Home Hemodialysis

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Instructions for Use

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

Definitions

Skilled Care: Skilled nursing, skilled teaching and skilled rehabilitation services when all of the following are true:
- Must be delivered or supervised by licensed technical or professional medical personnel in order to obtain the specified medical outcome, and provide for the safety of the patient,
- Ordered by a Physician,

- Not delivered for the purpose of helping with activities of daily living, including dressing, feeding, bathing or transferring from a bed to a chair,
- Requires clinical training in order to be delivered safely and effectively, and
- Not Custodial Care, which can safely and effectively be performed by trained non-medical personnel.

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 the member specific benefit plan document 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. On average, individuals must receive HD treatment three times a week for a duration of three or more hours.

Home HD allows individuals to conduct treatment in the convenience of a home environment. Treatment can be performed around one's daily activities in contrast to a clinic's available time slots. Home HD also enables individuals to perform dialysis more frequently or for longer durations, resulting in improved health, reduced symptoms, and a longer and higher quality of life. Home HD systems are similar to those used in the clinic, although they are more user-friendly and possess numerous safety features to minimize complications.
The most popular treatment regimens include:

- Conventional – Three times a week for three to four hours or longer, much like the regimen in a clinic.
- Short daily – Five to seven times a week. Treatments usually last about two hours each.
- Nocturnal – Slow treatment, performed six nights a week or every other night for six to eight hours.

(National Kidney Foundation (NKF), home hemodialysis, 2015)

Individuals suitable for home hemodialysis (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 home hemodialysis 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; Schatell, 2007; Walker et al., 2015; NICE, 2018)

Vascular access is necessary to provide adequate blood flow to accomplish treatment for hemodialysis. 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 (AVG; 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 immeasurably.

See the following websites for more information regarding access:

- Dialysis Access: Society for Vascular Surgeons: https://vascular.org/patient-resources/vascular-treatments/dialysis-access
- Hemodialysis Access Fistula First: http://www.homedialysis.org/life-at-home/articles/hemodialysis-access-fistula-first
- Home Dialysis Central: http://www.homedialysis.org/
- Buttonhole Cannulation: https://www.kidney.org/atoz/content/buttonhole-technique
- National Kidney Foundation Clinical Practice Guidelines for Hemodialysis Adequacy. This document includes information regarding vascular access: https://www.kidney.org/professionals/guidelines/hemodialysis2015

(Accessed February 3, 2020)

See the following website for more information regarding setting up a home hemodialysis: http://www.renalandurologynews.com/setting-up-a-home-hemodialysis-program/article/234862/. (Accessed February 3, 2020)

For information regarding home hemodialysis training, see the following:

- The Medicare Benefit Policy Manual Chapter 11, Section 30.2 Home Dialysis Training. Available at: https://www.cms.gov/manuals/Downloads/bp102c11.pdf
- National Kidney Foundation. Available at: https://www.kidney.org/atoz/content/homehemo

(Accessed February 3, 2020)

Most dialysis clinics require a person to train with a partner who will be in the home while the person receives treatment. See the following website for more information: https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/home-hemodialysis/Pages/home-hemodialysis.aspx. (Accessed February 3, 2020)

Clinical Evidence

The medical literature includes a number of studies that evaluated the relative effects on survival of home hemodialysis (HHD) compared to outpatient hemodialysis at a dialysis center. There are several observational studies that suggest that longer and more frequent dialysis sessions may result in significant improvements in selected clinical outcomes.

Choi et al. (2020) examined a national cohort of incident end-stage renal disease patients that was comprised of 1,993 and 16,514 patients transitioning to HHD and peritoneal dialysis (PD), respectively, from 2007 to 2011. The HHD patients were matched with PD patients. PD patients who transitioned within 12 months of starting dialysis had similar mortality risks, while PD patients who transitioned >12 months after starting dialysis had an 83% higher risk for mortality (hazard ratio 1.83; 95% CI 1.33-2.52). 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 HHD counterparts. It was concluded that additional studies are warranted to investigate clinical implications of these differences.

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 peritoneal dialysis (PD), taking age and comorbidity into account. Patients starting HHD as initial renal replacement therapy (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 intention-to-treat (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 IHD and 456 PD patients, respectively. Median survival was longer for HHD in intention-to-treat analyses: 18.5 years compared with 11.9 for IHD ($p < 0.001$) and 15.0 for PD ($p = 0.002$). 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 ($p > 0.05$). 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.

