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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Dialysis Services

- Facility
- In Home
- Nocturnal
- Short Daily
- Ultrafiltration for the Treatment of Congestive Heart Failure

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Medicare Benefit Policy Manual, Chapter 8 - Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims
National Coverage Determinations (NCD)	Ultrafiltration, Hemoperfusion and Hemofiltration (110.15)
Local Coverage Determinations (LCD)	Frequency of Hemodialysis (L37504)
Local Coverage Article	Billing and Coding: Frequency of Hemodialysis (A55676)

For Non-Medicare Members

Service	Criteria
Hemodialysis	**Standard hemodialysis 3 days a week** is covered for members with end stage renal disease. For home dialysis the following additional criteria must be met: 1. The member is stable on dialysis. 2. The member is free of complications and significant concomitant disease that would render home dialysis unsuitable or unsafe. 3. The member or caregiver is capable of completing a home dialysis training program and adhering to a prescribed treatment regimen. 4. Adequate caregiver is available during dialysis 5. Back-up arrangements have been made with the facility-based dialysis center.
Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.
Ultrafiltration for the Treatment of Congestive Heart Failure	There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

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If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

End-stage renal disease (ESRD) is defined as an irreversible decline in kidney function that is severe enough to be fatal without treatment. In 2008, the prevalence of ESRD in the United States was 547,982 (Collins 2011). Treatment options for patients with ESRD include kidney transplantation and dialysis. Kidney transplantation is the preferred treatment for ESRD; however, the demand for kidney transplant exceeds the supply of transplantable organs (Pauly 2009). Of the 547,982 patients with ESRD, approximately 382,343 patients received dialysis (Collins 2011).

Dialysis filters blood to rid the body of harmful wastes, extra salt, and water. There are two types of dialysis peritoneal dialysis and hemodialysis. The majority of patients are treated using hemodialysis; however, there is no consensus on the optimal dose and frequency of hemodialysis. Difference hemodialysis regimens include: conventional hemodialysis, nocturnal hemodialysis, and short-daily hemodialysis (Toussaint 2010).

There are two types of dialysis: 1) Peritoneal dialysis: Removes waste products via the peritoneum, the membrane that lines the inside of the abdomen. The membrane is bathed in a special fluid called dialysate that is placed into the abdomen through a small tube, and after a designated period of time, the fluid is drained and replaced by new fluid. 2) Hemodialysis: Access is through surgical placement of an arteriovenous fistula, generally in the forearm, and less commonly by a venous catheter. After access is established, the fistula is connected to a hemodialysis machine that drains the blood, bathes it in dialysate solution and returns it to the bloodstream.

Conventional hemodialysis consists of three treatment sessions per week, with each session lasting 3 to 5 hours. Treatments can be performed in a dialysis center, hospital, or at home. Although this is a life-saving treatment, mortality in patients with ESRD is still remarkably high. Compared to the general population, mortality is four times higher in patients under 30 receiving dialysis and six times higher in patients over 65. Additionally, patients receiving dialysis often experience hypertension, fluid overload and the attendant cardiac sequelae, anemia, mineral and bone disorders, inflammation, poor nutritional status, poor functional status, and psychological disorders (Bayliss 2009, Ng 2010). Moreover, this approach to dialysis is inconvenient for patients receiving treatment in a dialysis center or hospital, who must travel to a dialysis unit several times a week.

Both nocturnal hemodialysis (typically 6-8 hours, 3-7 nights per week) and short-daily hemodialysis (typically 1.5-3 hours, 4-6 days per week) can take place at home or at a dialysis center. It is thought that increasing the frequency and duration of hemodialysis will lead to less fluid gain leading to improved blood pressure control, increased hemodynamic stability, and increased efficiency of solute clearance. A potential harm is an increased risk of vascular access complications due to more frequent use (Ng 2010, Toussaint 2010).

There are several hemodialysis devices approved by the FDA for home use. Some are large, non-portable devices that require modifications to the home electrical and plumbing systems. These include the Fresenius 2008K and the B. Braun Dialog Plus. Others are smaller and portable. The NxStage System One is specifically designed for home use; it does not require infrastructure changes.

Medical Technology Assessment Committee (MTAC)

Frequent Home Dialysis

08/04/2008: MTAC REVIEW

Evidence Conclusion:

Objective 1:

- There is insufficient evidence that home nocturnal dialysis improves important health outcomes compared to in-center dialysis. An RCT found improvement in LV mass and phosphate level, intermediate outcomes, and mixed findings in QOL. There is weak evidence from a single cohort study that nocturnal dialysis lowers the

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rate of dialysis-related or cardiovascular-related hospitalizations. In this cohort study, all-cause hospitalizations did not decrease significantly.

