Home Hemodialysis

Policy Number: CS057.O
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➲ Instructions for Use

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Related Community Plan Policies

- Home Health, Skilled, and Custodial Care Services
- Private Duty Nursing Services

Commercial Policy

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Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Idaho	Home Hemodialysis (for Idaho Only)
Indiana	None
Kansas	Home Hemodialysis (for Kansas Only)
Kentucky	Home Hemodialysis (for Kentucky Only)
Louisiana	None
Nebraska	None
New Jersey	Home Hemodialysis (for New Jersey Only)
New Mexico	Home Hemodialysis (for New Mexico Only)
North Carolina	Home Hemodialysis (for North Carolina Only)
Ohio	Home Hemodialysis (for Ohio Only)
Pennsylvania	Home Hemodialysis (for Pennsylvania Only)
Tennessee	Home Hemodialysis (for Tennessee Only)

Coverage Rationale

Home hemodialysis without skilled care is proven and medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet all of the following criteria:

- Individual is stable on dialysis with no evidence of skilled care interventions being necessary during treatments; and
- Individual undergoing hemodialysis or non-professional caregiver has the ability to perform and maintain home hemodialysis and has received comprehensive training regarding proper protocol; and
- Absence of complications and significant concomitant disease that would cause home hemodialysis to be unsafe or unsuitable; and
- Individual has well-functioning vascular access

Home hemodialysis with skilled care is proven and medically necessary as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease who meet all of the following criteria:

- Individual is stable on dialysis and not at increased risk as a result of having the procedure performed outside a dialysis center venue; and
- Individual undergoing hemodialysis or non-professional caregiver is not capable of performing home hemodialysis; and
- Individual has medical contraindications to leaving home for hemodialysis; and
- Individual has well-functioning vascular access; and
- Staff assisted home hemodialysis protocols generally match those provided in the hemodialysis center (i.e., 3 times per week, 3-4-hour treatments); the exact dialysis therapy employed is determined on an individual basis by the attending nephrologist

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
90963	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90964	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2-11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90965	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12-19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents
90966	End-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older
90967	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients younger than 2 years of age
90968	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 2-11 years of age
90969	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 12-19 years of age
90970	End-stage renal disease (ESRD) related services for dialysis less than a full month of service, per day; for patients 20 years of age and older
90989	Dialysis training, patient, including helper where applicable, any mode, completed course
90993	Dialysis training, patient, including helper where applicable, any mode, course not completed, per training session
99512	Home visit for hemodialysis

HCPCS Code	Description
S9335	Home therapy, hemodialysis; administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing services coded separately), per diem

Description of Services

For individuals with end-stage renal disease (ESRD), hemodialysis (HD) is an option for “renal replacement” therapy. HD includes two components, “ultrafiltration,” which is employed to remove extra fluid, and “dialysis,” which relies on diffusion

to remove small molecule waste products. In practice, these are delivered by channeling a portion of an individual's blood flow into an extracorporeal circuit, which includes an artificial kidney within which the critical therapeutic processes take place. Control and monitoring of these functions are regulated by features built into the dialysis machine. Conventional HD is performed three times a week for three to four hours or longer each time resulting, for some patients, in improved health, reduced symptoms, and a longer and higher quality of life.

Home hemodialysis (HHD) allows individuals to conduct treatment in the convenience of their home environment. Treatment can be performed around the individual's daily activities instead of a dialysis center's available time slots (National Kidney Foundation, 2015). HHD systems are similar to those used in a dialysis center, although they are more user-friendly and possess numerous safety features to minimize complications.

Individuals suitable for HHD include those who:

- Have the ability and motivation to learn to carry out the process and the commitment to maintain treatment
- Are stable on dialysis
- Are free of complications and significant concomitant disease that would cause HHD to be unsafe or unsuitable
- Have a good functioning vascular access
- Have a caregiver who has made an informed decision to assist
- Have a suitable space that could be adapted within their home environment

(Rioux et al., 2015; Walker et al., 2015; NICE, 2018)

Vascular access is necessary to provide adequate blood flow to accomplish treatment for HD. There are a variety of options available to achieve vascular access. Arteriovenous fistulas (AVFs) are the "gold standard" since they are associated with far fewer complications than arteriovenous grafts (AVGs) (a piece of synthetic "blood vessel" is interposed between artery and vein), and indwelling dialysis catheters (generally inserted into a large vein in the neck). Although individuals performing HHD are sometimes intimidated by the needle sticks necessary to obtain access through an AVF or an AVG, they should be encouraged to learn to perform them. While indwelling dialysis catheters require no skin puncture, they increase the infection risk.

Clinical Evidence

Evidence suggests that there might be a health outcomes and quality of life benefit in select patients from home hemodialysis (HHD) versus conventional in-center hemodialysis (HD). The quality of this evidence is, however, low, and mostly derived from observational studies. Furthermore, data are mixed on the benefit of routine more frequent versus thrice weekly HD.

