

HOME HEMODIALYSIS

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Related Policies

- [Home Health Care](#)
- [Private Duty Nursing Services \(PDN\)](#)
- [Skilled Care and Custodial Care Services](#)

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

CONDITIONS OF COVERAGE

Applicable Lines of Business/ Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefits Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes
Precertification with Medical Director Review Required	No
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	Home

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Home hemodialysis without professional staff assistance is proven and/or medically necessary as an alternative to facility-based hemodialysis for treating patients with end-stage renal disease who meet ALL of the following criteria:

- Patient is stable on dialysis with no evidence of complex skilled interventions being necessary during treatments; **and**
- Patient 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 professional staff assistance is proven and/or medically necessary as an alternative to facility-based hemodialysis for treating patients with end-stage renal disease who meet ALL of the following criteria:

- Patient is stable on dialysis and not at increased risk as a result of having the procedure performed outside a dialysis center venue; **and**
- Patient has well-functioning vascular access; **and**
- Patient has medical contraindications to leaving home for hemodialysis; **and**
- Patient 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.

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 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

CPT Code	Description
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

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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 patients 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 a patient'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, patients must receive HD treatment three times a week for a duration of three or more hours.

Home HD allows patients 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 patients 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)

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 HHD patients 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 Web sites for more information regarding access:

- Hemodialysis Access Fistula First: <http://www.homedialysis.org/life-at-home/articles/hemodialysis-access-fistula-first>. (Accessed November 8, 2017)
- Home Dialysis Central: <http://www.homedialysis.org/>. (Accessed November 8, 2017)
- Buttonhole Cannulation: <https://www.kidney.org/atoz/content/buttonhole-technique>. (Accessed November 8, 2017)
- National Kidney Foundation Clinical Practice Guidelines for Hemodialysis Adequacy. This document includes information regarding vascular access: <https://www.kidney.org/professionals/guidelines/hemodialysis2015>. (Accessed November 8, 2017)

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 November 8, 2017)

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>. (Accessed November 8, 2017)

- National Kidney Foundation. Available at: <https://www.kidney.org/atoz/content/homehemo>. (Accessed November 8, 2017)

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 Web site for more information: <https://www.niddk.nih.gov/health-information/health-topics/kidney-disease/home-hemodialysis/Pages/home-hemodialysis.aspx>. (Accessed November 8, 2017)

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. Most studies were comprised of highly selected patients who had the ability to perform and maintain home hemodialysis. In some studies, patients were self-selected or were permitted to choose their preferred dialysis modality. Patients treated with HHD tended to be younger, to have fewer comorbidities, and to be at lower risk of morbidity and mortality compared with patients who were treated in hospitals or clinics.

Kotanko et al. (2015) analyzed the effects of frequent hemodialysis (HD) on blood pressure in the randomized controlled Frequent Hemodialysis Network trials. The daily trial randomized 245 patients to 12 months of 6× ("frequent") vs. 3× ("conventional") weekly in-center hemodialysis; the nocturnal trial randomized 87 patients to 12 months of 6× weekly nocturnal HD vs. 3× weekly predominantly home-based hemodialysis. In the daily trial, compared with 3× weekly HD, 2 months of frequent HD lowered predialysis systolic blood pressure by -7.7 mmHg and diastolic blood pressure by -3.9 mmHg. In the nocturnal trial, compared with 3× weekly HD, 2 months of frequent HD lowered systolic blood pressure by -7.3 mmHg and diastolic blood pressure by -4.2 mmHg. In both trials, blood pressure treatment effects were sustained until month 12. Frequent HD resulted in significantly fewer antihypertensive medications (daily: -0.36 medications; nocturnal: -0.44 medications). The authors concluded that frequent HD reduces blood pressure and the number of prescribed antihypertensive medications.

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.

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.

In an observational cohort study, Weinhandl et al. (2014) assessed if daily hemodialysis is associated with lower hospitalization risk. The study participants included Medicare-enrolled daily (5 or 6 sessions weekly) home hemodialysis (HHD) patients initiating NxStage System One use from January 1, 2006, through December 31, 2009, and contemporary thrice-weekly in-center hemodialysis patients, matched 5 to 1. For 3,480 daily HHD and 17,400 thrice-weekly in-center hemodialysis patients in intention-to-treat analysis, the HR of all-cause admission for daily HHD versus in-center hemodialysis was 1.01. Cause-specific admission HRs were 0.89 for cardiovascular disease, 1.18 for infection, 1.01 for vascular access dysfunction, and 1.02 for other morbidity. Regarding cardiovascular disease, first admission and readmission HRs for daily HHD versus in-center hemodialysis were 0.91 and 0.87, respectively. Regarding infection, first admission and readmission HRs were 1.35 and 1.03, respectively. Protective associations of daily HHD with heart failure and hypertensive disease were most pronounced, as were adverse associations of daily HHD with bacteremia/sepsis, cardiac infection, osteomyelitis, and vascular access infection. The authors concluded that all-cause hospitalization risk was similar in daily HHD and thrice-weekly in-center hemodialysis patients. However, risk of cardiovascular-related admission was lower with daily HHD, and risk of infection-related admission was higher. The authors stated that more attention should be afforded to infection in HHD patients.

