

FDA Clears Tablo Home Dialysis Device

By Bridget M. Kuehn

The US Food and Drug Administration cleared Outset Medical's Tablo device for home dialysis in March. It was previously cleared for in-center and hospital use.

The clearance will give patients a second option for home hemodialysis in addition to Fresenius' NxStage System One device, which has been available since 2017. The clearance was based on a 30-patient, multicenter trial that met its endpoints for safety and efficacy and in patients who received home dialysis with the device 4 times a week for 32 weeks after an in-center lead-in and transition period. The news comes at a time when demand for home dialysis is high as a result of the COVID-19 pandemic. The desire to stem the spread of the virus among the high-risk dialysis population has created a need for more options that allow patients with the virus or those at high risk to isolate themselves from others.

"[COVID-19] really has put a spotlight on the need to increase our capacity to treat patients in isolated environments," said Leslie Trigg, CEO of Outset Medical. "Giving patients and providers a second choice for a home hemodialysis device can only help increase the amount of isolation dialysis treatment that's available."

Currently, only about 12% of the more than 500,000 US dialysis patients receive their treatments at home, according to Outset Medical. But even before the COVID-19

pandemic, there was growing interest in increasing access to home hemodialysis. The Advancing American Kidney Health (AAKH) initiative created by executive order in July 2019 is expected to help increase the number of patients on home dialysis. The AAKH will create payment incentives to increase patient access to home dialysis and kidney transplants.

Richard Crawford, a dialysis patient who participated in the Tablo trial, said he was very excited about the device finally being available. Crawford said he likes the device because it was easy to set up in just 20 minutes compared to 4 hours with other home dialysis devices he has used and didn't require help from his family to set up. He and his nephrologist agreed his clearance was better on the device, he said.

"It will provide self-empowerment and make it easier for families," he said. The device requires only an electrical outlet and uses tap water, so it also requires less storage space at home. Crawford said he hopes to be able to get the device for home use now that it is available.

Trigg said Outset Medical plans a "thoughtful, more measured rollout" of the Tablo for home use. They will start by working with nephrologists who are already using the device, which was previously cleared for use at dialysis centers and in hospitals. They plan to provide a 24-7 support system for home patients.

The home rollout of Tablo is also being balanced against a surge in demand for the device for hospitals, according to a press release from Outset Medical. Because the device is so portable and nurses can be trained to use it in a matter of hours, hospitals are using it to expand the availability of dialysis. It is being used for isolation dialysis, acute dialysis needs, and in parts of the hospital where it isn't normally available.

"Tablo has definitely been pressed into service all across the country," Trigg said. "You don't often get an opportunity like this maybe in your entire career to get to be a part of something that really, really deeply matters." ■

References

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Cricket Assists Cigna in Kidney Care

Cricket Health, a company that aims to provide cost-effective integrated nephrology and dialysis, has begun to leverage its high-tech approach to kidney care by helping major insurer Cigna identify patients who may need further care.

Cigna was a supporter of Cricket's vision and plans and, along with other funding entities, invested in Cricket Health. Cigna's contribution was part of a \$24 million funding round in 2018.

Now Cricket, which bills itself as an evidence-based firm, will use its technology expertise to identify and assist patients who have early to late kidney disease. Cricket attracted early investors and supporters because the company had designed a machine-learning algorithm that now will work to identify which Cigna customers might need attention.

Cricket's algorithm relies on claims data; thus, there is no need for electronic health records or clinical test data. Using claims data lets Cricket run continuous risk assessment monitoring of Cigna's patient population inexpensively, the company noted in a media release.

Noted Cricket Health cofounder and Chief Executive Officer Arvind Rajan: "Directing patients toward home care options when possible will be es-

pecially critical as more Americans are urged to stay home to prevent the spread of the novel coronavirus." Rajan, speaking to <https://www.fercehealthcare.com/special-report/cricket-health>, added that the current health crisis "has underlined the importance of the Cricket model of care even more sharply."

That model begins with Cricket's algorithm to identify potential kidney health problems. Identified patients would become part of a nephrology practice that provides several alternatives, including remote care, in-person care, and at-home care.

For patients identified as part of the Cigna California work, Cricket Health plans to deploy a care

management team with the goal of reducing hospitalizations and managing progression of disease; helping patients whose disease is progressing to understand treatment, including from conservative care, dialysis in appropriate locations, and transplantation; and encouraging patients to select the best care options for themselves and their families.

"Cigna has been an industry leader in adopting data to improve early detection and treatment for other chronic diseases," Rajan said. "Together, we will apply the same evidence-based, multidisciplinary approach to chronic kidney disease and end stage renal disease." ■