Cheetham et al., (2024) performed a systematic review and meta-analysis to evaluate the benefits and harms of HHD versus in-center HD in adults with kidney failure. The systematic review included one cross-over randomized controlled trial (RCT) and 39 non-randomized studies of interventions (NRSI). The study results revealed uncertainty whether HHD, compared to in-center HD, was associated with a decrease in cardiovascular death (relative risk [RR] 0.92; 95% confidence interval [CI] 0.80 to 1.07; two NRSIs, 30,900 individuals; very low certainty evidence) or all-cause death (RR 0.80; 95% CI 0.67 to 0.95; nine NRSIs, 58,984 individuals; very low certainty evidence). It was uncertain whether HHD was associated with a decrease in hospitalization rate (mean deviation [MD] -0.50 admissions per patient-year; 95% CI -0.98 to -0.02; two NRSIs, 834 individuals; very low certainty evidence), compared with in-center HD. It was uncertain whether HHD, compared to in-center HD, was associated with receipt of kidney transplantation (RR 1.28; 95% CI 1.01 to 1.63; six NRSIs, 10,910 individuals; very low certainty evidence) and a shorter recovery time post-dialysis (MD -2.0 hours; 95% CI -2.73 to -1.28; two NRSIs, 348 individuals; very low certainty evidence). Additionally, it was uncertain if HHD was associated with decreased systolic blood pressure (BP) (MD -11.71 mmHg; 95% CI -21.11 to -2.46; four NRSIs, 491 individuals; very low certainty evidence) and decreased left ventricular (LV) mass index (MD -17.74 g/m^2; 95% CI -29.60 to -5.89; two NRSIs, 130 individuals; low certainty evidence). There was insufficient data found to evaluate the relative association of HHD and in-center HD with fatigue or vascular access outcomes. Few studies reported the same patient-reported outcome measures, which limited the ability to perform a meta-analysis or compare outcomes. The authors concluded that based on low to very low certainty evidence, HHD, compared with in-center HD, has uncertain associations or may be associated with decreased cardiovascular and all-cause death, hospitalization rate, slower post-dialysis recovery time, and decreased systolic BP and LV mass index. None of the findings suggested increased risk with

HHD compared to in-center HD, but the analysis was not set up to test non-inferiority. Limitations of the systematic review include that data were primarily obtained from retrospective cohort studies, including many small observational studies, prone to confounding and potential selection bias. There was also variation between studies regarding outcome reporting that limited the ability to perform meta-analyses. Subgroup and sensitivity analyses were also not performed due to the

small number of studies available for each outcome. (Weinhandl et al., 2015 and Weinhandl et al., 2012, which were previously cited in this policy, are included in this systematic review.)

Shah et al., (2024) retrospectively compared the risks of cardiovascular events, cardiovascular death, and all-cause death in patients with incident end-stage kidney disease (ESKD) on daily HHD and peritoneal dialysis (PD). Using data from the United States Renal Data System (USRDS), the study included 68,645 patients, 18 years and older, who initiated home dialysis within 6 months of the first ESKD service date. The mean age of patients was 64 ±15 years and 42.3% were women. The mean follow-up time was 1.8 ±1.6 years. The study results revealed an unadjusted cardiovascular event rate of 95.1 per thousand person-years (PTPY) (95% CI, 93.6 to 96.8). The cardiovascular event rate was higher in patients on HHD than on PD (127.8 PTPY; 95% CI, 118.9 to 137.2 versus 93.3 PTPY; 95% CI, 91.5 to 95.1). However, the adjusted risk of cardiovascular events was slightly lower in patients on HHD than on PD (hazard ratio [HR] 0.92; 95% CI, 0.85 to 0.997). Patients on HHD also had a 42% lower adjusted risk of stroke (HR 0.58; 95% CI, 0.48 to 0.71), 17% lower adjusted risk of acute coronary syndrome (HR, 0.83; 95% CI, 0.72 to 0.95), and no difference in risk of heart failure (HR 1.05; 95% CI, 0.94 to 1.16). Additionally, when compared to PD, patients on HHD had a 22% lower adjusted risk of cardiovascular death (HR 0.78; 95% CI, 0.71 to 0.86) and an 8% lower adjusted risk of all-cause death (HR 0.92; 95% CI, 0.87 to 0.97). The authors concluded, HHD is associated with a decreased risk of stroke, acute coronary syndrome, cardiovascular death, and all-cause death, relative to PD. Limitations of the study include the retrospective observational design, unvalidated comorbidity reporting, lack of treatment session details and prescription patterns, variability in the quality and completeness of the data, and absence of information on residual renal function and urine output. Further studies in patients with ESKD were recommended to better understand factors associated with differences in cardiovascular outcomes by type of home dialysis modality.

Bitar et al. (2024) retrospectively compared the risk of major adverse cardiovascular events (MACEs) in patients performing home dialysis with patients undergoing in-center HD. The study included 968 patients in Finland, aged 18 years or older, who were on CAPD (continuous ambulatory peritoneal dialysis) (n = 162), automated peritoneal dialysis (APD) (n = 229), HHD (n = 145), or in-center HD (n = 432) at day 90 from the beginning of dialysis therapy. The unadjusted study results revealed that 195 patients (20%) experienced a MACE during the 5-year follow-up. The cumulative incidence of first MACE was similar for in-center HD and CAPD, but higher for APD and HHD. Compared with in-center HD, MACE HR was 1.22 (95% CI 0.73 to 2.05) for CAPD, 0.86 (95% CI 0.47 to 1.57) for APD, and 0.67 (95% CI 0.30 to 1.50) for HHD, after adjustment for possible confounders. Of note, compared to in-center HD, PD was associated with a lower risk of MACE among female patients (HR 0.37; 95% CI 0.14 to 0.99) and higher risk among male patients (HR 1.80; 95% CI 1.11 to 2.92). The authors concluded that, in the study population, the risk of MACE was comparable across in-center and home dialysis modalities. Though, further research is required to study why there were differences observed in PD between the male and female patients. Limitations of the study include the retrospective, observational design and lack of data for some variables. The authors noted the numbers of patients and cardiovascular events was low and the study does not have the statistical power to show small differences between the dialysis modalities. The results may also not be generalized to other settings where home dialysis patient selection varies.

