

ONLINE APPENDIXES

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## **Outpatient dialysis services**

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ONLINE APPENDIX

# 6-A

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**Considering alternative  
dialysis treatment options:  
Use of more frequent  
hemodialysis and  
home dialysis**

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## Clinical evidence about more frequent hemodialysis

Several recent randomized clinical trials (RCTs) have found improved outcomes and quality of life associated with hemodialysis furnished five or more times per week compared with three times weekly hemodialysis. These studies include:

- An RCT that the Kidney Foundation of Canada sponsored found that frequent nocturnal hemodialysis significantly improved the primary outcome—mean left ventricular mass difference—compared with conventional hemodialysis (Culleton et al. 2007).
- The Frequent Hemodialysis Network–Daily Trial reported that, compared with conventional hemodialysis, short daily hemodialysis improved left ventricular mass and physical health (Chertow et al. 2010). This trial was sponsored by the National Institutes of Health (NIH) and CMS.
- The Frequent Hemodialysis Network–Nocturnal Trial found no differences in the coprimary

outcomes (changes in left ventricular mass and physical health) among patients randomized to receive either nocturnal hemodialysis six times per week or conventional hemodialysis (Rocco et al. 2011). The researchers found that patients in the nocturnal group had improved control of hyperphosphatemia and hypertension (secondary outcome measures). This trial was also sponsored by NIH and CMS.

Another type of more frequent hemodialysis eliminates the two-day gap in dialysis inherent in thrice weekly hemodialysis regimens. Such an approach—hemodialysis every other day—has gained interest with the publication of an NIH-funded study that found, among thrice-weekly hemodialysis patients, the occurrence of increased mortality and cardiovascular admissions on the day after the two-day gap in hemodialysis treatments compared with the one-day gap between treatments (Foley et al. 2011). ■

### Considering alternative dialysis treatment options: Use of more frequent hemodialysis and home dialysis

Very few dialysis patients are furnished, in facilities or in their homes, more frequent hemodialysis—a regimen of hemodialysis furnished five or more times per week during the day or nocturnally. In 2010, the most recent year for which data are available, according to CMS data, about 1 percent of hemodialysis patients (about 3,300 patients) received more frequent hemodialysis. Nonetheless, based on new clinical evidence showing improvement in patients' outcomes, there is increased interest in the use of more frequent hemodialysis and every-other-day hemodialysis (see text box).

Likewise, a relatively small proportion (8 percent) of patients dialyze at home—using either home hemodialysis or peritoneal dialysis (United States Renal Data System 2012). Compared with in-center dialysis, researchers have concluded that home-based dialysis offers patients

greater autonomy, improved quality of life, and enhanced satisfaction. Home dialysis, by eliminating the need to travel to a facility for treatment, may have greater potential to support more frequent hemodialysis.

Commission staff convened a panel of clinicians who treat dialysis patients and a patient representative to discuss the use of more frequent hemodialysis and the use of home dialysis methods. The objective of the panel was to explore the pros and cons of more frequent hemodialysis and home dialysis.

#### Summary of panel discussion

Panelists recognized the clinical benefits of more frequent hemodialysis and every-other-day hemodialysis compared with thrice weekly hemodialysis and the advantages of home-based methods compared with in-center care. Nonetheless, they acknowledged that, because of the relatively small number of participants, enrollment criteria, and relatively short follow-up period, the research studies on more frequent hemodialysis are not generalizable to all dialysis patients.

Panelists discussed why home dialysis and more frequent hemodialysis may not be an option for all patients. Panelists said that patient motivation and, for home patients, having a supportive partner, are two important factors associated with the successful use of more frequent hemodialysis. They discussed the issues and trade-offs associated with patients' deciding to undergo more frequent hemodialysis and home dialysis. On the one hand, there is greater independence, flexibility, and satisfaction among patients undergoing home dialysis. On the other hand, some patients might prefer in-center dialysis because of the greater social interaction and support they receive. For home patients, lifestyle issues—including storage of equipment and supplies—affect their choice of home versus in-center dialysis. In addition, some patients lack a partner at home to assist them with home hemodialysis. And, because of the greater time commitment of more frequent dialysis compared with thrice weekly, some patients and their partners may experience fatigue and burnout.