The FREEDOM (Following Rehabilitation, Economics and Everyday-Dialysis Outcome Measurements) Study is a prospective cohort study investigating the clinical and economic benefits of daily (6 times per week) at home hemodialysis (HD). In an interim report, Jaber et al. (2010) examined the long-term impact of daily HD on depressive

symptoms, measured using the Beck Depression Inventory (BDI) survey and post dialysis recovery time, and a previously validated questionnaire. The BDI survey and post dialysis recovery time question were administered at baseline, and changes were assessed at months 4 and 12. A total of 239 participants were enrolled (intention-to-treat cohort) and 128 completed the study (per-protocol cohort). The percentage of patients with depressive symptoms (BDI score >10) significantly decreased during 12 months. Similarly, in the per-protocol cohort, there was a significant decrease in post dialysis recovery time over 12 months. The intention-to-treat analysis yielded similar results. The percentage of patients experiencing prolonged post dialysis recovery time (≥ 60 minutes) also significantly decreased. The investigators concluded that daily HD is associated with long-term improvement in depressive symptoms and post dialysis recovery time.

In an interim report for the FREEDOM prospective cohort study, Finkelstein et al. (2012) examined the long-term effect of at-home short daily hemodialysis on health-related quality of life, as measured by the SF-36 health survey. This was administered at baseline, 4 and 12 months after initiation of short daily hemodialysis to 291 participants (total cohort), of which 154 completed the 12-month follow-up (as-treated cohort). At the time of analysis, the mean age was 53 years, 66% were men, 58% had an AV fistula, 90% transitioned from in-center hemodialysis, and 45% had diabetes mellitus. In the total cohort analysis, both the physical- and mental-component summary scores improved over the 12-month period, as did all 8 individual domains of the SF-36. The as-treated cohort analysis showed similar improvements with the exception of the role-emotional domain. Significantly, in the as-treated cohort, the percentage of patients achieving a physical-component summary score at least equivalent to the general population more than doubled. According to the authors, at-home short daily hemodialysis is associated with long-term improvements in various physical and mental health-related quality of life measures.

Weinhandl et al. (2012) used a matched-cohort design to assess relative mortality in daily home hemodialysis and thrice-weekly in-center hemodialysis patients between 2005 and 2008. The authors matched 1873 home hemodialysis patients with 9365 in-center patients (i.e., 1:5 ratio) selected from the prevalent population in the US Renal Data System database. The cumulative incidence of death was 19.2% and 21.7% in the home hemodialysis and in-center patients, respectively. In the intention-to-treat analysis, home hemodialysis associated with a 13% lower risk for all-cause mortality than in-center hemodialysis. Cause-specific mortality hazard ratios (HRs) were 0.92 for cardiovascular disease, 1.13 for infection, 0.63 for cachexia/dialysis withdrawal, 1.06 for other specified cause, and 0.59 for unknown cause. Findings were similar using as-treated analyses. According to the authors, these data suggest that relative to thrice-weekly in-center hemodialysis, daily home hemodialysis is associated with a modest increase in survival. The authors stated that continued surveillance should better identify causes of mortality and determine whether treatment effects are homogeneous throughout the dialysis population.

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.

Jayanti et al. (2013) evaluated home hemodialysis (HHD) in a study that included 166 patients. All patients were followed up prospectively until a switch to alternative modality, to include 4528 patient-months of follow-up and about 81 508 HHD sessions during an 8-year period (January 2004-December 2011). Twenty-four patients switched to an alternative modality during the period. Combined technique survival (HHDC) as a composite of training (HHDtr) and at home (HHDhome) was analyzed and clinical predictors of HHD modality failure since the commencement of the program were calculated using Cox regression analysis. Technology-related interruptions to dialysis over a 12-month period and patient-reported reasons for quitting the program were analyzed. Technique survival at 1, 2 and 5 years was 90.2, 87.4, 81.5% (HHDC) and 98.4, 95.4 and 88.9% (HHDhome) when censored for training phase exits, death and transplantation. The combined HHDC modality switch rate is 1 in 192 patient-months of dialysis follow-up. Age >60 years, diabetes, cardiac failure, unit decrease in Hb and increasing score of age-adjusted Charlson--comorbidity index were significantly associated with technique failure. Significant clinical predictors of HHD technique failure in a multivariate model were diabetes and cardiac failure. The majority (61%) switched to an alternative modality for non-medical reasons. The composite of operator error and mechanical breakdown resulting in temporary HHD technique failure was 0.7% per year. The authors concluded that HHD training and technique failure rate are low. Technical errors are infrequent too. Diabetes and cardiac failure are associated with significant risk of technique failure. Although absolute rates are low, training failure is proportionally quite significant, highlighting the importance of reporting the composite technique failure rate (to include early HHD training phase) in HHD programs.

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 Web site for more information: <http://clinicaltrials.gov/ct2/results?term=home+hemodialysis&Search=Search>. (Accessed November 8, 2017)

National Institute for Health and Care Excellence (NICE 2002)

A review was performed by NICE to provide guidance on the location where hemodialysis is carried out. The recommendations note that patients suitable for home hemodialysis will 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 render home hemodialysis 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

*For additional information on vascular access [click here](#).

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 November 8, 2017)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Dialysis systems are classified under the product codes FII, FKT, KDI and ONW. There were numerous 510(k) approvals for codes FII, FKT, and KDI and not all of these approvals 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 November 8, 2017)

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 November 8, 2017)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2018T0476M]

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
03/01/2018	<ul style="list-style-type: none"> Updated and reorganized coverage rationale; replaced language indicating “[the listed services] are medically necessary” with “[the listed services] are <i>proven and/or</i> medically necessary” Updated supporting information to reflect the most current description of services, clinical evidence, FDA information, and references Archived previous policy version DIALYSIS 006.11 T1