Zhu (2024) retrospectively assessed the racial and ethnic differences between in-center HD and HHD. Using USRDS data, the study included 548,453 patients on in-center HD and 14,202 patients on HHD. The major independent variable was race/ethnicity, defined as White, Black, Hispanic, Asian, or Others. The study results revealed minorities were significantly less likely to use HHD than Whites (Blacks: odds ratio [OR], 0.568, 95% CI, 0.546-0.592; Hispanics: OR, 0.510, 95% CI, 0.477-0.544; Asians: OR, 0.689, 95% CI, 0.619-0.766; Others: OR, 0.453, 95% CI, 0.390-0.525; $p < 0.001$). Most minorities were younger and had fewer comorbidities than Whites. All minority groups displayed significantly lower mortality and hospitalization incidences than Whites. After confounding for major risk factors, HHD showed a significantly lower risk of death than in-center HD (overall cohort: OR, 0.686, 95% CI, 0.641-0.734; White: OR, 0.670, 95% CI, 0.612-0.734; Blacks: OR, 0.717, 95% CI, 0.644-0.799; Hispanics: OR, 0.715, 95% CI, 0.575-0.889; Others: OR, 0.473, 95% CI, 0.265-0.844). The authors concluded there were substantial racial and ethnic variations in HHD use and health outcomes. However, due to the relatively small sample size of minorities on HHD, more matched samples and long-term patient follow-up were necessary to make firm conclusions. Another limitation of the study was the absence of data on some clinical indicators, socioeconomic traits, and pre-dialysis nephrology care. This data may have provided insight into the observed racial and ethnic inequalities. Further research is needed regarding racial and ethnic differences between in-center HD and HHD outcomes to ensure equitable pre-dialysis nephrology care.

ECRI completed a clinical evidence assessment of the NxStage System One (NxStage Medical, Inc.) for HHD. The assessment focused on the NxStage System One's safety and effectiveness and how it compared with other HHD systems or dialysis methods. The study selection criteria included clinical studies of individuals with kidney failure, undergoing HHD with the NxStage System One, that reported on patient-oriented outcomes, e.g., quality of life (QOL), conversion to in-center dialysis, need for hospitalization, mortality, and adverse events (AEs). ECRI identified and reviewed 10 published studies that reported on 12,536 individuals: two nonrandomized comparison studies and six case

series. Three publications reported on one clinical trial. ECRI noted that the studies may have some potential for overlap of included individuals. However, this could not be confirmed from the available information. ECRI concluded renal replacement therapy (RRT) with the NxStage System One for HHD is safe and sustainable long term. The NxStage System One appears to improve QOL. Through a six-year follow-up, the NxStage System One is associated with low hospitalization and low conversion rates to in-center HD. How well the NxStage System One compared with other HHD options could not be determined because comparison studies provided very-low-quality evidence. Large, controlled trials comparing the NxStage System One with other HHD devices and reporting on long-term patient-oriented outcomes are needed to address evidence gaps. ECRI noted the limitations of the ten studies include a high risk of bias due to two or more of the following: small study size, retrospective design, single-center focus, lack of randomization, and no controls. Each of the two comparison studies compared the NxStage System One with a different HHD modality. Only one study, which was reported in three publications, reported on QOL. The studies included individuals with varying severity of disease and varied HD protocols. This limited result generalization and interpretation (ECRI, 2023a).

ECRI completed a clinical evidence assessment of the Tablo® Hemodialysis System (Outset Medical, Inc.) for HHD. The assessment focused on the Tablo's safety and effectiveness and how it compared with other HHD systems or dialysis methods. The study selection criteria included clinical studies of individuals with kidney failure, undergoing HHD with the Tablo, that reported on patient-oriented outcomes, e.g., QOL, conversion to in-center dialysis, need for hospitalization, mortality, and AEs. ECRI identified and reviewed two published studies from one 8-week, multicenter, prospective clinical trial that reported on 30 individuals. One study assessed HHD using the Tablo in individuals with end-stage renal disease (ESRD) and reported on adherence to treatment protocol and AEs. The other study reported on time to recovery, QOL, and sleep quality. ECRI concluded that the clinical evidence indicates HHD with the Tablo is feasible. However, the evidence is insufficient to determine how well the Tablo works for HHD in individuals with kidney failure. Large, controlled trials comparing the Tablo with other HHD systems and reporting on long-term patient-oriented outcomes are needed to assess safety and effectiveness. ECRI noted the limitations of the two studies include small sample size, no comparisons of interest (i.e., other HHD devices or dialysis methods), no control group, lack of randomization, unreported patient-oriented outcome measures (e.g., hospitalization or conversion to in-center dialysis), and short follow-up times (ECRI, 2023b).

In a multicenter cohort study (Ok et al., 2023), thrice-weekly extended HHD was compared with in-center conventional HD in a large patient population with a long-term follow-up. Three hundred and forty-nine patients starting HHD were matched with 1,047 concurrent patients on in-center conventional HD by using propensity scores. The primary outcome was overall survival. Secondary outcomes were technique survival, hospitalization, and changes in clinical, laboratory, and medication parameters. The mean duration of dialysis session was 418 ±54 minutes in HHD and 242 ±10 minutes in patients on in-center conventional HD. All-cause mortality rate was 3.76 and 6.27 per 100 patient-years in the HHD and the in-center conventional HD groups, respectively. In the intention-to-treat (ITT) analysis, HHD was associated with a 40% lower risk for all-cause mortality than in-center conventional HD. In HHD, the 5-year technical survival was 86.5%. It was reported that HHD treatment provided better phosphate and BP control, improvements in nutrition and inflammation, and reduction in hospitalization days and medication requirement. The authors concluded that these results indicated that extended HHD is associated with higher survival and better outcomes compared to in-center conventional HD. The findings are however limited by the observational design with possible residual confounding, such as healthier and higher resources participants more likely to choose HHD.

Using USRDS data, Shah et al. (2023) retrospectively evaluated an observational cohort of 42,849 patients who started HHD. The association of sex and race/ethnicity with the outcome of all-cause mortality was evaluated. In the study cohort, 40.4% were women, and 57.4% were White. Women on HHD had higher unadjusted death rates (26.9 versus 22.4) compared with men. There was no difference in adjusted all-cause mortality between men and women, but women had an 8% higher adjusted risk of all-cause mortality at 1-year after initiating HHD. Hispanic, White, and Black patients had higher unadjusted death rates compared with Asians and Native Americans (25.1 versus 24.8 versus 23.2 versus 17.4 versus 16.6 per 100 person-years). There was no difference in adjusted all-cause mortality in Black, Hispanic, and Native Americans compared with White patients, while Asians had a lower risk of all-cause mortality than did White patients. There was no difference in adjusted 1-year mortality for Asian, Black, Hispanic, and Native American patients compared with White patients. The authors concluded that women had higher adjusted 1-year mortality than did men. However, both women and men had comparable survival on long-term follow-up after adjusting for socioeconomic status and other covariates in the home dialysis population. There were no racial/ethnic differences in adjusted mortality in the home dialysis population in the long-term follow up, except for Asians who had lower mortality than did White patients. Residing in midwestern geographical region was associated with a higher adjusted risk of mortality in the HHD population.

