



Medical Coverage Policy

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Coverage Policy Number..... 0229

Staff-Assisted Home Hemodialysis

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, 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 customer’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 customer’s benefit plan document always supersedes 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 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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see “Coding Information” below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy

will be denied as not covered. 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. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses the presence of a professional (e.g., nurse) during home hemodialysis treatments.

Coverage Policy

Under most benefit plans, coverage for staff-assisted home hemodialysis is subject to the terms, conditions and limitations of the applicable benefit plan's Home Health Care benefit and schedule of copayments.

Professional staff-assisted home hemodialysis (Current Procedural Terminology [CPT][®] code 99512) is considered medically necessary when ALL of the following criteria are met:

- individual is stable on hemodialysis and not at increased risk as a result of having the procedure performed outside of a dialysis facility
- individual has a well-functioning vascular access
- individual has a medical contraindication to leaving home for hemodialysis
- individual or non-professional caregiver is not capable of performing home hemodialysis and has failed adequate training for home hemodialysis
- local hemodialysis facilities/centers have declined to accept you for in-facility hemodialysis

Staff-assisted home hemodialysis that does not meet the above criteria is considered not medically necessary.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

General Background

Dialysis is a treatment for individuals whose kidneys are failing. There are two types of dialysis, hemodialysis and peritoneal dialysis, that both perform normal kidney functions, filtering waste and excess fluid from the blood. 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 kidney disease (CKD) or end-stage renal disease (ESRD) dialysis is the only way, other than a kidney transplant, to prolong life. CKD 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 type of dialysis chosen is dictated by the patient's needs and the nephrologist's clinical judgment as to which treatment will be best tolerated.

In hemodialysis, a hemodialyzer acts as an artificial kidney to remove waste products from the blood and help restore the body's chemical balance. Getting the patient's blood to the hemodialyzer requires access to the patient's blood vessels. Vascular access is provided by an arteriovenous (AV) fistula, an AV graft, or a central vein catheter (Brenner, 2007). To determine the type of access most suitable for an ESRD patient, a history must be taken and physical examination of the patient's venous, arterial, and cardiopulmonary systems must be performed. The characteristics of the patient's arterial, venous, and cardiopulmonary systems determine the best type of access and location for the patient (National Kidney Foundation [NKF], 2015). An arteriovenous (AV) fistula is accomplished by a surgical procedure that 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.

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 can be performed in various settings, including home, outpatient facility, or hospital. Facility-based dialysis is generally performed three times per week for three to five hours at a hospital or dialysis center.

A patient who is stable on dialysis; is not at increased risk by having the procedure performed outside of a dialysis facility; has well-functioning vascular access; and has caregiver 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 generally more intensive than the intermittent schedule for conventional, in-center hemodialysis. 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. The patient and caregivers are responsible for maintaining the dialysis equipment.

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, 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 five to seven times per week for one to four hours each day, and nocturnal hemodialysis is performed five to seven times per week for six to ten hours. Home hemodialysis affords the patient a degree of scheduling flexibility, which is not always possible in a center. Disadvantages of home hemodialysis include: a six to eight week training period for the family member or support person; the need to maintain the same schedule as the patient; and caregiver stress or psychologic burden of feeling responsible for the patient's safety.

Generally, home hemodialysis requires a caregiver who is trained with the patient in home hemodialysis and assists in the treatment. The NxStage System One has been approved for solo

use of the device for home hemodialysis during waking hours. The Tablo® Hemodialysis System (Outset Medical, Inc, San Jose, CA) has recently been approved for home use and according to the vendor website it features an integrated water purification system, the ability to produce dialysate on demand, a simplified user interface and wireless connectivity for data transfer.