- There is insufficient evidence that home short-daily dialysis improves health outcomes compared to in-center dialysis. One statistical analysis found a lower mortality rate with short daily dialysis compared to national rates, but patients may have differed in ways that affect outcomes, and there was potential financial bias.

Objective 2:

- There is insufficient evidence that home nocturnal dialysis 6 nights a week improves important health outcomes compared to home hemodialysis 3 times a week.
- There is insufficient evidence that home short-daily dialysis 5 or more times a week improves important health outcomes compared to home hemodialysis 3 times a week

Articles: Assessment objectives:

1) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional in-center dialysis 3 times a week.
2) To determine whether frequent home nocturnal or home short daily dialysis leads to better health outcomes in patients with end-stage renal disease compared to home dialysis 3 times a week.

Important health outcomes are survival, hospitalizations and quality of life.

Objective 1: Comparison with in-center hemodialysis One randomized controlled trial (Culleton et al., 2007) and two cohort studies (Bergman et al., 2008; Schwartz et al., 2005) comparing frequent nocturnal home hemodialysis to in-center hemodialysis were identified and critically appraised. Case series were not reviewed due to the availability of higher-grade evidence. The studies on short-daily hemodialysis were all case series. Most were small (<15 patients) and or included patients who primarily received dialysis in-center and thus were not suitable for critical appraisal. The strongest study identified compared outcomes in 117 patients on short-daily dialysis (84% at home) to outcomes of patients from a national database receiving conventional dialysis (Blagg et al., 2006). The Blagg study was critically appraised. *Objective 2: Comparison with home hemodialysis 3 times a week*

One comparative study was identified, and critically appraised (Mahadevan et al., 2006). This was a small retrospective cohort study comparing outcomes in patients who received home nocturnal dialysis either six nights per week or on alternate nights (3-4 times a week). An RCT by the Frequent Hemodialysis Network (FHN) is underway comparing nocturnal home hemodialysis 3 versus 6 times a week. The study is currently recruiting patients; the estimated completion date is January 2010 (Clinicaltrials.gov). *Studies reviewed include:*

Blagg CR, Kjellstrand CM, Ting GO, Young BA. Comparison of survival between short-daily hemodialysis and conventional hemodialysis using the standardized mortality ratio. Hemodialysis International 2006; 10: 371-374. See Evidence Table Culleton BF, Walsh M, Klarenbach SW et al. Effect of frequent nocturnal hemodialysis vs conventional hemodialysis on left ventricular mass and quality of life. JAMA 2007; 298: 1291-1299. See Evidence Table Bergman A, Fenton SSA, Richardson RMA, Chan CT. Reduction in cardiovascular related hospitalization with nocturnal home hemodialysis. Clin Nephrol 2008; 69: 33-39. See Evidence Table Schwartz DI, Pierratos A, Richardson RMA et al. Impact of nocturnal home hemodialysis on anemia management in patients with end-stage renal disease. Clin Nephrol 2005; 63: 202-208. See Evidence Table Mahadevan K, Pellicano R, Reid A et al. Comparison of biochemical, hematological and volume parameters in two treatment schedules of nocturnal home hemodialysis. Nephrology 2006; 11: 413-418. See Evidence Table.

The use of home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Nocturnal Dialysis

04/18/2011: MTAC REVIEW

Evidence Conclusion: There is insufficient evidence to determine whether nocturnal dialysis leads to better health outcomes in patients with end-stage renal disease compared to conventional dialysis 3 times a week. There is fair evidence that short-daily dialysis leads to improvements in intermediate outcomes such as left ventricle mass and physical-health composite score compared to conventional dialysis 3 times a week. **Articles:** Studies were selected for review if they included at least 25 subjects and assessed the effect of nocturnal or short-daily dialysis on health outcomes. The majority of studies identified were non-randomized, observational studies. As these studies are more prone to bias, they were not selected for review. An RCT that compared the quality of life of patients receiving nocturnal dialysis to conventional dialysis was not selected for review as it did not have adequate power. A recent RCT comparing short-daily dialysis to conventional dialysis was selected for review.

