



August 28, 2017

## **NxStage Medical Announces FDA Clearance for Solo Home Hemodialysis Using NxStage® System One™**

### **First clearance of its kind gives trained NxStage patients freedom to dialyze without a care partner**

LAWRENCE, Mass., Aug. 28, 2017 /PRNewswire/ -- NxStage Medical, Inc. (Nasdaq: NXTM), [a leading medical technology company focused on advancing renal care](#), today announced that the U.S. Food and Drug Administration (FDA) has cleared its System One for solo home hemodialysis, without a care partner, during waking hours.



Since receiving its first clearance for home hemodialysis from the FDA in 2005 and the first and only home nocturnal hemodialysis clearance in 2014, the NxStage System One has provided over 14 million treatments to thousands of patients in their homes around the world, during the day and at night. However, certain patients have not had access to this therapy option due to the fact that the System One's indication has required that a care partner be present when a patient performs home hemodialysis. This new expanded indication provides both new and existing System One patients, trained to perform solo home hemodialysis, the freedom to dialyze at home without a care partner during waking hours.

"Patients have been asking for an FDA-cleared solo option for years," stated Dr. Allan Collins, Chief Medical Officer, NxStage. "Many patients have been turned away from home hemodialysis simply because they did not have a care partner. The ability to train and treat solo provides a broader patient base with access to the clinical and quality of life benefits associated with home hemodialysis."

"We are thrilled with this milestone achievement," said Todd Snell, SVP of QA, Regulatory & Clinical Affairs, NxStage. "Our interaction with the FDA first began at a patient preference workshop followed by regular dialogue throughout the pre-submission and submission processes. The solo home hemodialysis clearance makes NxStage the first company to formally conduct a patient preference study leading to a label expansion."

"With much credit to our decade long history in the home, we continue to do amazing things for dialysis patients," said Joe Turk, President, NxStage. "As a company, we are incredibly passionate about providing patients with as much freedom and flexibility as possible to do their dialysis therapy when they want and where they want, day or night. This expanded indication for solo therapy is another significant step forward for patients."

NxStage will be working with its customers and partners to implement additional patient training for this new indication later this year and into 2018. Interested patients should talk to their nephrologist and care teams to fully understand both the risks and benefits of solo therapy to determine if solo home hemodialysis is right for them.

*A trained and qualified patient may dialyze alone, without a care partner present (solo home hemodialysis), provided the patient and physician agree that solo home hemodialysis is appropriate. Certain risks associated with hemodialysis treatment are increased when performing solo home hemodialysis because no one is present to help the patient respond to health emergencies. If patients experience needles coming out, blood loss, or very low blood pressure during solo home hemodialysis, they may lose consciousness or become physically unable to correct the health emergency. Losing consciousness or otherwise becoming impaired during any health emergency while alone could result in significant injury or death. Additional ancillary devices and training are required when performing solo home hemodialysis. Patients should consult with their physician to understand the risks and responsibilities associated with solo home hemodialysis using the NxStage System One.*

### **About the NxStage System One**

The NxStage System One is the first and only truly portable hemodialysis system cleared specifically by the FDA for home hemodialysis, home nocturnal hemodialysis and solo home hemodialysis. Its simplicity and revolutionary size (just over a foot tall) are intended to allow convenient use in patients' homes and give patients the freedom to travel with their therapy. When combined with the NxStage PureFlow SL Dialysis Preparation System, patients are able to further simplify, using ordinary tap water to create dialysis fluid on demand. Unlike conventional hemodialysis systems, the System One requires no special infrastructure to operate. Under the guidance of their physician, patients can use the NxStage System One, with their trained partners (or for patients prescribed to receive solo dialysis, alone), where, how and when it best meets their needs, including while they are sleeping - at home or on vacation and at a medically appropriate treatment frequency. In addition, NxStage's Nx2me Connected Health platform collects important NxStage System One and patient information for flexible viewing, monitoring and reporting that may improve patient management and patient retention, as well as simplify alternative site care. [www.nxstage.com](http://www.nxstage.com).

### **About NxStage Medical**

NxStage Medical, Inc. (Nasdaq: NXTM) is a leading medical technology company, headquartered in Lawrence, Massachusetts, USA, that develops, manufactures and markets innovative products for the treatment of end-stage renal disease (ESRD) and acute kidney failure. NxStage also has established a small number of dialysis clinics committed to the development of innovative care delivery models for patients with ESRD. For more information on NxStage and its products and services, please visit the Company's websites at [www.nxstage.com](http://www.nxstage.com) and [www.nxstagekidneycare.com](http://www.nxstagekidneycare.com).

### **Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this release that are not clearly historical in nature are forward-looking, and the words "anticipate," "believe," "expect," "estimate," "plan," and similar expressions are generally intended to identify forward-looking statements. Actual results may differ materially from those indicated by these forward-looking statements as a result of various important factors including those that are discussed in NxStage's filings with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2017. NxStage is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements, whether as a result of new information, future events or otherwise.

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