Panelists talked about the importance of providers and patients discussing home versus in-center treatment and the alternatives for patients with end-stage renal disease, including transplantation, peritoneal dialysis, and more frequent hemodialysis. Researchers have found patient counseling before starting dialysis is a strong determinant of choosing home-based methods. Panelists also discussed the lack of physician education and training in home dialysis and more frequent hemodialysis.

Finding adequate round-trip transportation to dialysis centers is a concern to patients and providers alike. Shortening and skipping hemodialysis treatments is common even among thrice weekly in-center patients, and these behaviors have been partly linked to transportation problems (Bleyer et al. 1999, Gordon et al. 2003). A recent Commission analysis found that the number of nonemergency ambulance transports among dialysis patients has increased rapidly in recent years, about twice as fast as all other ambulance transports (Medicare

Payment Advisory Commission 2012). Home dialysis, by eliminating the need to travel to a facility for treatment, may have greater potential to support more frequent hemodialysis.

The panelists discussed Medicare payment issues, including obtaining coverage from Medicare's administrative contractors for more than thrice-weekly hemodialysis treatments, and Medicare's payment for training patients to undergo home hemodialysis (see text box, p. 5).

### **Future issues to consider**

Panelists discussed improving efforts to educate patients and providers about home dialysis methods. Panelists also suggested improved incentives for home-based dialysis directed at patients and providers (e.g., by adjusting physician payment rates and beneficiary copayment levels). In the future, the Commission could consider exploring such initiatives.

The Commission intends to monitor use of home dialysis by patients overall and by race in 2012 and beyond. Use of home dialysis methods has steadily declined, from 17 percent in the early 1990s to about 8 percent in 2010. However, under the modernized payment method, the use of home dialysis has modestly increased. CMS reports that the proportion of beneficiaries receiving home dialysis increased from about 8 percent in 2009 to nearly 9 percent in 2011 (Centers for Medicare & Medicaid Services 2012). The Commission's analysis also finds a similar increase in the proportion of dialysis beneficiaries receiving home dialysis.

While we are encouraged by this modest increase in use of home dialysis between 2009 and 2011, we are concerned that the differences in use of home dialysis by race remain unchanged. The proportion of home dialysis beneficiaries who are African American remained at 26 percent in each year (2009–2011). By contrast, about 36 percent of all dialysis beneficiaries are African American in each year. ■

## Summary of Medicare's payment policies on paying for more frequent hemodialysis

Currently, Medicare's payment rate is based on a regimen of three dialysis treatments per week. The Medicare Benefit Policy Manual states that: (1) the usual pattern of hemodialysis consists of three treatments weekly and these treatments are covered routinely, (2) peritoneal dialysis sessions are covered routinely at the same frequency as hemodialysis, and (3) Medicare's administrative contractors (MACs) shall consider requiring medical justification in instances in excess of this frequency.

Three MACs covering 12 states have issued local coverage determinations (LCDs) that contain the medical justification language under which the provision of more than three dialysis treatments per week is medically reasonable and necessary and a Medicare-covered service. The medical justification that the three MACs use is similar but not identical.<sup>1</sup>

Our preliminary analysis of 2011 claims submitted by dialysis facilities suggests that the provision of more than three hemodialysis treatments per week is relatively frequent; for most beneficiaries, though, it appears to be time limited. Specifically, our preliminary

analysis found that in 2011 about 30 percent of beneficiaries received more than three dialysis treatments during at least one week of the year. For beneficiaries receiving additional treatments: (1) 80 percent received more than three treatments per week for no more than two weeks during the year; and (2) they received an average of four treatments per week (median = 4, mode = 4). This finding is consistent with the LCDs of two of the three MACs that explain that "in general, only a fourth session each week will be covered if the service meets the criteria of this policy."

