

Company

Outset Medical, Inc.

Drug or Device Name

Tablo® Hemodialysis System

Category

Medical Technology

Compound/Technical Name

Hemodialysis delivery system and water purification system

Trade Name

Tablo Hemodialysis System

Date of Approval

03/30/2020

Therapeutic Categories

Nephrology

Indications

The Tablo Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home.

Background

Hemodialysis is a life-sustaining therapy that cleanses the blood using a machine to do the work the patient's kidneys once did. As necessary as dialysis is, the rigid and demanding regimen of clinic appointments and travel time undermine patients' quality of life and medical outcomes. People with end-stage renal disease (ESRD) typically travel to clinics three or more times per week for scheduled, four-hour dialysis sessions.

These clinics are facing staffing shortages, forcing nurses to stretch themselves to ensure every patient gets the right care and treatment. Dialysis-trained nurses, specifically, can be difficult to find and retain. Add to this the complexity of the clinic itself – standard dialysis machines often require separate water treatment rooms, equipment and supplies. These understaffed clinics are overrun with complexity and are struggling to provide dialysis patients with the life-saving treatment they need.

Home hemodialysis is the future of care. Not only does it help safeguard immunocompromised patients, but it can also better enable individualized ultrafiltration rates, dialysis durations and treatment frequencies. Equally important, it can restore precious independence, dignity and time to patients who have been forced to adhere to the clinics' schedules and processes.

Unfortunately, home hemodialysis has long been easier said than done. Conventional home hemodialysis machines for most patients have been too complex to master, requiring extensive training and onerous 8-to-9-hour preparation sessions before treatment. And despite over 30 million people in the world needing dialysis, the treatment has not meaningfully changed in 30 years.

Until now. Thanks to Outset Medical, a new alternative for kidney patients has finally arrived. It's more than a simple step change; it's a revolutionary innovation – think iPhone vs. rotary phone, electric car vs. gas engine, and satellite vs. AM radio.

Development

Outset Medical embarked on its mission a decade ago, committing to making dialysis treatments simple and accessible for patients in need. The organization realized that kidney patients want the same things out of life that everyone does, but clinic time and travel were getting in the way. Thus, everyone in the company holds the conviction that kidney treatment should fit into patients' lives, not the other way around.

The patient has always been, and will always continue to be, the focus of Tablo's development. To understand patient challenges, the R&D team interviewed hundreds of dialysis patients, sat with them through treatment and witnessed them struggling with outdated and complicated dialysis technology. In 2014, after 10 years of R&D, the team unveiled the Tablo® Hemodialysis System, receiving FDA clearance for hospital use. Soon after, in 2020, Tablo received FDA clearance for home use – the first new home dialysis device cleared in over 15 years.

That was a godsend for patients yearning to reclaim their favored lifestyles, and the evidence was convincing. Satisfaction was high and error rates were a fraction of those associated with competing technologies.

In recent FDA-reviewed human factors studies, healthcare professionals, patients and care partners completed a three-hour training. An independent facilitator then asked them to perform thousands of tasks. Among healthcare professionals, there was a 0.5% use error rate, roughly half of what a competitor's study reported. The patient and care partner group had a 0.9% use error rate, less than a quarter of that reported in the competitor's study. At the end of 2021, the Centers for Medicare and Medicaid Services (CMS) deemed Tablo as the only significant clinical improvement over legacy technology. The key was putting patients first.

Innovation

Tablo is a one-of-its-kind, self-contained device offering consumer product simplicity – including an intuitive touchscreen, wireless connectivity and real-time integrated water purification – in a compact unit suitable for homes, hospitals and clinics. Sleek, intelligent and cloud-connected, Tablo enables patients to manage their own dialysis and physicians to monitor patients and dialysis data from anywhere remotely.

Tablo directly addresses the staggering complexity that has discouraged patients from managing their dialysis at home. This 35-inch-tall dialysis clinic on wheels feels familiar to any patient who has used a smartphone or tablet. The intuitive, interactive touchscreen displays 3D animations and conversational instructions to simplify system set-up, treatment and alarm resolution. Meanwhile, other home dialysis machines present patients with complex codes, cumbersome equipment and complicated setup.

Different than other machines, Tablo uniquely provides a large range of dialysis modalities in one device, including extended treatment up to 24 hours, sustained low-efficiency dialysis (SLED), intermittent hemodialysis (IHD) and ultrafiltration (UF). Durations can range from 30 minutes to 24 hours.

Clinicians and patients consider Tablo a breakthrough in home hemodialysis. In a recent survey of 184 nephrologists, 98% said its features would make them more likely to recommend home hemodialysis to their patients. In a survey of more than 200 U.S. dialysis patients, 77% said the device's features would make them more likely to try home hemodialysis.

Tablo presents numerous benefits to patients and the health system: the device is simple to use and requires a third of the training compared to other home dialysis devices, leading to a higher patient retention rate and patients feeling better following their transition to Tablo. Additionally, Tablo can lower the cost of healthcare to the entire system.

Kidney disease is a tremendous burden for patients. As Tablo is demonstrating, the treatment no longer has to

add to it.

Pubmed

Extension of Tablo TrEatmeNt Duration (XTEND) study: successful 24 h prolonged therapy with Tablo in critical patients (<https://pubmed.ncbi.nlm.nih.gov/36271326/>)

Self-care training using the Tablo hemodialysis system (<https://pubmed.ncbi.nlm.nih.gov/33047477/>)

Safety and efficacy of the Tablo hemodialysis system for in-center and home hemodialysis (<https://pubmed.ncbi.nlm.nih.gov/31697042/>)

Patient-reported outcomes from the investigational device exemption study of the Tablo hemodialysis system (<https://pubmed.ncbi.nlm.nih.gov/32851807/>)

Results of human factors testing in a novel Hemodialysis system designed for ease of patient use (<https://pubmed.ncbi.nlm.nih.gov/27194590/>)

Attachments

- 1656450733Home_Hemodialysis_with_the_Tablo_System_The_First_1000_Real-World_Treatments.pdf
- 1656450742Policies_to_Support_Home_Dialysis_Patients_Patients_Need_Help_Too.pdf
- 1656450860High_Treatment_Adherence_and_Low_Ultrafiltration_Rates.pdf
- 1656450868Patient_Device_Preference_for_Home_Hemodialysis_A_Subset.pdf
- 1656450876Self-care_training_using_the_Tablohemodialysis_system.pdf
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- Initial Experience With Home Hemodialysis Using the Tablo Hemodialysis System.pdf