I n 1972, when the Medicare Act provided people in the United States with coverage for renal replacement therapy, 40 percent of patients were doing home hemodialysis (HHD). In 2003, only 0.7 percent of the dialysis population in this country were doing HHD. The Aksys Company was founded in January 1991 to develop an HHD machine that would be patient friendly; reduce the labor of setting up, putting on, and tearing down; provide ultrapure water; and reuse the dialyzer and blood tubing to reduce cost. Since then, the following advances in HHD devices have continued to evolve.

The Baxter VIVIA hemodialysis system is designed to deliver high-dose hemodialysis in the home. The machine provides reuse of the dialyzer and blood lines by means of heat disinfection and automatic prime and rinseback; an integrated access disconnect system; an animated, patient-friendly, graphic user interface; wireless connectivity to the clinic; an integrated heparin pump; an integrated water treatment source; and online dialysate generation. The device provides all types of hemodialysis. It is not portable and does not have an integrated blood pressure monitor system. The Baxter VIVIA Hemodialysis System

The 2008K@Home machine, developed from the Fresenius Medical Care 2008 in-center series, was introduced as the Baby K@Home in 2004, withdrawn from the market in 2008, and reintroduced in 2010 with approval from the U.S. Food and Drug Administration (FDA) for home therapy. This machine, which provides all types of hemodialysis, has a standard platform as used in a center, is reliable and easy to maintain, provides ultrapure water, and uses standard supplies. It has automated prime and rinseback, and a blood pressure monitor and a heparin pump are integrated in the device. The dialysate concentration can be adjusted in a manner similar to that used by in-center machines. A patient interface assists patients with setup and interacts with alarms. Remote real-time monitoring is provided by iCare connectivity. WetAlert, a wireless wetness monitor at the needle site, will stop the blood pump if the alarm is activated. The machine is not portable and requires an external water treatment source and significant home remodeling. The 2008K@Home machine

NxStage Medical, Inc., was founded in December 1998. The NxStage System One was approved for hemodialysis in July 2003 and for HHD in June 2005. NxStage System One

Technical Advances in Home Hemodialysis

By Robert S. Lockridge, Jr.

NxStage System One is being used by more than 6000 patients in the United States (i.e., 95 percent of HHD patients in this country) and has performed more than 6 million short daily treatments with low-dialysate-flow hemodialysis at home.

The machine is a cycler (similar to the peritoneal dialysis cycler platform) and has a disposable drop-in cartridge with blood and dialysate lines and dialyzer attached. There is no blood or dialysate interface with the device; thus, disinfection involves removing the disposable cartridge and wiping down the machine. Ultrapure dialysate is provided in sterile 5-L bags, by the Pure Flow system, or by both. The Pure Flow, approved by the FDA in 2008, is a compact, self-contained, disposable deionization water filtration system with a simple faucet or an under-sink connection with a standard electric outlet; thus, it requires no significant home remodeling. The Pure Flow makes a 60-L sack of lactate base dialysate in 7 hours that can be used for as long as 96 hours from the time of preparation. Maintenance of the cycler and Pure Flow is provided through FedEx exchange by the patient of the cycler and Pure Flow components. The device provides short daily low-dialysate-flow hemodialysis five times a week.

Continued on page 12
Impact of the Prospective Payment System (PPS) on Home Hemodialysis

By Allen R. Nissenson, MD, FACP, FASN, Chief Medical Officer at DaVita HealthCare Partners and Emeritus Professor of Medicine at the David Geffen School of Medicine at UCLA.

The vast majority of patients with end-stage renal disease (ESRD) undergoing dialysis receive this care through a Medicare entitlement enacted in 1972. Up until 2011, payment for dialysis treatments included one payment for the basic treatment itself, including all of the associated costs, and a separate payment for injectable medications (primarily erythropoietin, vitamin D, and iron) and some laboratory tests. In January 2011 the Prospective Payment System (PPS)—sometimes called “the bundle”—approach to payment was initiated, so-called because the basic payment plus the payment for injectable medications (and some laboratory tests) were bundled together into a single payment. In addition, the provisions of the PPS included withholding 2 percent of the bundled payment, which could be earned back if dialysis facilities met certain quality outcomes. The PPS applied to patients independent of dialysis modality or site of care, so included home hemodialysis (HDH) patients, although the quality metric related to dialysis adequacy was not included for such patients who were receiving more than three treatments per week.

When the PPS was implemented there was a measurable increase in the number of patients selecting peritoneal dialysis (PD) as a dialytic modality. While there are many factors that led to this occurrence, it was clear that total costs of care for PD patients were lower than for in-center hemodialysis (ICHD) patients, and the PPS further incentivized PD since the weekly payment was the same for PD and ICHD, but the costs for PD were lower. A similar increase in growth of HDH has not been seen, however, and the PPS does not favorably reward placement of patients on this form of therapy. It should be noted that the current PPS payment level is not sufficient to pay for the costs of dialysis, thus necessitating cost shifting from patients with other forms of insurance in order to maintain viability of dialysis facilities.

There is currently a lack of granular data on the costs of HDH training, including retraining and “fakie” training for patients who switch out of the therapy in the first 3 to 6 months. In addition, the lack of a payment policy by Medicare to cover the costs of more frequent dialysis makes it challenging to provide more than three treatments, even at home. If the clinical value of more frequent dialysis can be convincingly demonstrated, and patients live longer, are healthier and remain out of the hospital, have an enhanced experience of their treatments, and a better quality of life, the imperative will be on the kidney care community to convince Medicare to: 1) reimburse for the additional treatments under the current fee-for-service system, or 2) move more rapidly to the value-based fully bundled or capitated system where the upfront costs of providing more treatments are more than offset by savings in keeping patients healthier.

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