



**Presentation to Institute of Medicine
Committee on Determination of Essential Health Benefits Public Workshop**

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Medical Necessity and Coverage Determinations

- Medical coverage is typically described as “reasonable and necessary,” a vague definition, which can inhibit innovation and patient choice.
- Medicare dialysis reimbursement policy is virtually unchanged from that of 40 years ago (standard 3 treatments weekly, with variations for medically justifiable requests by the nephrologist). This inhibits utilization of new modalities, including but not limited to daily dialysis that can be performed in the home.
- The overwhelming majority of dialysis patients receives traditional in-center hemodialysis three times weekly and generally do not utilize various home dialysis modality options. Recent technologies have resulted in additional home therapy models, making home dialysis possible for a more kidney patients. The new systems are often easier to use than previous technologies. New therapies also may be more convenient for patients in the workforce, may eliminate transportation challenges to the dialysis center, and make travel more accessible.
- A recently completed daily dialysis trial jointly sponsored by NIH and CMS demonstrated that frequent dialysis (six hemodialysis treatments weekly) improved left ventricular mass and self-reported health, compared to conventional hemodialysis therapy.
- Dialysis is a life-sustaining therapy and should best fit the needs of the individual patient. Treatment choice should help patients accomplish their short- and long-term goals, so that chronic kidney disease is not a barrier to their needs.
- A majority of the nation’s end stage kidney disease patients receive dialysis treatments, rather than receive a kidney transplant. The gap between the number of individuals on a kidney wait list and the number of transplants continues to widen, making a transplant less likely unless the patient has a living donor. In addition, coverage limitations may be a barrier to transplantation, even though it is the most cost-effective alternative for appropriate candidates with kidney failure. For example, private insurance frequently will pay for a prospective living organ donor’s medical tests only if the individual actually donates, yet in many instances multiple prospective donors may be required before one is determined to be an appropriate donor for that patient.



Consequences of Benefit Design

- Early detection and intervention strategies have been demonstrated to prevent or delay the progression of chronic kidney disease and its complications, but insurers often do not maximize utilization of these proven services.
- As with any chronic disease with a slow progression, insurers could spend resources on interventions, only to have a policy holder move to another insurer by the time the disease reaches more advanced and more costly stages. This is magnified in CKD, as virtually all ESRD patients are covered by Medicare 30 months after the start of kidney replacement therapy (or in the case of those who do not have group health coverage, three months after the start of therapy).
- An individual with advanced CKD is very likely to have other health conditions and much more likely to die of complications prior to needing renal replacement therapy. For example, Stage 4 kidney patients are far more likely to die of congestive heart disease than to progress to dialysis.
- As noted in the 2010 U.S. Renal Data System Annual Report (Vol 1, p. 67), considering that a CKD patient is more likely to have a cardiovascular event and die than to reach ESRD, it is imperative to identify CKD (by testing urine for microalbumin) among individuals who have been diagnosed with diabetes and/or hypertension, both to monitor risk factors for cardiovascular events and death as well as to address the progression of kidney disease. However, in the context of private insurance, probability is such testing is only .32 for individuals with diabetes (or diabetes and hypertension) and much lower (.04) for hypertensive-only patients.

Benefit Limits

- Much in the way the Affordable Care Act prohibits lifetime and annual benefit limits, NKF believes limits on specific benefits should not occur. As previously stated, there should not be a limit on the modality or number of dialysis sessions for a patient if the patient and his or her health team agree more frequent dialysis is beneficial. Access to kidney transplantation, whether from a living donor or deceased donor, and access to repeated transplants after graft failure also should not be limited. Another critical essential benefit for transplant recipients is coverage of necessary immunosuppressive drugs and of laboratory tests and post-transplant follow-up examinations performed by the transplant physician on an annual basis, to ensure the best outcomes for the transplant recipient.