Mathew et al. (2018) conducted a systematic review and meta-analyses to compare the association of mortality and hospitalization in patients undergoing intensive hemodialysis (HD), compared with conventional HD or PD. The review included cohort studies with comparator arm and randomized controlled trials (RCTs) with >50% of adult patients (≥18 years) comparing any form of intensive HD (>4 sessions/wk or >5.5 h/session) with any form of chronic dialysis (PD, HD ≤4 sessions/wk or ≤5.5 h/session), that reported at least 1 predefined outcome (mortality or hospitalization). Twenty-three studies with a total of 70,506 patients were included. The authors noted that the overall quality of evidence was low or very low for critical outcomes. Outcomes such as quality of life, transplantation, and vascular access outcomes were not included in the review. The authors stated that compared with conventional HD, nocturnal home HD, nocturnal in-center HD, and short daily home HD were all significantly associated with decreased mortality.

Miller et al. (2018) conducted a systematic review to compare home hemodialysis (HHD) and in-center HD (ICHD) outcomes for survival, hospitalization, cardiovascular (CV), nutrition, and quality of life (QoL). Regarding mortality, 10 of 13 trials reported 13-52% reduction; three trials found no differences. According to 6 studies, blood pressure and left ventricular size measurements were generally lower in HHD patients compared to similar measurements in ICHD patients. Regarding nutritional status, conflicting results were reported (8 studies); some found improved muscle mass, total protein, and body mass index in HHD vs. ICHD patients, while others found no significant differences. There were no significant differences in the rate of hospitalization between HHD and ICHD in the 6 articles reviewed. Seven studies on QoL demonstrated positive trends in HHD vs. ICHD populations. The authors concluded that despite limitations in the current data, 66% of the publications reviewed (29/44) demonstrated improved clinical outcomes in patients who chose HHD. Even though HHD may not be preferred in all patients, 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 United States.

Ramar et al. (2017) conducted a systematic review that included comparative randomized controlled trials or observational studies with no restriction on language, published from 2000 to 2014, involving at least 5 adult dialysis patients 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 (I^2) was used to assess the variability in study effects related to study differences rather than chance. Twenty-five international studies with 74,833

maintenance dialysis patients were included. Interventions with multidisciplinary care or home dialysis were associated with a lower mortality and hospitalizations.

Sinclair et al. (2017) completed a health technology assessment (HTA) evaluating dialysis modalities for the treatment of end-stage kidney disease (ESKD). The aim of the HTA was to inform policy questions regarding the optimal treatment for eligible patients 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. The authors concluded that home-based hemodialysis is an appropriate modality option for the treatment of ESKD.

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

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 report was based on research conducted by the Evidence-based Synthesis Program (ESP) Center funded by the Department of Veterans Affairs, Veterans Health Administration. 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 hemodialysis. Therefore, home-based dialysis may be an acceptable and sometimes preferred alternative to in-center hemodialysis. 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. (Weinhandl et al. (2015), Weinhandl et al. (2012), and Jayanti et al. (2013), which were previously cited in this policy, are included in the Ishani et al. (2017) systematic review.)

Agraharkar et al. (2002a) presented data on 28 patients with severe debilitating and terminal illnesses. These patients were receiving dialysis at their home administered by a registered nurse according to a dialysis prescription provided by an attending nephrologist. According to the authors, end stage renal disease (ESRD) patients with severe disability can continue dialysis at home. The authors concluded that certain patients, such as those with terminal illnesses or severe debilities who require ambulance transportation, staff-assisted home hemodialysis (SAHD) can be an efficacious modality of dialysis.

Agraharkar et al. (2000b) describe 4 patients that have had problems receiving in-center hemodialysis (ICHD) for various reasons. When these patients were switched to staff-assisted home hemodialysis (SAHD), the dialysis core indicators improved compared with ICHD and the patients needed significantly fewer hospitalization days. The authors indicated that in patients who cannot be easily transferred and in patients with neuropsychiatric disorders, SAHD can be a more efficacious modality of dialysis. The authors concluded that SAHD is safe for selected patients. The authors recommend that SAHD be considered as a viable option for patients who may face significant difficulty in receiving ICHD.

Several registered trials relevant to home hemodialysis were identified on ClinicalTrials.gov. See the following website for more information: http://clinicaltrials.gov/ct2/results?term=home+hemodialysis&Search=Search. (Accessed February 3, 2020)

Professional Societies

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

The 2015 NKF/KDOQI clinical practice guidelines for hemodialysis adequacy state that home long hemodialysis (6-8 hours, 3 to 6 nights per week) should be considered for patients with end-stage kidney disease who prefer this therapy for lifestyle considerations. The guideline recommends 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. See the following

website for more information: https://www.kidney.org/professionals/guidelines/hemodialysis2015. (Accessed February 3, 2020)

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.

Dialysis systems are classified under the product codes FII, FKT, KDI and ONW. There were numerous 510(k) clearances for codes FII, FKT, and KDI and not all of these clearances are for home hemodialysis systems. See the following website for more information (enter product code FII, FKT, KDI or ONW): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 3, 2020)

Additional product information on other home dialysis products may be found using product codes: FJK (set, tubing, blood, with and without anti-regurgitation valve [hemodialysis system and accessories]); FKP (system, dialysate delivery, single patient); FKR (subsystem, proportioning [hemodialysis system and accessories); KOC (accessories, blood circuit, hemodialysis) KPO (dialysate concentrate for hemodialysis (liquid or powder), available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed February 3, 2020)

Centers for Medicare and Medicaid Services (CMS)

Medicare does not have a National Coverage Determination (NCD) for home dialysis. Local Coverage Determinations (LCDs) do not exist at this time.