Fotheringham et al. (2021) conducted a stepped-wedge cluster randomized trial looking at a collaborative series approach to increase the patient's ability to perform five or more tasks while completing HHD. This study included 12 renal centers who recruited patients on in-center HD with sites randomized into early and late participation in a 12-month invention

series of collaboration that included data collection, learning events, Plan-Study-Do-Act cycles, and teleconferences repeated every 6 weeks, supported by a faculty, co-production, materials, and a nursing course. The primary outcome was the proportion of patients undertaking five or more HD-related tasks or HHD. Secondary outcomes included independent HD, QOL, symptoms, patient activation, and hospitalization. There were 586 patients on HD recruited. The proportion performing 5 or more tasks or HHD increased from 45.6% to 52.3%, however after analysis by step the adjusted OR for the intervention was 1.63 (95% CI 0.94 to 2.81, p = 0.08). At the end of the study, 28.3% of patients doing less than 5 tasks at baseline performed five or more tasks. Independent or HHD increased from 7.5% to 11.6%, but the remaining secondary endpoints were unaffected. The intervention did not increase dialysis related tasks being performed by in-center based patients, but there was an increase in HHD as well as an increase in the number of tasks among patients who were doing fewer than five at baseline.

Shafi et al., 2020 performed a systematic review to study the effects of more frequent or longer HD on clinical outcomes, (QOL), and symptoms in individuals with ESRD. Usual care was defined as in-center HD three times per week with less than 4 hours per treatment, more frequent HD as four or more treatments per week, and longer HD as 4 or more hours per treatment. The systematic review consisted of three RCTs, one non-randomized trial, and 13 observational studies. Compared to the population of individuals in the U.S. on HD, study populations were younger, healthier, and had a longer life expectancy. Two RCTs concluded that the pre-dialysis systolic BP and antihypertensive medication use were lower in the active treatment groups. However, the intervention was not blinded, BP measurements were not standardized, and antihypertensive medication use was based on self-report, all of which can bias these results. When taking all the studies together, the strength of evidence (SOE) was low that more frequent HD compared to usual care: lowered mortality, the composite outcome of risk of death or increase in LV mass, and risk of death or decrease in physical health; lowered LV mass and heart rate variability; and improved QOL and patient reported symptom measures, BP, and metabolic measures. The SOE was low that more frequent and longer HD compared to usual HD: improved BP; and shortened time to recovery (TTR) after HD. The SOE was low that vascular access complications were more frequent with either more frequent or more frequent and longer HD, compared to usual care. The overall SOE is low that selected widespread individuals on HD with low expected mortality and minimal residual kidney function may benefit from more frequent HD with a lower risk of death, lowering of BP, reduction in antihypertensive medication use, and lowering of LV mass. Nevertheless, these benefits need to be balanced with an increased risk of vascular access complications and doubt about the effect on total mortality. Some of the studies of more frequent HD were conducted among in-center HD whereas most individuals receiving frequent HD in the U.S. are treated at home using HD systems not tested in all the RCTs. Therefore, the authors' conclusion is limited to this setting: more frequent in-center HD may improve clinical outcomes, mortality, and QOL or patient-reported symptom measures. (Weinhandl et al., 2015 and Weinhandl et al., 2012, which were previously cited in this policy, are included in this systematic review.)

Outset Medical sponsored a prospective, multicenter, open label, non-randomized, cross-over study evaluating the use of the Tablo Hemodialysis System for in-center HD and HHD (NCT02460263). The study included 30 participants with ESRD on stable dialysis regimens. Participants underwent HD four times per week during a one-week, in-center HD run-in period; an 8-week, in-center HD treatment period, a 4-week, HHD transition period, and an 8-week, HHD treatment period. Using data from this study, Plumb et al., 2020 evaluated the safety and efficacy of the Tablo Hemodialysis System. The primary efficacy endpoint, weekly standard $Kt/V_{urea} \geq 2.1$, was achieved in 99.5% and 98.3% of measurements during the in-center HD and HHD periods, respectively. The average weekly standard Kt/V_{urea} was 2.8 for both periods. The secondary efficacy endpoint, delivery of ultrafiltration (UF) within 10% of the prescribed UF, was achieved in 94% of in-center HD and 94% of HHD treatments. The primary safety endpoint, the number of prespecified AEs observed, was also achieved. There were two prespecified AEs observed during the in-center HD period and six AEs observed during the HHD period. No AEs were determined to be related to the Tablo Hemodialysis System. The authors concluded that the Tablo Hemodialysis System is safe and effective for HHD. (This study is included in the systematic review by Cheetham et al., 2024 and the clinical evidence assessment by ECRI, 2023b.) Using data from the same study, Chertow et al. (2020) further evaluated the safety of the Tablo Hemodialysis System using patient-reported data on TTR, general health status, and sleep quality and related symptoms. The median TTR was 1.5 hours (10^{th}, 90^{th} percentile range 0.17 to 12, mean TTR 3.68 ±5.88 hours) during the in-center HD period and 2 hours (10^{th}, 90^{th} percentile range 0 to 6.0, mean TTR 3.04 ±5.14 hours) during the HHD period (Wilcoxon signed rank p = 0.57). Median index values obtained using the EuroQoL 5-dimension 5-level questionnaire were similar during the in-center HD period (0.832, 10^{th}, 90^{th} percentile range 0.617 to 1, mean 0.817 ±0.165) and the HHD period (0.826, 10^{th}, 90^{th} percentile range 0.603 to 1, mean 0.821 ±0.163) (Wilcoxon signed rank p = 0.36). Additionally, participants reported feeling alert or well-rested, both with in-center HD or HHD, with little difficulty falling or staying asleep, or feeling tired and worn out. The authors concluded, participants using the Tablo Hemodialysis System reported similar TTR, general health status, and sleep quality and related symptoms for both in-center HD and HHD. (This study is included in the systematic review by Cheetham et al., 2024 and the clinical evidence assessment by ECRI, 2023b.) Study limitations include small sample size and brief study period. Plumb et al., 2020 also noted the average age of participants was younger than the average age of patients receiving dialysis in the U.S.