Under the bundled payment method, to teach a beneficiary to dialyze at home, Medicare pays an add-on (of \$33.44) to the base payment rate adjusted based on the geographic wage index for nursing salaries to account for the hourly nursing time for dialysis training treatments. Medicare pays for up to a maximum of 15 training sessions for peritoneal dialysis and 25 training sessions for hemodialysis. Some stakeholders have raised concerns about the number of hemodialysis training sessions that Medicare pays providers to teach beneficiaries to dialyze at home. ■

## Endnotes

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1 The three LCDs are: CMS–L32755, CMS–L31578, and CMS–L30566. All three LCDs cover more than three weekly dialysis sessions for beneficiaries with one of the following diagnoses: (1) other fluid overload, (2) hyperpotassemia, (3) acute pericarditis in diseases classified elsewhere, (4) left heart failure, (5) congestive heart failure unspecified, (6) edema, (7) acute edema of lung unspecified, (8) unspecified complication of pregnancy, and (9) supervision of other high-risk pregnancy. Two of the three LCDs also cover more treatments per week for beneficiaries diagnosed with transfusion-associated circulatory overload, and one of

the three LCDs also covers more treatments per week for beneficiaries with diagnoses of disorders of phosphorus metabolism, other specified hypotension, secondary hyperparathyroidism, and other specified disorders resulting from impaired renal function. One LCD states that mechanical failure would also be considered reasonable and medically necessary for an additional hemodialysis treatment. One of the MACs reported, in 2009, a substantial increase in the number of claims billing for more than three dialysis treatments per week (CMS–A49168).

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ONLINE APPENDIX

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## **Trends in kidney transplantation**

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## Trends in kidney transplantation

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Kidney transplantation is a lifesaving medical procedure for which the demand far exceeds the transplantable organ supply. Transplantation improves clinical outcomes compared with dialysis. When no living kidney donor is available, patients with end-stage renal disease (ESRD) must rely on the limited supply of cadaveric donor organs.

Multiple factors affect access to kidney transplantation: (1) a kidney allocation policy that uses immunologic factors to match kidneys to potential recipients; (2) the rate of kidney transplants from living donors; (3) patients' attitudes and preferences, clinical characteristics, and socioeconomic status; (4) patients' education and referral to a transplant center by physicians and dialysis facilities that treat dialysis and predialysis patients; and (5) the criteria used by transplant centers that determine placement on the kidney waiting list (such as physical health, mental health, social support, insurance status, and financial support).

Although the principle of equity is emphasized in the distribution of this limited resource, several studies document that kidney transplantation rates differ by patients' demographic and socioeconomic characteristics.

For example, access to kidney transplantation and organ donation rates vary by race. Data from the United States Renal Data System show that in 2010:

- White ESRD patients accounted for 61 percent of ESRD patients and 60 percent of transplant recipients.
- African Americans accounted for 32 percent of ESRD patients and 26 percent of transplant recipients.
- Asian Americans and Native Americans together accounted for 7 percent of ESRD patients and 10 percent of transplant recipients.

Researchers also find differences in access to kidney transplantation based on patients' sex and income. Compared with White, male, and higher income patients, African American, female, and lower income patients were less likely to complete the pretransplant workup (Alexander and Sehgal 1998). Overall, demand for kidney transplantation has grown faster than supply. Between 2006 and 2010, demand—as measured by the number of ESRD individuals wait-listed for a kidney—increased on average by 6 percent per year while supply—as measured by the number of kidney transplantations—has decreased

on average by 0.4 percent per year (United States Renal Data System 2012).

From the patient's perspective, the transplantation process involves a series of steps that include: (1) being educated about transplantation, (2) being interested in transplantation and referred to a transplant center, (3) completing the transplant center's workup and being placed on at least one kidney waiting list, and (4) moving up the waiting list and receiving a transplant. The factors affecting this process are complex. Unequal transplantation rates reflect the matching process that considers the immunologic compatibility of donor kidneys with potential recipients; patient-level factors, including patients' knowledge of renal treatment options, their preferences, and their clinical characteristics; and provider-level factors, including the process by which nephrologists and dialysis facilities educate patients about different treatment opportunities and the evaluation process that transplant centers use to place patients on the kidney waiting list.

