Policy Number	DME102.009
Policy Effective Date	10/15/2025

Intraurethral Valve Drainage Device for Impaired Detrusor Contractility

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Initial
An intraurethral valve drainage device (i.e., inFlow™ device) **may be considered medically necessary** as an alternative to intermittent catheterization for individuals with permanent urinary retention due to impaired detrusor contractility.

NOTE 1: One inFlow device may be covered no more than once every 29 days.

Continuation
Documentation of continued medical necessity of the inFlow device beyond the first 3 months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner conduct a clinical reevaluation and document that the individual continues to use and is benefiting from the inFlow device.

NOTE 2: Documentation of use and clinical benefit is demonstrated by:

1. An in-person encounter by the treating practitioner with documentation that urinary symptoms are improved; and
2. The treating practitioner verifies the individual's adherence to use of the inFlow device.

If the above criteria are not met, continued coverage of the inFlow device and related accessories will be considered **not medically necessary**.

NOTE 3: If the practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the individual is benefiting from the inFlow device as defined in criteria 1 and 2 above, continued coverage of the inFlow device will commence with the date of that re-evaluation.

Policy Guidelines

If there is discontinuation of usage of the inFlow device at any time, the supplier is expected to ascertain this and stop billing for the equipment and related accessories and supplies.

Description

Impaired detrusor contractility (IDC) (or detrusor underactivity [DUA]) can result in permanent chronic urinary retention. Individuals diagnosed with IDC are unable to spontaneously urinate because of insufficient bladder muscle contractions, which can be caused by a number of conditions. When an individual is unable to void at all or unable to empty well enough to prevent urinary tract infections (UTIs), overflow incontinence, bladder stones, or damage to upper urinary tracts, chronic bladder drainage management must be considered. (2)

Although commonly used, urinary catheters are associated with UTIs, low quality of life, and encrustation, especially with chronic use. In those with DUA who must use urinary catheters daily, these problems can be amplified. Intermittent catheterization, the gold standard for bladder management in this population, can be challenging for certain groups of patients, particularly the elderly, visually impaired, mentally handicapped, and those with limited manual dexterity.

The inFlow™ Intraurethral Valve-Pump and Activator is a temporary, replaceable urethral valve-pump for women with incomplete bladder emptying, due to IDC. The inFlow is promoted as an alternative to urinary catheters. The device consists of a small catheter with an internal, magnetically-activated pump-valve mechanism which is placed in the female urethra for up to 29 days or less. (3) Upon activation by a battery-powered wand held low over the pubic area, the valve opens and the pump induces urine flow. Under patient control, the device blocks urine flow when continence is desired, and an internal pump draws urine out of the bladder when activated by the user. Proper device sizing and initial insertion is done by a physician. Subsequent device replacements are self-inserted, or inserted by a caregiver, approximately every 29 days.

Regulatory Status

The inFlow™ Intraurethral Valve-Pump and Activator was approved by the U.S. Food and Drug Administration (FDA) as a Class II device through the *de novo* approval process in 2014 for "use in female patients 18 years of age or older who have incomplete bladder emptying due to impaired detrusor contractility of neurologic origin, and who are capable of operating it in accordance with instructions or who have trained caregivers. The device must be replaced every 29 days (or less)." (4)

Rationale

This policy is based on a review of coverage guidance from the Centers for Medicare and Medicaid Services (CMS) specific to urological supplies. (1)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	0596T, 0597T
HCPCS Codes	A4341, A4342

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

Local Coverage Determination

1. Centers for Medicare and Medicaid Services. Local Coverage Determination for Urological Supplies (L33803) (January 01, 2024). Available at: <https://www.cms.hhs.gov> (accessed August 13, 2025).

Other

2. Hartigan SM, Dmochowski RR. The inFlow intraurethral valve-pump for women with detrusor underactivity: A summary of peer-reviewed literature. J Spinal Cord Med. 2022; 45(4):489-497. PMID 33054612
3. Vesiflo. How Is the inFlow Used. Available at: <https://www.vesiflo.com> (accessed August 15, 2025).

4. U.S. Food and Drug Administration. De Novo Classification Request for inFlow™ Intraurethral Valve-Pump and Activator. 2014. Available at: <https://www.accessdata.fda.gov> (accessed August 18, 2025).

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
10/15/2025	Document updated with literature review. The following change was made to Coverage: 1) Revised medically necessary statement to include "as an alternative to" and removed the criteria requiring a "failure and/or intolerance to" intermitted catheterization; 2) Added not medically necessary statement; and 3) Added NOTE 3. No new references added.
06/15/2024	Reviewed. No changes.
11/15/2023	New medical document. Initial: An intraurethral valve drainage device (i.e., inFlow™ device) may be considered medically necessary for individuals with permanent urinary retention due to impaired detrusor contractility when there is documented failure and/or intolerance to intermittent catheterization. NOTE 1: One inFlow device may be covered no more than once every 29 days. Continuation: Documentation of continued medical necessity of the inFlow device beyond the first 3 months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner conduct a clinical reevaluation and document that the member continues to use and is benefiting from the inFlow device. NOTE 2: Documentation of use and clinical benefit is demonstrated by: 1) An in-person encounter by the treating practitioner with documentation that urinary symptoms are improved; and 2) The treating practitioner verifies the beneficiary's adherence to use of the inFlow device.