In an observational cohort study, Choi et al. (2020) examined a national cohort of patients with incident ESRD that was comprised of 1,993 and 16,514 patients transitioning to HHD and PD, respectively, from 2007 to 2011. Patients on HHD were matched with patients on PD. The patients on PD who transitioned within 12 months of starting dialysis had similar mortality risks, while patients who transitioned > 12 months after starting dialysis had an 83% higher risk for mortality. The authors noted there was no meaningful survival difference in the first 12 months between HHD and PD, but patients who transitioned to PD after 12 months of dialysis had worse survival than their counterparts on HHD. It was concluded that additional studies are warranted to investigate the clinical implications of these differences.

In a cohort study, Rydell et al. (2019) analyzed the long-term effects of HHD on patient survival and on subsequent renal transplantation, compared with institutional hemodialysis (IHD) and PD, taking age and comorbidity into account. Patients starting HHD as initial RRT were matched with patients on IHD or PD, according to gender, age, Charlson Comorbidity Index and start date of RRT, using the Swedish Renal Registry. Survival analyses were performed as ITT (disregarding changes in RRT) and per-protocol (as on initial RRT). A total of 152 patients with HHD as initial RRT were matched with 608 patients on IHD and 456 patients on PD, respectively. Median survival was longer for HHD in ITT analyses: 18.5 years compared with 11.9 for IHD and 15.0 for PD. The difference remained significant in per-protocol analyses omitting the contribution of subsequent transplantation. Patients on HHD were more likely to receive a renal transplant compared with IHD and PD, although treatment modality did not affect subsequent graft survival. The authors concluded that HHD as initial RRT showed improved long-term patient survival compared with IHD and PD. This survival advantage persisted after matching and adjusting for a higher transplantation rate. Dialysis modality had no impact on subsequent graft survival. The findings are limited by the observational nature of the study. (This study is included in the systematic review by Cheetham et al., 2024.)

Mathew et al. (2018) conducted a systematic review and meta-analyses to compare the association of mortality and hospitalization in individuals undergoing intensive HD, compared with conventional HD or PD. The review included cohort studies with comparator arm and RCTs with > 50% of individuals ≥ 18 years of age, comparing any form of intensive HD (> 4 sessions/week or > 5.5 hours/session) with any form of chronic dialysis (PD, HD ≤ 4 sessions/week or ≤ 5.5 hours/session), that reported at least one predefined outcome (mortality or hospitalization). Twenty-three studies, including two RCTs, with a total of 70,506 individuals were included. The authors noted that the overall quality of evidence was low or very low for critical outcomes. Outcomes such as QOL, transplantation, and vascular access outcomes were not included in the review. The authors stated that compared with conventional HD, nocturnal HHD, nocturnal in-center HD, and short daily HHD were all significantly associated with decreased mortality.

Miller et al. (2018) conducted a systematic review to compare HHD and in-center HD outcomes for survival, hospitalization, cardiovascular, nutrition, and QOL. Regarding mortality, 10 of 13 trials reported 13-52% reduction; and three trials found no differences. According to six studies, BP and LV size measurements were generally lower for individuals on HHD compared to similar measurements for individuals on in-center HD. Regarding nutritional status, conflicting results were reported (eight studies). Some studies found improved muscle mass, total protein, and body mass index for individuals on HHD versus individuals on in-center HD, while other studies found no significant differences. There were no significant differences in the rate of hospitalization between HHD and in-center HD in the six articles reviewed. Seven studies on QOL demonstrated positive trends in HHD versus in-center HD. The authors concluded that despite limitations in the current data, 66% of the publications reviewed (29/44) demonstrated improved clinical outcomes in individuals who chose HHD. Even though HHD may not be preferred in all individuals, the authors concluded that a review of the literature suggests that HHD should be provided as a modality choice for substantially more than the current 1.8% of HHD patients in the U.S.

The Frequent Hemodialysis Network (FHN) Daily Trial (NCT00264758) was a multicenter, randomized trial that included 245 participants assigned to either in-center frequent HD (six times weekly) or conventional in-center HD (three times weekly). Inclusion criteria into the study were fairly broad, including ESRD requiring chronic RRT, age 13 years or above, weight above 30 kg, and achieved mean eKt/V > 1.0 for last two baseline HD sessions. Two primary composite outcomes were determined at one year, death or one-year change from baseline in LV mass, as assessed by cardiac resonance imaging, and death or one-year change in physical health, as assessed by a RAND® heath survey. Chertow et al. (2010) reported that both composite outcomes showed significant benefit in the frequent-dialysis group compared with the conventional-dialysis group (HR 0.61; 95% CI 0.46 to 0.82 for death or change in LV mass and HR 0.70; 95% CI 0.53 to 0.92 for death or change in physical health). This study also showed benefits in predetermined secondary outcomes to the frequent dialysis group, such as a decrease in LV mass, improved BP control, and phosphate balance but not on cognitive performance, depression, serum albumin concentration, or use of erythropoiesis-stimulating agents. Kotanko et al. (2015) further analyzed the results of this intervention and found that frequent HD reduces BP and the number of prescribed antihypertensive medications. It was found that frequent in-center HD led to improved self-reported general mental health and aspects of health-related QOL including a shorter recovery time after a HD session. In this analysis, frequent HD reduced LV end-diastolic volume, LV end-systolic volume, and right ventricular (RV) end-diastolic volume, but did not

affect the ratio between LV mass/LV end-diastolic volume, which is a marker for LV remodeling. The primary clinical benefit of the FHN Daily Trial appeared to be better volume control, which contributed to better BP control and lower LV mass. Adverse effects included more arteriovenous access interventions and increased intradialytic hypotensive events. The study also has several limitations. The sample size was insufficient to determine the effects of frequent in-center HD on death, cause-specific death, hospitalization, or other events. Chertow et al. (2016) then examined the effects of randomization to the 12-month intervention of frequent versus conventional in–center HD on mortality during extended follow-up and found that frequent in–center HD intervention reduced long-term mortality (HR 0.54; 95% CI 0.31 to 0.93), suggesting that frequent HD may benefit selected patients with ESRD. These latest findings are however limited by crossover to different renal replacement approaches after the randomization. (Chertow et al., 2010, Kotanko et al., 2015, and Chertow et al., 2016, are included in the systematic review by Shafi et al., 2020.)