Lower rates of renal transplantation, particularly among African Americans, partly reflect the immunologic (including blood type and antibodies in the blood) matching process of donors to recipients. Reducing the number of biological mismatches improves the outcomes of kidney transplantation; as a result, the matching process gives priority to candidates who have fewer mismatches. Researchers report that because of racial and ethnic differences in the frequency of alleles (any one of two or more genes) at a given site on a chromosome, Whites are more likely than people in other racial and ethnic groups to find a good match in the cadaver kidney pool (Roberts et al. 2004). This difference, coupled with the matching process, increases the transplantation rate among White candidates and reduces access for candidates with less common blood types and antibodies in the blood, including those who are members of minority groups (Roberts et al. 2004).

A recent study shows the importance of these immunologic factors in access to kidney transplantation. According to Hall and colleagues, a change in the relative priority given to tissue matching in 2003 significantly decreased, but did not eliminate, racial disparity in access to transplantation for individuals on the kidney waiting list (Hall et al. 2011). In 2003, the United Network for Organ Sharing, the private nonprofit organization that manages the U.S. organ transplant system, eliminated giving priority to a specific immunologic factor (HLA-B

antigen) in the process that matches cadaver kidneys to potential recipients. These researchers estimate a 23 percent reduction in the disparity for wait-listed African Americans and Whites after the policy change in 2003.

Differences in access may also stem from differences in transplants from live donors, which, in 2010, accounted for about 35 percent of all transplant procedures (United States Renal Data System 2012). By race, Whites accounted for 75 percent of live donor procedures, compared with 14 percent for African Americans, 10 percent for Asian Americans, and 1 percent for Native Americans. Researchers note that there are fewer living donors among African Americans, increasing the dependence of African American patients on cadaver organs (Young and Gaston 2000). According to some researchers, interventions that attempt to reduce transplant disparities should prioritize the improvement of live donation rates for African Americans (Hall et al. 2011).

Differences in kidney transplantation rates may also reflect patient factors, such as lack of knowledge about transplantation, concerns about surgery and adverse effects of medication, and mistrust of the medical system. In addition, some patients are not able to receive a transplant because of the presence of medical contraindications, such as a recent history of substance abuse, cancer, a serious infection (including from dental disease), and significant cardiovascular disease.

Provider-level factors can also affect access to kidney transplantation. Dialysis facilities and physicians who treat dialysis patients have an important role in educating patients about renal treatment options, including transplantation and home dialysis, and referring patients to a transplant center. The literature on the relationship between the role of the dialysis facility and access to transplantation is mixed. Some researchers have found that patients treated at for-profit facilities are less likely to undergo transplantation, while other researchers have not reached this conclusion. Some dialysis providers contend that the decision about whether patients are included on the transplant wait list and ultimately undergo transplantation is the responsibility of the transplant center. Because these factors are outside their purview, dialysis providers argue that these measures should not be used to assess their quality.

The process used by transplant centers plays an important role in determining which candidates are placed on the kidney waiting list. For most transplant centers, the

process for placing individuals on the waiting list includes evaluating the patient's physical and mental health (American Society of Transplantation 2006). Other factors that transplant centers consider are the patient's ability to carry out necessary posttransplant treatment plans, patient's education, and patient's financial resources, including insurance covering the transplant procedure and the anti-rejection medicines needed after transplantation (Volk et al. 2011). According to experts in the field, transplant centers' selection committees rule out patients with psychosocial barriers, including lack of or inadequate social support (no spouse, family, or friends).

The Commission reviewed the following initiatives sponsored by the Secretary of Health and Human Services that have focused on reducing racial disparities in kidney transplantation and educating patients about kidney transplantation and donation.

### **Centers for Disease Control and Prevention**

The Centers for Disease Control and Prevention's Healthy People 2020 initiative includes objectives to increase the proportion of dialysis patients on the kidney wait list (by 10 percent to 18.8 percent) and to increase the proportion of patients with treated chronic kidney disease who receive a kidney transplant (Department of Health and Human Services 2011a). Nonetheless, neither this initiative nor the recent initiative by the Secretary to address racial disparities in minority health includes activities specific to reducing racial disparities in transplantation (Department of Health and Human Services 2011b).

