

FOR IMMEDIATE RELEASE

CMS Establishes National Pricing for the inFlow[™] Voiding Prosthesis CPT[®] Codes

Major Reimbursement Milestone Expands Patient Access to the Only Catheter-Free Solution for Women with Permanent Urinary Retention

Redmond WA, November 12, 2024 - Vesiflo, Inc. today announced a major reimbursement milestone for its inFlow™ Voiding Prosthesis, following the Centers for Medicare & Medicaid Services (CMS) decision to establish national pricing for the CPT® codes related to physician procedures for the device. This decision, included in the Calendar Year 2026 Medicare Physician Fee Schedule (PFS) Final Rule (CMS-1832-F), will take effect January 1, 2026, ensuring consistent nationwide coverage for physicians treating women with permanent urinary retention (PUR).

In previously issuing nationally priced in Flow supply codes as part of the 2025 Physician Fee Schedule, CMS cited strong physician support for this "important, life-enhancing technology."

"The inFlow voiding prosthesis is the only alternative to lifelong urinary catheter use for women suffering from permanent urinary retention caused by neurological conditions such as multiple sclerosis, spinal cord injury, spina bifida, and multiple system atrophy," said Kevin Connolly, CEO of Vesiflo. "We deeply appreciate CMS' leadership in removing payment barriers that have limited access to this transformative technology."

Unlike traditional catheters that *passively* drain urine, the inFlow *actively* empties the bladder using unique technology for non-contact energy transfer, mimicking natural urination and allowing normal use of a toilet. By restoring this essential activity of daily living, the inFlow not only improves health outcomes—it also restores independence and dignity. Clinical studies have shown that inFlow users experience fewer urinary tract infections and significant improvements in quality of life compared to the current standard of care, clean intermittent catheterization (CIC).

Dr. Richard Schmidt, co-inventor of the Medtronic InterStim, has praised the breakthrough, noting, "There are no good alternatives for women who require chronic catheterization. The inFlow device is truly remarkable in its ability to virtually restore the functional behavior of the bladder. No other product, drug can accomplish this to the same degree."

Based in Redmond, Washington, Vesiflo is a privately held medical device company developing innovative alternatives to urinary catheters. The inFlow Voiding Prosthesis is the first in a series of solutions designed to redefine bladder management and improve quality of life for patients with chronic urological conditions. For more information, please visit www.vesiflo.com