Rocco et al. (2011) reported the main results of a companion study to the FHN Daily Trial, the FHN Nocturnal Trial (NCT00271999). The FHN Nocturnal Trial randomly assigned 87 participants to 6-times weekly night home dialysis (NHD) or 3-times-weekly HD (primarily at home) for 1-year. Inclusion criteria were similar as in the FHN Daily Trial, except that participants were all adults and willing to perform HD at home. Participants were enrolled starting in March 2006 and follow-up was completed by May 2010. The investigators randomized 87 participants to three times per week conventional HD or to nocturnal HD six times per week, all with single-use high-flux dialyzers. The 45 participants in the frequent nocturnal arm had a 1.82-fold higher mean weekly stdKt/V(urea), a 1.74-fold higher average number of treatments per week, and a 2.45-fold higher average weekly treatment time than the 42 participants in the conventional arm. There was not a significant effect of nocturnal HD for either of the two coprimary outcomes, death or LV mass (measured by magnetic resonance imaging) (HR 0.68), or of death or RAND Physical Health Composite (HR 0.91). Possible explanations for the LV mass result include limited sample size and participant characteristics. Secondary outcomes included cognitive performance, self-reported depression, laboratory markers of nutrition, mineral metabolism and anemia, BP and rates of hospitalization, and vascular access interventions. Participants in the nocturnal arm had improved control of hyperphosphatemia and hypertension, but no significant benefit among the other main secondary outcomes. There was a trend for increased vascular access events in the nocturnal arm. The authors were unable to demonstrate a definitive benefit of more frequent nocturnal HD for either co-primary outcome. After the 1-year trial concluded, study participants were free to modify their HD prescription. Rocco et al. (2015) obtained dates of death and kidney transplantation through July 2011 using linkage to the USRDS and queries of study centers and used log-rank tests and Cox regression to relate mortality to the initial randomization assignment. Median follow-up for the trial and post-trial observational period was 3.7 years. In the nocturnal arm, there were two deaths during the 12-month trial period and an additional 12 deaths during the extended follow-up. In the conventional arm, the numbers of deaths were one and four, respectively. In the NHD group, the overall mortality HR was 3.88 (95% CI, 1.27-11.79; p = 0.01). Using as-treated analysis with a 12-month running treatment average, the HR for mortality was 3.06 (95% CI, 1.11-8.43; p = 0.03). Six-month running treatment data analysis showed an HR of 1.12 (95% CI, 0.44- 3.22; p = 0.7). These results should be interpreted cautiously due to a surprisingly low (0.03 deaths/patient-year) mortality rate for individuals randomly assigned to conventional HHD, low statistical power for the mortality comparison due to the small sample size, and the high rate of HD prescription changes. Adverse effects included more arteriovenous vascular access interventions and accelerated loss of residual renal function. The trial concluded that participants randomly assigned to NHD had a higher mortality rate than those randomly assigned to conventional HD. The authors concluded that the implications of this result require further investigation. (Rocco et al., 2011 and Rocco et al., 2015 are included in the systematic review by Shafi et al., 2020.)

Several additional analysis combined data from the FHN Daily and FHN Nocturnal trials comparing frequent versus conventional therapy (three times per week):

- Garg et al. (2017) examined whether participants receiving frequent HD had better health-related QOL compared to participants receiving conventional HD. After one year in the Daily Trial, participants assigned to frequent in-center HD reported a higher feeling thermometer score, better general health, and a shorter recovery time after a dialysis session compared to standard thrice-weekly dialysis. After one year in the Nocturnal Trial, participants assigned to frequent HHD also reported a shorter recovery time after a dialysis session, but no statistical difference in their feeling thermometer or general health scores compared to standard HHD schedules. Participants receiving day or nocturnal HD on average recovered approximately one hour earlier from a frequent compared to conventional HD session. Participants treated in an in-center dialysis facility reported better health-related QOL with frequent compared to conventional HD. (This study is included in the systematic review by Shafi et al., 2020.)
- Chan et al. (2013) examined the impact of frequent in-center and home nocturnal HD on LV and RV volumes, LV remodeling, global systolic function, and explored which, if any, baseline participant characteristics modified these effects. In the Daily Trial, frequent HD resulted in significant reductions in LV end diastolic volume, LV end systolic volume, RV end diastolic volume, and a trend for RV end systolic volume compared with conventional therapy. The magnitude of reduction in left and RV end diastolic volumes with frequent HD was accentuated among participants with residual urine output < 100 ml/d. In the Nocturnal Trial, there were no significant changes in left or RV volumes.

The frequent dialysis interventions had no substantial effect on the ratio of LV mass/LV end diastolic volume in either trial. Frequent in-center HD reduced LV and RV end systolic and diastolic ventricular volumes as well as LV mass, but it did not affect LV remodeling.

