

American Medical Association Issues New CPT Code for Nuwellis' Aquadex Ultrafiltration

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The newly classified code expands access to life-saving, novel fluid removal technology

EDEN PRAIRIE, Minn., July 13, 2021 (GLOBE NEWSWIRE) -- In an effort to increase the availability of life-saving ultrafiltration therapy to people experiencing fluid overload, the American Medical Association (AMA) has issued a new Category III Current Procedural Terminology (CPT®) code, 0692T for Therapeutic Ultrafiltration. The new CPT code will come into effect on January 1, 2022, at which time providers can utilize the code when using Aquadex® to deliver ultrafiltration to adults and children (20 kg or more). Aquadex is developed and marketed by Nuwellis, Inc. (Nasdaq: NUWE).

A specific code for ultrafiltration was granted after a thorough review and validation that the technology met the criteria for a Category III CPT code. The CPT codes created and maintained by the AMA CPT Editorial Panel are widely used by third party payers including Medicare, Medicaid and commercial health plans. The approved Therapeutic Ultrafiltration Category III CPT code will be in effect for at least five years.

"Having an ultrafiltration-specific CPT code is a critical milestone for Nuwellis. Reimbursement is an integral aspect of hospital administration decision making and can play a huge role in whether patients will have access to life-saving technologies," said Nestor Jaramillo, Jr., president and CEO of Nuwellis. "We appreciate the recognition of the therapeutic benefit of ultrafiltration by the medical societies who supported the application. We are confident the Category III CPT code will enable patient access through adoption by providers who prescribe ultrafiltration for their fluid-overloaded patients."

"If it were entirely up to providers, we would always use the most innovative technologies to treat our patients," said Dr. Maria V. DeVita, Chief Nephrologist, Lenox Hill Hospital, New York, New York. "Yet the reality is, the healthcare system is immensely dynamic and components such as reimbursement must be considered when choosing the best tools to include in our armamentarium. This reimbursement opens access to more hospitals and ultimately patients across the nation who otherwise may not have had access to ultrafiltration, and that is news worth celebrating."

About Nuwellis

Nuwellis, Inc. (Nasdaq:NUWE) is a medical device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on developing, manufacturing and commercializing the Aquadex SmartFlow® System for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, Minn., with a wholly-owned subsidiary in Ireland. The Company has been listed on the Nasdaq Capital Market since February 2012, previously branded as CHF Solutions (Nasdaq:CHFS).

About the Aquadex SmartFlow System

The Aquadex SmartFlow® System delivers clinically proven therapy using a simple, flexible and smart method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow System is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both having received training in extracorporeal therapies.

Forward-Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the new market opportunities and anticipated growth in 2021 and beyond. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercialization strategy, the impact of the COVID-19 pandemic, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our post-market clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. Nuwellis does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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