Policy Number	DME102.009
Policy Effective Date	04/01/2026

Intraurethral Valve Drainage Device for Impaired Detrusor Contractility

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

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 re-evaluation 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

Detrusor underactivity (DUA), as defined by the International Continence Society, is a diagnosis based on urodynamic investigations, generally with relevant symptoms and signs, manifested by low detrusor pressure or short detrusor contraction in combination with a low urine flow rate resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span. Some women with DUA may have permanent chronic urinary retention. (2)

When women with DUA are 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, they must employ one of the few clinical options available for bladder drainage. The most common options are urinary catheters which can lead to a significant change in quality of life, toileting behaviors, and may not be feasible for some to perform independently.

In women with DUA, who must use urinary catheters daily for the rest of their lives, these problems can be amplified and become frequent. Additionally, clean intermittent catheterization (CIC), the gold standard for bladder management in this population, provides particular challenges 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 impaired detrusor contractility of neurologic origin. (3) 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. To operate, the activator's operating button is depressed and held to open the device valve and turn on the pump, which actively draws urine out of the bladder at a flow rate similar to that of normal urination. When urination is complete, the patient releases the button but continues to hold the activator in place for approximately 3 seconds until it beeps and its LED turns from green to red. This signals that pumping has ceased and the valve has closed, restoring continence until the next desired void. Proper device sizing and initial insertion is done by a physician.

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)

Centers for Medicare and Medicaid Services
While Medicare does not currently have a national coverage determination (NCD) on intraurethral valve drainage devices, a local coverage determination (LCD) (L33803-revision 13) was released in 2026. (1) The LCD allows for initial coverage of the inFlow device as an alternative to intermittent catheterization for patients with permanent urinary retention (PUR) due to impaired detrusor contractility (IDC) under the following circumstances: "One (1) inFlow device may be covered no more than once every 29 days. Claims for the inFlow device billed more than once every 29 days will be denied as not reasonable and necessary. Continued coverage beyond the first three months of therapy requires that no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner must conduct a clinical re-evaluation and document that the beneficiary continues to use and is benefiting from the inFlow device."

If the practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the beneficiary 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.

Documentation of use and clinical benefit must be demonstrated by both an in-person encounter by the treating practitioner with documentation that urinary symptoms are

improved, as well as verification from the treating practitioner of the beneficiary's adherence to use of the inFlow device.

Limitations of coverage include:

- If the above criteria are not met, continued coverage of the inFlow device and related accessories will be denied as not reasonable and necessary.
- 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."

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®) ©2025 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, 2026). Available at: <https://www.cms.hhs.gov> (accessed January 6, 2026).

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 January 6, 2026).
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 January 6, 2026).

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**
04/01/2026	Document updated. Coverage unchanged. No new references added.
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.