



Outset Medical's Tablo® Hemodialysis System Receives Landmark TPNIES Approval From CMS

November 1, 2021

TPNIES approval to provide additional reimbursement for Tablo home dialysis treatments

SAN JOSE, Calif.--(BUSINESS WIRE)--Nov. 1, 2021-- [Outset Medical, Inc.](#) (Nasdaq: OM) ("Outset") today announced that its Tablo® Hemodialysis System has received the first-ever approval from the Centers for Medicare & Medicaid Services (CMS) for a Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). This pioneering decision will help encourage healthcare providers to embrace new technology enabling more patients to dialyze at home and reclaim their independence.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20211101005342/en/>



The Tablo® Hemodialysis System combines consumer product simplicity, wireless connectivity, and real-time integrated water purification in one, compact 35-inch unit. Named a substantial clinical improvement by CMS, Tablo is the first product approved for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). (Photo: Business Wire)

TPNIES is a recently enacted program by CMS to increase access to new and innovative medical technologies for end-stage renal disease (ESRD) patients. Introduced in 2020, the add-on payment addresses barriers in the ESRD bundled payment system that discourage providers from adopting new technologies when they come to market. As part of the TPNIES approval, healthcare providers will have access to supplemental reimbursement over the next two years to support their patients' use of Tablo at home.

"For too long ESRD patients have faced a lack of innovation and options for their kidney treatment, restricting how, when and where they dialyze," said Leslie Trigg, Outset Medical's Chief Executive Officer. "At Outset, we have

always believed that dialyzing at home is vital to restoring identity, autonomy and a sense of self-worth for those managing kidney disease. Today's news is a victory for innovation and patient choice."

More than half a million Americans depend on dialysis treatments three or more times per week. And while there are few physical limitations on who can receive home hemodialysis treatment, only two percent of people currently do, despite data indicating more favorable outcomes with home compared to in-center hemodialysis. Receiving in-center dialysis can create a significant burden on patients, impacting their quality of life, ability to maintain employment and adherence to their dialysis treatment regimen.

"Doing in-center dialysis treatments during the first year of the COVID-19 pandemic was terrifying," said Tablo patient Ron Kapke. "When my healthcare team suggested home hemodialysis with Tablo in early 2021, I jumped at the opportunity and never turned back. Recovery time after Tablo is so much shorter, allowing me to get back to the job I love — farming — within thirty minutes post treatment. My life has become so much more enjoyable, my energy has returned, and I dare say that there is a sense of normalcy returning."

Tablo offers a new level of simplicity aimed at solving the problems that have limited home dialysis adoption to date, including burdensome training requirements, complex machine operation and time-consuming preparation before treatments. Designed to reduce the costs and complexity of dialysis, while simplifying the patient and provider experience, Tablo is an all-in-one solution, with integrated water purification and the ability to deliver multiple dialysis treatment types in a compact 35-inch unit. A connected and intelligent device, Tablo has two-way communication with the cloud, which allows treatment data to be sent electronically and enables physicians to remotely monitor patients at home.

"Outset's Tablo Hemodialysis System not only addresses a 15-year gap in dialysis innovation, but it also delivers a device that is far easier and safer for users to navigate," said Dr. Varshi Broumand, System Dialysis Medical Director at CHRISTUS Health. "Since most adults in the United States now have smartphones with similar touchscreen interfaces, patients have felt at home with Tablo's touchscreen, on-screen animations and step-by-step instructions. This comfort has made the dialysis experience easier on patients, resulting in fewer complications and hospitalizations. There's no question that when it comes to patient comfort and delivering superior outcomes, home dialysis via Tablo is the undisputed winner."

The TPNIES approval was made after a comprehensive review of Tablo's technology, as well as an open public comment period. Nearly 200 comments supportive of Tablo as a significant innovative improvement over the existing technology were submitted by healthcare providers, clinicians and patients during this process.

About Outset Medical, Inc.

Outset is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. Tablo is a registered trademark of Outset Medical, Inc.

Forward-Looking Statements

This press release may contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements include statements regarding Outset's expectations with respect to the anticipated benefits of the TPNIES approval. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, which could cause actual results and other events to differ materially from those expressed or implied in such statements. These risks and uncertainties include risks described in the Risk Factors section of Outset's most recent annual report on Form 10-K and quarterly report on Form 10-Q filed with the U.S. Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof and

should not be unduly relied upon. Outset disclaims any obligation to update these forward-looking statements.



View source version on [businesswire.com](https://www.businesswire.com/news/home/20211101005342/en/): <https://www.businesswire.com/news/home/20211101005342/en/>

Nicole Shannon
Director, Marketing Communications for Outset Medical
nshannon@outsetmedical.com

Source: Outset Medical, Inc.