Medicare covers home dialysis and associated items required for home dialysis, when criteria are met. Refer to the Medicare Benefit Policy Manual, Chapter 11, §30 – Home Dialysis and the Medicare Integrity Manual, Chapter 5, § 5.10- Period of Medical Necessity Home Dialysis Equipment. (Accessed February 12, 2020)

References

Agraharkar M, Barclay C, Agraharkar A. Staff-assisted home hemodialysis in debilitated or terminally ill patients. Int Urol Nephrol. 2002a;33(1):139-44.

Agraharkar M, Du Y, Ahuja T, Barclay C. Comparison of staff-assisted home hemodialysis with in-center hemodialysis and in-hospital hemodialysis. Home Hemodial Int. 2002b;6,58-62.

Choi SJ, Obi Y, Ko GJ, et al. Comparing patient survival of home hemodialysis and peritoneal dialysis patients. Am J Nephrol. 2020 Jan 28:1-9.

Ishani A, Slinin Y, Greer N, et al. Comparative effectiveness of home-based kidney dialysis versus in-center or other outpatient kidney dialysis locations – a systematic review [internet]. Washington (DC): Department of Veterans Affairs (US); 2015 Apr.

Jayanti A, Nikam M, Ebah L, et al. Technique survival in home haemodialysis: a composite success rate and its risk predictors in a prospective longitudinal cohort from a tertiary renal network programme. Nephrol Dial Transplant. 2013 Oct;28(10):2612-20.

Kasza J, Wolfe R, McDonald SP, et al. Dialysis modality, vascular access and mortality in end-stage kidney disease: A bi-national registry-based cohort study. Nephrology (Carlton). 2016 Oct;21(10):878-86.

Mathew A, McLeggon JA, Mehta N, et al. Mortality and hospitalizations in intensive dialysis: a systematic review and meta-analysis. Can J Kidney Health Dis. 2018 Jan 10;5:2054358117749531.

Miller BW, Himmele R, Sawin DA, et al. Choosing home hemodialysis: a critical review of patient outcomes. Blood Purif. 2018;45(1-3):224-229.

National Institute for Health and Care Excellence (NICE). Renal replacement therapy and conservative management. NICE guideline [NG107]. October 2018.

National Kidney Foundation (NKF/KDOQI) clinical practice guideline for hemodialysis adequacy: 2015 update. Am J Kidney Dis. 2015;66(5):884-930. National Kidney Foundation (NKF). Home hemodialysis. 2015.

Pierratos A, McFarlane P, Chan CT: Quotidian dialysis—Update 2005. Curr Opin Nephrol Hypertens 14:119-124, 2005.

Ramar P, Ahmed AT, Wang Z, et al. Effects of different models of dialysis care on patient-important outcomes: a systematic review and meta-analysis. Popul Health Manag. 2017 Mar 23.

Rioux JP, Marshall MR, Faratro R, et al. Patient selection and training for home hemodialysis. Hemodial Int. 2015 Apr;19 Suppl 1:S71-9.

Rydell H, Ivarsson K, Almquist M, et al. Improved long-term survival with home hemodialysis compared with institutional hemodialysis and peritoneal dialysis: a matched cohort study. BMC Nephrol. 2019 Feb 13;20(1):52.

Schatell D. MATCH-D: a roadmap to home dialysis therapy. Nephrol News Issues. 2007 Oct;21(11):41, 43-4.

Sinclair A, Cimon K, Loncar M, et al. Dialysis modalities for the treatment of end-stage kidney disease: A Health Technology Assessment [Internet]. Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2017 Mar. Available from http://www.ncbi.nlm.nih.gov/books/NBK531991/. Accessed February 3, 2020.

Walker RC, Blagg CR, Mendelssohn DC. Systems to cultivate suitable patients for home dialysis. Hemodial Int. 2015 Apr;19 Suppl 1:S52-8.

Weinhandl ED, Liu J, Gilbertson DT, et al. Survival in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. J Am Soc Nephrol. 2012;23(5):895-904.

Weinhandl ED, Nieman KM, Gilbertson DT, et al. Hospitalization in daily home hemodialysis and matched thrice-weekly in-center hemodialysis patients. Am J Kidney Dis. 2015 Jan;65(1):98-108.

Policy History/Revision Information

Date	Summary of Changes
08/01/2020	Template Update • Reformatted policy; transferred content to new template
04/01/2020	Supporting Information • Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information • Archived previous policy version 2019T0476O

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. 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.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.