The presence of a professional (e.g., nurse) during dialysis treatments, or staff-assisted dialysis, is considered a convenience and not medically necessary. In rare, specific situations staff-assisted home hemodialysis may be considered medically necessary. In addition to the patient being stable on dialysis and having a well-functioning vascular access the following are also required for staff-assisted dialysis to be considered medically necessary and not a convenience:

- the patient has a medical contraindication to leaving home for hemodialysis
- the patient or non-professional caregiver is not capable of performing home hemodialysis and has failed adequate training for home hemodialysis
- local hemodialysis facilities/centers have declined to accept the patient for in-facility hemodialysis

U.S. Food and Drug Administration (FDA)

Devices that have been developed to be used for hemodialysis at home include:

- NxStage System One™ (NxStage Medical, Inc., Lawrence, MA) received U.S. Food and Drug Administration (FDA) 501(k) clearance for use in the home in 2005. According to 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.” In August 2017, the NxStage System One received FDA 501(k) clearance for solo home hemodialysis during waking hours (K171331).
- Fresenius Medical Care received FDA 501(k) clearance (K121421, K150708) February 2011 for the Fresenius 2008K@5home™ (Fresenius Medical Care, Waltham, MA). According to the FDA summary, the device is indicated for acute and chronic dialysis therapy in an acute or chronic facility. The 2008K@home is also indicated for hemodialysis in the home and must be observed by a trained and qualified person as prescribed by a physician.
- Tablo® Hemodialysis System (Outset Medical, Inc, San Jose, CA) received U.S. Food and Drug Administration (FDA) 501(k) clearance December 2019. In March 2020, the FDA indication included that the device is also indicated for use in the home. In January 2022, the products under 510(k) numbers K190793 and K200741 were recalled due to possibility of heat-related damage. A new, updated system was approved in July 2022. The indications for Table Hemodialysis System and Table Cartridge are:
 - The Tablo Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician’s prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home.
 - The Tablo Cartridge (K190793) is a single use, disposable arterial and venous bloodline set intended to provide extra-corporeal access during hemodialysis. The Tablo Cartridge is compatible only with the Tablo Hemodialysis System.

Professional Societies/Organizations

American Association of Kidney Patients (AAKP): this organization notes that people who are successful doing home hemodialysis are usually highly motivated and would like to maintain the

lifestyle they had before renal failure. The patient and doctor decide together if home hemodialysis is the best therapy option. The following should be considered:

- willingness to train and learn how to do the therapy at home
- ability to control and use the equipment
- availability of a care partner to assist with your treatments
- basic reading and writing skills
- desire to take greater responsibility for your care

A person on home hemodialysis and their care partner will train together with a home dialysis training nurse or social worker. This training is done until everyone feels confident that self-treatment at home will be successful. Training takes between four to six weeks. During training, the following skills are taught to the patient and care partner:

- Care for the access
- Take blood pressure
- Setup dialysis machine and test the alarms
- Insert needles
- Monitor treatments and take notes
- Order supplies
- Recognize problems or potential problems and reporting of them to nurse or doctor
- Safely dispose of medical wastes

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD		No NCD found.	
LCD		No LCD found.	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
2. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
99512	Home visit for hemodialysis

***Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.**

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2. Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 11, End Stage Renal Disease (ESRD); Section 30.2 Hemodialysis Training. (Rev. 257, 03-01-19). Accessed Oct 1, 2024. Available at: <https://www.cms.gov/manuals/Downloads/bp102c11.pdf>
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determinations (LCDs) alphabetical index. Accessed Oct 1, 2024. Available at URL address: https://www.cms.gov/medicare-coverage-database/indexes/lcd-alphabetical-index.aspx?Cntrctr=373&ContrVer=1&CntrctrSelected=373*1&DocType=Active%7cFuture&s=All&bc=AggAAAQAAAA&
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Revision Details

Type of Revision	Summary of Changes	Date
Annual review	<ul style="list-style-type: none"> • Updated to new template and formatting standards. No changes to coverage criteria. 	11/15/2023
Annual review	<ul style="list-style-type: none"> • No changes to coverage statements 	11/15/2024

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