The following study was critically appraised: FHN Trial Group. In-center hemodialysis six times per week versus three times per week. *N Engl J Med 2010;* 363:2287-2300. See Evidence Table

The use of nocturnal dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

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Frequent Home Dialysis

08/20/2012: MTAC REVIEW

Evidence Conclusion:

Survival – There is lower quality evidence upon which to draw conclusions about survival with home versus in-center hemodialysis. Three observational studies specifically reported on death or measures of mortality and survival with home hemodialysis compared to in-center hemodialysis. One study had no deaths and therefore found no difference. The two other studies favored home hemodialysis but were either small or had a higher likelihood of residual confounding (Kaiser 2011).

Since the Kaiser review, a recent matched-cohort study was identified that included 11,508 subjects assessed the relative mortality between daily home hemodialysis and thrice-weekly in-center hemodialysis. Results from this study suggest that home hemodialysis may be associated with a reduction in all-cause mortality compared to thrice-weekly in-center hemodialysis (HR 0.87, 95% CI 0.78-0.97, P=0.01). Limitations of the study include: residual confounding, approximately 1 in 4 home hemodialysis patients switched to in-center hemodialysis, more patients in the in-center treatment group were dually eligible for Medicare and Medicaid, and the cause of death was unknown in 10-20% of cases (Weinhandl 2012).

Hospitalizations – There is lower quality evidence upon which to draw conclusions about hospitalizations with home versus in-center hemodialysis. One nested-case control study favored home hemodialysis in terms of hospitalizations per patients and two additional studies appeared to possibly favor home hemodialysis but were underpowered (Kaiser 2011).

Quality of life – The evidence is of insufficient quantity and quality to draw conclusions on quality of life with home versus in-center hemodialysis. Two small observational studies did not find differences in quality of life with home versus in-center hemodialysis. One study reported that both groups had about the same number of subjects working (Kaiser 2011).

Change in left ventricular mass – No studies were identified that evaluated this outcome (Kaiser 2011).

Blood pressure control – There is lower quality evidence upon which to draw conclusions. Two studies reported significant decreases in blood pressure measures with home hemodialysis compared to in-center hemodialysis. One study also appeared to favor home hemodialysis in terms of need for antihypertensive medications (Kaiser 2011).

Nutritional status and serum albumin – There are lower quality evidence upon which to draw conclusions. Three observational studies reported mixes results on measures of serum albumin, with one study significantly favoring home as compared to in-center hemodialysis. One study found no difference in intradialytic weight gain with home versus in-center hemodialysis (Kaiser 2011).

Vascular access complications/ Safety – The studies evaluating vascular access complications have been very small and the results were somewhat mixed. One study evaluated the operations (per patient) due to vascular access and found no significant difference, but the data tended toward favoring home hemodialysis. Another small study appeared to favor in-center, but the study was not adequately powered to evaluate this outcome. In terms of other safety reports, one small study appeared to have more machine malfunctions with home hemodialysis, another study reported that a composite measure of intradialytic adverse events appeared to favor home hemodialysis, but this was not significant (Kaiser 2011).

Articles: In March 2011, Kaiser reviewed alternative approaches to hemodialysis. Since the Kaiser review three observational studies were identified. Two studies were excluded as they did not compare in-center hemodialysis to home hemodialysis. The remaining observational study was selected for review.

Several studies were identified that reanalyzed results from the FHN trial; however, they were not selected for review since the FHN trial evaluated whether short-daily in-center hemodialysis improved patient outcomes compared to conventional in-center hemodialysis, and whether nocturnal home hemodialysis improved patient outcomes compared to conventional home hemodialysis. The following article and medical technology assessment were selected for review: Kaiser Permanente. Alternative approaches to hemodialysis: short “daily” and nocturnal. March 2011. The committee voted to accept the Kaiser technology assessment. The studies were insufficient to draw conclusions on clinical benefit as compared to standard forms of dialysis.

Frequent Home Dialysis

10/12/2020: MTAC REVIEW

Evidence Conclusion:

- There is a lack of high-quality randomized controlled trials assessing the effectiveness of frequent home hemodialysis versus conventional in-center hemodialysis in patients with ESRD.

