



**Kaiser Foundation Health Plan
of Washington**

Clinical Review Criteria

Frequent Dialysis - Greater Than 3 Days a Week

- Facility
- In Home
- Nocturnal
- Short Daily

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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)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Proposed LCD – Frequency of Hemodialysis (DL37504)

For Non-Medicare Members

Standard dialysis 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) Dialysis, 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.

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, KPWA 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: on home nocturnal or short daily dialysis versus in-center dialysis 3 times a week:

One RCT and two cohort studies were identified that compared nocturnal home dialysis to in-center dialysis 3 times a week. The RCT (Culleton et al., 2007) found statistically significant improvement in the primary outcome, LV mass, a surrogate marker for cardiovascular disease. Among other secondary outcomes, phosphate level was significantly lower in the nocturnal home dialysis group, and there was no significant between group differences in calcium level and anemia. Two cohort studies matched patients who received nocturnal dialysis to similar patients receiving conventional in-center dialysis 3 times a week. Bergman et al. (2008) found significantly lower dialysis-related or cardiovascular-related hospital admissions (the primary outcome) in the group converted to nocturnal dialysis, but no significant difference in all-cause hospitalization. Schwartz et al., (2005) also had significant findings for the primary study outcomes, increase in hemoglobin concentration and increase in the proportion of patients who were EPO-free after 12 months. None of the studies had mortality as an outcome.

There are fewer published studies on short-daily dialysis. A statistical analysis (Blagg et al., 2006) found a lower mortality rate in 117 patients who received short-daily dialysis either in-center or at home compared to national rates on patients receiving conventional hemodialysis (standardized mortality ratio=0.39). Patients who received short-daily dialysis may have differed from those in the national database, and there were financial links between the authors of this study and the home dialysis device used in the study.

Evidence on home nocturnal or short daily dialysis versus home dialysis 3 times a week:

No randomized controlled trials were identified, and there were no comparative studies with mortality as an outcome. The highest grade of evidence comparing different frequencies of home nocturnal dialysis is a retrospective cohort study by Mahadevan and colleagues (2006). The investigators evaluated biological parameters in 13 patients receiving nocturnal dialysis 6 nights a week and 21 patients receiving nocturnal dialysis every other night (3-4 times a week). After 3-6 months of follow-up, levels of urea, creatinine and PTH were all significantly lower in the group treated 6 nights/week, and there were no significant differences between groups in phosphate, calcium, albumin and homocystine levels, or in use erythropoietin or phosphate binders. There were no significant differences at follow-up in the proportion of patients taking phosphate binders, calcitrol, blood

pressure medications or erythropoietin. The evidence is limited due to lack of randomization (there may have been pre-existing differences between groups) and the small sample size (may be underpowered).

There is no high-grade evidence on health outcomes associated with short daily dialysis at home versus home hemodialysis 3 times a week.

Conclusions:

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 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: *Short-daily dialysis compared to conventional dialysis:* A recent RCT that included 245 patients and evaluated whether short-daily dialysis (1.5 to 2.75 hours, six times per week) would improve patient outcomes compared to conventional dialysis (2.5 to 4 hours, three times per week). There were two composite primary outcome variables: death or 12-month change in left ventricle mass as assessed by cardiac MRI, and death or 12-month change in physical-health composite score from the RAND 36-item health survey. Compared to conventional dialysis, frequent dialysis was associated with favorable changes in both of the primary composite outcomes. As the mortality rate in both groups was low, the bulk of the treatment effect was seen in intermediate

outcomes. The sample size was insufficient to determine the effects of frequent versus conventional dialysis on overall mortality, cause-specific mortality, or hospitalizations (FHN Trial Group 2010). *Nocturnal dialysis compared to conventional dialysis*: There is no high-quality evidence on health outcomes associated with nocturnal dialysis versus conventional dialysis. The majority of studies identified assessed intermediate outcomes such as mineral metabolism. Very few studies had mortality as an outcome. Results from these studies are inconsistent due to the low-quality of the studies. **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. A 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*.

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 is lower quality evidence upon which to draw conclusions. Three observational studies reported mixed 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.

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

Creation Date	Review Dates	Date Last Revised
08/04/2008	07/06/2010 ^{MDCRPC} , 05/03/2011 ^{MDCRPC} , 03/06/2012 ^{MDCRPC} , 10/02/2012 ^{MDCRPC} , 08/06/2013 ^{MPC} , 06/30/2014 ^{MPC} , 04/07/2015 ^{MPC} , 02/02/2016 ^{MPC} , 12/06/2016 ^{MPC} , 10/03/2017 ^{MPC} , 08/07/2018 ^{MPC}	10/02/2012

^{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

Codes

No specific codes for this service