

# Restoring Fluid Balance. Transforming Care.

# Nuwellis Receives Increased Reimbursement Rate for Aquadex SmartFlow® Therapy from the Centers for Medicare and Medicaid

November 4, 2024

Reimbursement rate to increase 397% per day effective January 1, 2025

New rate expected to encourage adoption of ultrafiltration therapy in the outpatient setting

MINNEAPOLIS, Nov. 04, 2024 (GLOBE NEWSWIRE) -- <u>Nuwellis. Inc.</u> (Nasdaq: NUWE), a commercial-stage medical device company committed to transforming the lives of people with fluid overload, is pleased to announce that the <u>Centers for Medicare and Medicaid Services</u> (CMS) will reassign the Aquadex ultrafiltration code to the outpatient reimbursement level most consistent with administration of ultrafiltration therapy and cost of treatment. Effective January 1, 2025, the payment rate will increase 397% from \$413 to \$1,639 per day.

Nestor Jaramillo, President and CEO of Nuwellis, expressed his excitement about the new payment rate, stating, "We are thrilled with the CMS' decision to reassign the code for Aquadex SmartFlow therapy, increasing the reimbursement rate for Aquadex SmartFlow therapy. This change underscores the clinical importance and cost-effectiveness of our ultrafiltration technology and will expand patient access to this life-saving therapy. It is well understood that providing care in an outpatient setting can be a better means to manage disease and prevent costly emergency hospitalizations. This policy update is a testament to our ongoing commitment to improving patient outcomes and advancing the standard of care in fluid management. We appreciate the support and guidance provided by Maria DeVita, MD, Chief of the Nephrology Division and the Training Program Director of the Nephrology Fellowship Program at Lenox Hill Hospital, and Jennifer Cowger, MD, Section Head of Heart Failure, Transplant and Mechanical Circulatory Support at Henry Ford Hospital, throughout the process."

This increase in reimbursement corresponds with the reassignment of therapeutic ultrafiltration CPT code 0692T from APC 5241 to APC 5242. The decision by CMS marks a significant milestone in the recognition of the value and effectiveness of Aquadex SmartFlow ultrafiltration therapy for treating fluid overload in heart failure patients. The reassignment to APC 5242 will provide a reimbursement pathway for ultrafiltration therapy delivered in an outpatient setting, which will help expand the number of patients who are able to receive the therapy as part of a sub-acute or chronic disease management program.

#### **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 commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly owned subsidiary in Ireland. For more information visit <a href="www.nuwellis.com">www.nuwellis.com</a> or visit us on LinkedIn or Twitter.

## 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 2024 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 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 due to new information, future events or otherwise.

#### **CONTACTS**

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Source: Nuwellis, Inc.