from the destruction of normal kidney tissues leading to loss of kidney function. Often there are no symptoms until the kidney has lost more than half its function. ESRD is the last stage of chronic kidney disease and 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.

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. Hemodialysis access, where blood is drawn from, is created either by an arteriovenous (AV) fistula, an arteriovenous (AV) graft or from a central venous catheter. If an AV access 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. An AV fistula is created by connecting a person's artery and vein, whereas an AV graft uses an artificial tube to connect the artery and vein.

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, 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.

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Hemodialysis is commonly used more than three times per week for hemodynamically fragile patients, for example 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 up to 3 treatments per week when prescribed by a physician for ESRD.

Hemodialysis treatment performed more than three times per week is considered medically necessary when one or more of the following conditions are refractory to dialysis three times per week:

- a. Hyperkalemia indicated by 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. Evidence of significant volume overload:
 - Marked daily weight gain;
 - 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 physician 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.

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Hemodialysis services and all medically necessary equipment and supplies used to furnish dialysis are considered medically necessary 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;
 - 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

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, characterized by a gradual loss of kidney function with kidney damage demonstrated by abnormalities in blood or urine markers or on renal imaging. An estimated or measured glomerular filtration rate (GFR) < 60 mL/min/1.73m² for ≥ 3 months can indicate CKD which is half the normal value of 125mg/min/1.73², measured in young adults. Kidney failure is defined as either a GFR of < 15 mL/min/1.73 m² or as the need for renal replacement therapy, such as dialysis or renal transplantation. Some causes of kidney failure are diabetes, hypertension, glomerulonephritis, cystic kidney disease, nephrotoxic agents, and infection. End-stage renal disease (ESRD) is manifested by signs and symptoms of uremia and treatment involves the maintenance of nutritional status, optimization of hemoglobin and serum phosphate, along with management of uremia, 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. Patients may choose to forego renal replacement, understanding that this choice may cause shortened survival.

A multi-center, randomized controlled trial was conducted through the Frequent Hemodialysis Network (FHN) Trial Group (2010), to determine the benefits of frequent in-center hemodialysis compared to conventional hemodialysis for patients with CKD. Patients were randomly selected

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to receive frequent hemodialysis six times per week (125 patients) or receive conventional hemodialysis at three times per week (120 patients) for 12 months. There were two coprimary composite outcomes; one was based on death or change in left ventricular mass, assessed by cardiac MRI, and the other based on death or change in the physical-health composite score of the RAND 36-item health survey. The secondary outcomes of the trial included cognitive performance, laboratory markers of nutrition, mineral metabolism, self-reported depression, blood pressure, rates of hospitalization and interventions related to vascular access.

The patients who received frequent hemodialysis averaged 5.2 treatments per week. These patients compared with those who received conventional hemodialysis demonstrated benefits in both coprimary composite outcomes, as well as, improved control of hypertension and hyperphosphatemia. However, patients in the frequent hemodialysis group were more likely to undergo interventions related to vascular access with no significant effects reported on cognitive performance, self-reported depression, or serum albumin.

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

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

Centers for Medicare and Medicaid – Local Coverage Determination LCD L34575 Frequency of Dialysis, effective date 3/10/2016, reviewed on August 2016 from <https://www.cms.gov/medicare-coverage-database>

Centers for Medicare & Medicaid Services. Medicare Benefit Policy Manual, Chapter 11, End Stage Renal Disease (ESRD). Reviewed August 23, 2016 from <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf>

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) - NIH; Vascular Access for Hemodialysis, July 2016; reviewed on August 23, 2016 from <https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/vascular-access-for-hemodialysis/Pages/index.aspx>

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

Specialty Matched Consultant Advisory Panel review 4/2017

Medical Director review 4/2017

The FHN Trial Group, N Engl J Med 2010 (updated January 5, 2011); 363:2287-2300 [December 9, 2010](#), DOI: 10.1056/NEJMoa1001593. In-Center Hemodialysis Six Times per Week versus Three Times per Week. Reviewed August 24, 2016.

Specialty Matched Consultant Advisory Panel review 4/2018

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Specialty Matched Consultant Advisory Panel review 4/2019

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Specialty Matched Consultant Advisory Panel review 4/2020

Medical Director review 4/2020

Specialty Matched Consultant Advisory Panel review 4/2021

Medical Director review 4/2021

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)
- 5/26/17 Revised “When Covered” section. No change in policy intent. Specialty Matched Consultant Advisory Panel review 4/2017. Medical Director review 4/2017. (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)
- 5/25/18 Minor updates to Description section. When Covered section revised by moving medically necessary equipment and supplies-items 1 and 2 below the medically necessary conditions for hemodialysis treatment performed more than three time per week. No change to policy intent. Policy Guidelines extensively revised. Specialty Matched Consultant Advisory Panel review 4/2018. Medical Director review 4/2018. (jd)
- 5/14/19 Minor revision to Description section. Under the When Covered section - removed item b, bullet 1: “in excess of 5 pounds per day.” No change to policy intent. Specialty Matched Consultant Advisory Panel review 4/2019. Medical Director review 4/2019. (jd)
- 4/28/20 Specialty Matched Consultant Advisory Panel review 4/2020. Medical Director review 4/2020. (jd)
- 5/4/21 References updated. Specialty Matched Consultant Advisory Panel review 4/2021. Medical Director review 4/2021. (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.