- Unruh et al. (2013) assessed the impact of in-center and nocturnal HD frequency on depressive symptoms and self-reported mental health. The authors noted that frequent in-center HD, as compared with conventional in-center HD, improved self-reported general mental health. Changes in self-reported depressive symptoms were not statistically significant. The authors were unable to conclude whether nocturnal HD yielded similar effects. As trial interventions were not blinded, this could have introduced a bias in the findings. The authors concluded that more rigorous studies are needed to determine if more frequent hemodialysis is warranted. (This study is included in the systematic review by Shafi et al., 2020.)
- Chan et al. (2012) examined the associations with LV mass with HD frequency and explored which if any factors influenced the therapeutic response to frequent HD. In the Daily Trial, frequent HD resulted in a significant reduction in LV mass, LV mass index, and percent change in geometric mean of LV mass. Similar trends were noted in the Nocturnal Trial but did not reach statistical significance compared to conventional therapy. In the Daily Trial, a more pronounced effect of frequent HD on LV mass was evident among patients with LV hypertrophy at baseline. Changes in LV mass were associated with changes in BP (conventional HD: Pearson correlation coefficient [R] = 0.28, p = 0.01, daily HD: R = 0.54, p < 0.001) and were not significantly associated with changes in other parameters. Frequent in-center HD reduced LV mass. There was no statistical difference in nocturnal. The authors concluded that the benefit of frequent in-center HD on LV mass may be mediated by valuable effects on BP. (This study is included in the systematic review by Shafi et al., 2020.)
- Hall et al. (2012) compared the studies looking at effects of frequency versus conventional related to measures of physical performance, health, and functioning. The authors noted that frequent in-center HD compared with conventional in-center HD improved self-reported physical health and functioning, but had no significant effect on objective physical performance. There were no significant effects of frequent nocturnal HD on the same physical metrics. (This study is included in the systematic review by Shafi et al., 2020.)
- Daugirdas et al. (2012) reviewed the effects of frequent HD on measures of chronic kidney disease (CKD) mineral and bone disorders. The results indicated that frequent HD did not have major effects on calcium or parathyroid hormone concentrations in either trial. The authors concluded that frequent HD facilitates control of hyperphosphatemia. Additionally, extended session lengths could allow more liberal diets and freedom from phosphorus binders. (This study is included in the systematic review by Shafi et al., 2020.)

Ramar et al. (2017) conducted a systematic review that included comparative RCTs or observational studies with no restriction on language, published from 2000 to 2014, involving at least five adult individuals on dialysis who received a minimum of 6 months of follow-up. The effect size was pooled and stratified by intervention strategy (multidisciplinary care, home dialysis, alternate dialysis settings, and electronic health record implementation). Heterogeneity was used to assess the variability in study effects related to study differences rather than chance. Twenty-five international studies with 74,833 individuals on maintenance dialysis were included. Interventions with multidisciplinary care or home dialysis were associated with a lower mortality and hospitalizations. The findings are however limited by the inclusion of observational studies.

Sinclair et al. (2017) completed a systematic review evaluating dialysis modalities for the treatment of ESKD in Canada. The aim of the study was to inform policy questions regarding the optimal treatment for eligible individuals and effective methods of implementation support for the various dialysis options reviewed through an assessment of the clinical effectiveness patient experiences and perspectives, ethical issues, and implementation issues of dialysis modalities for the treatment of ESKD. Forty-four articles were synthesized, six systematic reviews and 38 articles describing 34 primary studies. The authors concluded that home-based dialysis (HHD and PD) is an appropriate modality option for the treatment of ESKD. This conclusion was based on clinical effectiveness, cost-effectiveness, individual experiences, ethical considerations, and implementation issues. These modalities could be more widely implemented in Canada. However, the evidence is dominated by non-randomized studies. (Weinhandl et al., 2012, which was previously cited in this policy, is included in this systematic review.)

Kasza et al. (2016) compared the survival of patients undergoing HHD with a permanent vascular access, facility HD with a permanent vascular access, facility HD with a central venous catheter, and PD, using a cohort study design. There were 20,191 patients who underwent ≥ 90 days of dialysis (median 2.25 years, interquartile range 1 to 3.75 years). There were significant differences in age, gender, comorbidities, and other variables between treatment groups at baseline. Thirty percent of patients had at least one treatment change. Relative to facility HD with permanent access, the risk of death for patients undergoing HHD with a permanent access was lower in the first year. The findings were robust to unmeasured confounding within plausible ranges. The authors concluded that relative to facility HD with permanent vascular access, HHD conferred better survival prospects, while PD was associated with a higher risk, and facility HD with a catheter the

highest risk, especially within the first year of dialysis. (This study is included in the systematic reviews by Cheetham et al., 2024 and Sinclair et al., 2017.)

Piccoli et al. (2016) conducted a systematic review to analyze the relationship between dialysis schedule and pregnancy outcomes in pregnancies with chronic dialysis to clarify the major risks, outcomes, and treatment suggestions and to identify optimal regimens associated with the best pregnancy outcomes, with the least adverse effects for the mother and neonate. Meta-regression was performed in case series dealing with the larger subset patients on HD; case reports were analyzed separately (according to PD versus HD; conception before or during dialysis). The authors selected 101 full papers and 25 abstracts (36 series; 90 case reports), for a total of 681 pregnancies in 647 individuals. In the case series (574 pregnancies in 543 individuals), preterm delivery was extremely frequent (83%). Meta-regression analysis showed a relationship between hours of dialysis per week in HD and preterm delivery and was significant for preterm deliveries (< 37 gestational weeks) and for small for gestational age (SGA). SGA was closely associated with the number of dialysis sessions per week. Case report analysis suggested a lower incidence of SGA on HD versus PD. No evidence of an increased risk of congenital abnormality was found in the retrieved publications. The overall conclusion noted that data on pregnancy on dialysis are mixed but rapidly accumulating; the main determinant of outcomes on HD is the dialysis schedule.

A systematic review conducted by Ishani et al. (2015) compared the effectiveness of home-based kidney dialysis versus in-center or other outpatient kidney dialysis locations. The authors of the systematic review concluded that low-strength evidence suggests that home-based dialysis may provide similar health outcomes and at similar or lower costs for many patients compared to in-center HD. Therefore, home-based dialysis may be an acceptable and sometimes preferred alternative to in-center HD. According to the authors, information is limited on factors important in addressing selection of and barriers to home-based dialysis and remains an area of important research and health policy. (This study is included in the systematic review by Sinclair et al., 2017.) (Weinhandl et al., 2015, Weinhandl et al., 2012, and Jayanti et al., 2013, which were previously cited in this policy, are included in this systematic review.)