### **Health Resources and Services Administration**

The Division of Transplantation within the Health Resources and Services Administration has at last count 38 initiatives focused on minority groups. The primary pathways by which projects aimed at increasing access to transplantation for minorities are supported through the Organ Procurement and Transplantation Network (OPTN) and two grant programs: the Social and Behavioral Interventions to Increase Organ Donation Grant Program and the Public Education Efforts to Increase Solid Organ Donation Grant Program. The OPTN has a Minority Affairs Committee that attempts to address barriers to racial and ethnic minorities in gaining access to the transplant waiting list and ultimately receiving a transplant. In line with efforts to reduce disparities in transplantation, in 2012, the OPTN revised the kidney allocation policy so that a patient's position on the waiting

list is contingent upon the time spent on dialysis, rather than the time spent on the waiting list itself. This reduces the likelihood that a patient could gain unfair advantage by obtaining a preemptive referral for a transplant. OPTN does not actively promote live-donor kidney transplantation (LDKT), but its educational materials are clear that it is an option for transplant candidates.

The Social and Behavioral and Public Education grants are two- to three-year programs with an annual budget of \$1 million to \$1.25 million. Most Social and Behavioral grants targeted at reducing racial disparities in kidney transplantation focus on LDKT as a particularly good way for African Americans with ESRD to receive transplants because it bypasses the waiting list issues described above. The challenge with this therapy might be the unclear clinical implications for the donor of the kidney. Other studies looked at the interaction of race and socioeconomic status in terms of transplant outcomes and the effects of national and state laws on the incidence of LDKT in different regions. The Public Education grants focus instead on innovative strategies to register potential minority donors. These initiatives have taken place on college campuses, at the Motor Vehicles Administration, and in one case, at a local barbershop. The Health Resources and Services Administration makes project materials available to groups that wish to replicate the project with outside funding but will support similar projects only if they are in a different geographic area and target a different population. There is no systematic collection of information on projects after their completion, but many become outcome measures in quality assessment tools (i.e., the consent of the family to donate).

### **National Institutes of Health**

The National Institutes of Health (NIH) addresses racial disparities in kidney transplantation primarily through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The predominant pathways are through grants, patient and community outreach, and physician outreach. The most recent NIDDK grants, like grants from the Health Resources and Services

Administration, focus primarily on LDKT and increased rates of donation. NIDDK has several patient and community outreach initiatives, but in general these efforts do not actively seek out their target audience. They rely instead on traffic to their website and the efforts of community leaders like pastors and family matriarchs to disseminate their materials. The programs emphasize the early stages of chronic kidney disease and preventing or delaying progression to ESRD. They encourage African Americans to understand the connection between diabetes, high blood pressure, and kidney disease and to communicate those associated risks to their families and neighbors. They also discuss the pros and cons of transplantation and provide strategies for communicating with doctors about kidney disease and renal replacement therapy.

NIDDK also has extensive resources for physicians of patients with chronic kidney disease. They help primary care clinicians assess patients' disease severity, discuss treatment options with their patients, manage the progression of the disease, and educate patients about changes they can expect throughout the course of the disease. In these materials, kidney transplantation is not promoted per se but is instead presented beside peritoneal and hemodialysis as options whose favorability changes with the circumstances of each patient.

NIDDK also uses shared decision making to help patients weigh their options for renal replacement therapy. Shared decision making is a process by which, in situations with multiple clinically appropriate options, doctors share relevant clinical information about all the options, patients share their preferences and values, and the two parties arrive at a shared decision that incorporates the expertise of both parties. NIDDK supports a program that is developing a curriculum to train nephrologists in shared decision making to better engage their patients. The PREPARED trial, led by a team from Johns Hopkins University and supported by NIDDK grant funding, utilizes shared decision making to promote kidney transplantation among African Americans. ■

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