- The available evidence is of low quality, mainly from uncontrolled studies, and suggests:
    - Home hemodialysis may decrease mortality compared to in-center hemodialysis

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- No difference between groups in terms of all-cause mortality, hospitalization, cardiovascular mortality, access survival, and transplantation rate
- Mixed findings regarding quality of life and adverse events.
- Home hemodialysis may be comparable to in-center dialysis in patients with ESRD

The use of frequent home dialysis in the treatment of kidney disease does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Ultrafiltration in the Treatment of Congestive Heart Failure

08/07/2006: MTAC REVIEW

Evidence Conclusion: In conclusion, there is insufficient evidence to date to determine the efficacy and long-term safety of ultrafiltration versus standard care in acute decompensated heart failure, or to determine who would benefit most from the intervention.

Articles: The search yielded around 280 articles most of which were review articles, opinion pieces, or dealt with the technical aspects of the procedures. There was one RCT, and several small case series, many of which dated back in the 1980s and 1990s. The RCT and the relevant case series using the new UF device (System 100, CHF Solutions, Minneapolis, Minnesota) were selected for critical appraisal: Bart BA, Boyle A, Bank AJ, et al. Ultrafiltration versus usual care for hospitalized patients with heart failure. The Relief for Acutely fluid-overloaded Patients with Decompensated Congestive Heart Failure (RAPID-CHF) trial. J Am Coll Cardiol 2005; 46:2043-2046. **See** Evidence Table. MR, Saltzberg M, O'sollivan J, et al. Early ultrafiltration in patients with decompensated heart failure and diuretic resistance. J Am Coll Cardiol 2005;46:2047-2051. **See** Evidence Table.

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/17/2013: MTAC REVIEW

Ultrafiltration in the Treatment of Congestive Heart Failure

Evidence Conclusion: There is insufficient evidence to support the use of ultrafiltration as a first-line treatment in hospitalized ADHF with volume overload. There is insufficient evidence to determine the safety and efficacy of ultrafiltration in patients with ADHF who are refractory to diuretic therapy.

Results from UNLOAD trial, suggest, but do not provide good evidence, that ultrafiltration may provide better correction of volume overload than IV diuretics (given at the dose used in the trial) in patients hospitalized ADHF who are not resistant to diuretic therapy. The trial had its limitations and does not provide any evidence on the safest and most effective rates of fluid removal, duration of treatment, or the conditions for termination of ultrafiltration. There is evidence from the CARRESS-HF that IV loop diuretic-based therapy adding distal-acting diuretics, IV vasodilator and inotropic agents as needed is superior to ultrafiltration in patients with acute decompensated heart failure and worsening renal function. CARESS-HF results show increased incidence of worsening kidney function in the ultrafiltration group versus the stepped pharmacologic therapy group.

A large ongoing trial (AVOID-HF) (NCT01474200) involving 810 patients in 40 US centers is examining the effect of UF vs. intravenous diuretics in reducing hospitalization in patients with ADHF before worsening renal function.

Articles: UNLOAD trial (Costanzo et al 2007, evidence table 1) See Evidence Table. CARRESS-HF (Bart yet al 2012, evidence table 2) See Evidence Table

The use of ultrafiltration in the treatment of congestive heart failure does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

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

Frequent (Greater Than 3 Days a Week) Hemodialysis, Nocturnal or Short Daily, In Home or Facility - Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
99512	Home visit for hemodialysis
90999	Unlisted dialysis procedure, inpatient or outpatient
E1629	Tablo hemodialysis system for the billable dialysis service

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Ultrafiltration for the Treatment of Congestive Heart Failure
Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met
Non-Medicare - Considered Not Medically Necessary

CPT® or HCPC Codes	Description
0692T	Therapeutic ultrafiltration

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Creation Date	Review Dates	Date Last Revised
08/04/2008	07/06/2010 MDCRPC, 05/03/2011 MDCRPC, 03/06/2012 MDCRPC, 10/02/2012MDCRPC, 08/06/2013MPC, 06/30/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC ,08/07/2018MPC, 08/06/2019MPC, 08/04/2020MPC, 08/03/2021MPC, 08/02/2022MPC, 08/01/2023MPC, 03/12/2024MPC, 03/04/2025MPC	04/17/2024

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

Revision History	Description
12/09/2015	Added Medicare and Noridian links
10/29/2018	Updated the Medicare links
08/04/2020	Added Medicare LCA A55676; Added CPT codes 90999 and 99512
08/03/2021	Added the October 12, 2020 MTAC review
10/26/2022	Updated applicable codes, including new codes released 01/01/22 and 04/01/22.
04/17/2024	Merged “Ultrafiltration for the Treatment of Congestive Heart Failure” criteria and retitled to Dialysis Services

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