Slinin et al. (2015) conducted a systematic review to determine whether clinical and patient-centered outcomes in individuals with advanced CKD were improved by the following: earlier HD therapy initiation, more frequent or longer duration HD or use of low-flux compared to high-flux membrane. The authors included individuals with advanced CKD receiving HD. The review consisted of 32 articles from 19 trials. The interventions comprised, early versus late dialysis therapy initiation; more frequent (> 3 times a week) or longer duration (> 4.5 hours) compared to conventional HD; low- versus high-flux dialyzer membranes. Frequency and duration of HD included two RCTs looking at more frequent dialysis (4-7 sessions per week) was compared to dialysis 3 times per week. Although none of the studies was powered to assess mortality, moderate-quality evidence indicated that earlier dialysis therapy initiation (at estimated creatinine clearance of 10-14 mL/min) did not reduce mortality compared to later initiation (estimated creatinine clearance of 5-7 mL/min). More than thrice-weekly HD and extended-length HD during a short follow-up did not improve clinical outcomes compared to conventional HD and resulted in a greater number of vascular access procedures (very low-quality evidence). HD using high-flux membranes did not reduce all-cause mortality, but reduced cardiovascular mortality compared to HD using low-flux membranes (moderate-quality evidence). Limitations included that few studies were adequately powered to evaluate mortality. The overall findings among patients with advanced CKD without uremic symptoms found that initiating dialysis later did not lead to worse clinical outcome, nor did more frequent or extended dialysis improved clinical outcomes compared to conventional HD. The studies did not assess all-cause mortality or other clinical outcomes, but more frequent dialysis is associated with greater risk or vascular access related procedures.

Clinical Practice Guidelines

American Heart Association (AHA)

AHA concluded in a scientific statement regarding cardiovascular effects, that home dialysis, including HHD and PD, provides a more physiological approach to dialysis. Home dialysis, under many circumstances, can lead to improved cardiovascular outcomes, when compared to traditional thrice-weekly in-center HD. However, additional physiological studies of cardiovascular risk factors and function, as well as more generalizable outcome trials are needed to overcome biases. High-quality HHD and PD need to be more accessible to all patients with kidney failure. Nephrologists and non-nephrologists need better HHD and PD training to promote a shared decision-making model that includes adequate patient education and time to consider home dialysis, especially for individuals with cardiovascular disease. The interdisciplinary nephrology workforce also needs to expand so patients performing home dialysis receive training and technical support (Sarnak et al., 2022).

National Kidney Foundation/Kidney Disease Outcomes Quality Initiative (NKF/KDOQI)

The 2015 NKF/KDOQI clinical practice guidelines for hemodialysis adequacy state the following among other conclusions and recommendations:

- "We suggest that patients with end-stage kidney disease be offered in-center short frequent hemodialysis as an alternative to conventional in-center thrice weekly hemodialysis after considering individual patient preferences, the potential quality of life and physiological benefits, and the risks of these therapies."
- "Consider home long hemodialysis (6-8 hours, 3 to 6 nights per week) for patients with end-stage kidney disease who prefer this therapy for lifestyle considerations."
- "We recommend a target single pool Kt/V (spKt/V) of 1.4 per hemodialysis session for patients treated thrice weekly, with a minimum delivered spKt/V of 1.2."
- "In patients with significant residual native kidney function (Kru), the dose of hemodialysis may be reduced provided Kru is measured periodically to avoid inadequate dialysis."
- "Consider additional hemodialysis sessions or longer hemodialysis treatment times for patients with large weight gains, high ultrafiltration rates, poorly controlled blood pressure, difficulty achieving dry weight, or poor metabolic control (such as hyperphosphatemia, metabolic acidosis, and/or hyperkalemia)."

NKF/KDOQI (2015) also notes that:

- "Conventional HD remains the most common treatment for end-stage renal disease (ESRD) worldwide and is usually performed for 3 to 5 hours, 3 days per week."
- "The Work Group is unaware of any randomized trials of home short frequent HD and thus the group developed guideline statements only for in-center short frequent HD."
- "In summary, given inconclusive data regarding efficacy, and potentially increased risk of harm and mortality, no firm recommendations regarding home long frequent HD could be made by the Work Group."

National Institute for Health and Care Excellence (NICE)

NICE guidelines regarding RRT and conservative management state that patients should be offered a choice of dialysis modalities, at home or in-center, ensuring that the decision is informed by clinical considerations and patient preferences (NICE, 2018).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Refer to the following FDA website for more information on devices that are 510(k) cleared for home hemodialysis (HHD) (search by Device Name): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.
(Accessed January 10, 2025)

Devices developed and 510(k) cleared for HHD include:

- 2008K@home™ Hemodialysis Machine (Fresenius Medical Care)
- NxStage® System One™ (NxStage Medical, Inc.)
- NxStage Versi® HD with GuideMe software (NxStage Medical, Inc.)
- Quanta™ Dialysis System (Quanta Dialysis Technologies, Ltd.)
- Tablo® Hemodialysis System (Outset Medical, Inc.)

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Policy History/Revision Information

Date	Summary of Changes
06/01/2025	**Application** ***Idaho*** and ***Kansas*** • Added language to indicate this Medical Policy does not apply to the states of Idaho and Kansas; refer to the state-specific policy versions
05/01/2025	**Coverage Rationale** • Updated coverage criteria for home hemodialysis without skilled care as an alternative to facility-based hemodialysis for treating individuals with end-stage renal disease; replaced criterion requiring "*presence of* well-functioning vascular access" with "*individual has* well-functioning vascular access" **Supporting Information** • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS057.N

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state, or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state, or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state, or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state, or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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