



# MASSACHUSETTS

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## Medical Policy Urological Supplies

**Policy Number: 370**

BCBSA Reference Number: N/A

### Related Policies

None

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### Policy<sup>1</sup>

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

The medical necessity for use of a greater quantity of supplies than the amounts specified in the policy must be well documented in the member’s medical record and must be available upon request.

**Indwelling Catheters A4311, A4312, A4313, A4314, A4315, A4316, A4338, A4340, A4344, and A4346**  
**No more than one catheter per month** is considered **MEDICALLY NECESSARY** for routine catheter maintenance.

Non-routine catheter changes are considered **MEDICALLY NECESSARY** when documentation substantiates medical necessity, such as for the following indications:

1. Catheter is accidentally removed (e.g., pulled out by member)
2. Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter)
3. Catheter is obstructed by encrustation, mucous plug, or blood clot
4. History of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change frequency of more than once per month

A specialty indwelling catheter (A4340) or an all silicone catheter (A4344, A4312, or A4315) is considered **MEDICALLY NECESSARY** when the criteria for an indwelling catheter (above) are met and there is documentation in the member's medical record to justify the medical need for that catheter (such as recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex (not all-inclusive)).

In addition, the particular catheter must be necessary for the member. For example, use of a Coude (curved) tip indwelling catheter (A4340) in a female member is rarely reasonable and necessary. If documentation is requested and does not substantiate medical necessity, payment for A4340, A4344, A4312, or A4315 will be denied as **NOT MEDICALLY NECESSARY**.

A three-way indwelling catheter either alone (A4346) or with other components (A4313 or A4316) will be covered only if continuous catheter irrigation is reasonable and necessary. (Refer to [Continuous Irrigation of Indwelling Catheters](#) for indications for continuous catheter irrigations.) In other situations, A4346, A4313 and A4316 will be denied as **NOT MEDICALLY NECESSARY**.

#### **Catheter Insertion Trays A4310, A4311, A4312, A4313, A4314, A4315, A4316, A4353, and A4354**

One insertion tray is considered **MEDICALLY NECESSARY** per episode of indwelling catheter insertion.

More than one tray per episode will be denied as **NOT MEDICALLY NECESSARY**.

One intermittent catheter with insertion supplies (A4353) is considered **MEDICALLY NECESSARY** per episode of reasonable and necessary sterile intermittent catheterization ([see below](#)).

#### **Urinary Drainage Collection Systems A4314, A4315, A4316, A4354, A4357, A4358, A5102, and A5112**

Payment will be made for routine changes of the urinary drainage collection system as noted below.

Additional charges will be allowed for reasonable and necessary non-routine changes when the documentation substantiates the medical necessity, (e.g., obstruction, sludging, clotting of blood, or chronic, recurrent urinary tract infection).

#### **Usual Maximum Quantity of Supplies**

Code	Code Description	Number per month
A4314	Insertion tray with drainage bag with indwelling catheter, Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer or hydrophilic, etc.)	1
A4315	Insertion tray with drainage bag with indwelling catheter, Foley type, two-way, all silicone	1
A4316	Insertion tray with drainage bag with indwelling catheter, Foley type, three-way, for continuous irrigation	1
A4354	Insertion tray with drainage bag but without catheter	1
A4357	Bedside drainage bag, day or night, with or without antireflux device, with or without tube, each	2
A4358	Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with straps, each	2
A5112	Urinary drainage bag, leg or abdomen, latex, with or without tube, with straps, each	1

Code	Code Description	Number per 3 months
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each	1

Leg bags are indicated for members who are ambulatory or are chair or wheelchair bound.

The use of leg bags for bedridden members would be denied as **NOT MEDICALLY NECESSARY**.

If there is a catheter change (A4314, A4315, A4316, A4354) and an additional drainage bag (A4357) change within a month, the combined utilization for A4314, A4315, A4316, A4354, and A4357 should be considered when determining if additional documentation should be submitted with the claim. For example, if 1 unit of A4314 and 1 unit of A4357 are provided, this should be considered as two drainage bags, which is the usual maximum quantity of drainage bags needed for routine changes.

Payment will be made for either a vinyl leg bag (A4358) or a latex leg bag (A5112). The use of both is **NOT MEDICALLY NECESSARY**.

The medical necessity for drainage bags containing absorbent material such as gel matrix or other material, which are intended to be disposed of on a daily basis has not been established. Claims for this type of bag will be denied as **NOT MEDICALLY NECESSARY**.

#### **Intermittent Irrigation of Indwelling Catheters**

Supplies for the intermittent irrigation of an indwelling catheter are considered **MEDICALLY NECESSARY** when they are used on an as needed (non-routine) basis in the presence of acute obstruction of the catheter.

Routine intermittent irrigations of a catheter will be denied as **NOT MEDICALLY NECESSARY**. Routine irrigations are defined as those performed at predetermined intervals. In individual cases, a copy of the order for irrigation and documentation in the member's medical record of the presence of acute catheter obstruction may be requested when irrigation supplies are billed.

Covered supplies for reasonable and necessary non-routine irrigation of a catheter include either an irrigation tray (A4320) or an irrigation syringe (A4322), and sterile water/saline (A4217). When syringes, trays, sterile saline, or water are used for routine irrigation, they will be denied as **NOT MEDICALLY NECESSARY**.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as non-covered. Irrigating solutions such as acetic acid or hydrogen peroxide, which are used for the treatment or prevention of urinary obstruction (A4321), will be denied as **NOT MEDICALLY NECESSARY**.

#### **Continuous Irrigation of Indwelling Catheters**

Supplies for continuous irrigation of a catheter are considered **MEDICALLY NECESSARY** if there is a history of obstruction of the catheter and the patency of the catheter cannot be maintained by intermittent irrigation in conjunction with reasonable and necessary catheter changes.

Continuous irrigation as a primary preventative measure (i.e., no history of obstruction) will be denied as **NOT MEDICALLY NECESSARY**. Documentation must substantiate the medical necessity of catheter irrigation and in particular continuous irrigation as opposed to intermittent irrigation. The records must also indicate the rate of solution administration and the duration of need. This documentation must be available upon request.

Covered supplies for reasonable and necessary continuous bladder irrigation include a 3-way Foley catheter (A4313, A4316, and A4346), irrigation tubing set (A4355), and sterile water/saline (A4217). More than one irrigation tubing set per day for continuous catheter irrigation will be denied as **NOT MEDICALLY NECESSARY**.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as **NOT MEDICALLY NECESSARY**. Payment for irrigating solutions such as acetic acid or hydrogen peroxide will be based on the allowance for sterile water/saline (A4217).

Continuous irrigation is a temporary measure. Continuous irrigation for more than 2 weeks is rarely reasonable and necessary. The member's medical records should indicate this medical necessity and these medical records must be available upon request.

### Intermittent Catheterization

Intermittent catheterization is considered **MEDICALLY NECESSARY** when basic coverage criteria are met and the member or caregiver can perform the procedure.

For each episode of **MEDICALLY NECESSARY** catheterization, we provide coverage for:

- A. One catheter (A4351, A4352) and an individual packet of lubricant (A4332); or
- B. One sterile intermittent catheter kit (A4353) if additional coverage criteria (see below) are met.

Intermittent catheterization using a sterile intermittent catheter kit (A4353) is considered **MEDICALLY NECESSARY** when the member requires catheterization and the member meets **ONE** of the following criteria (1-5):

1. The member resides in a nursing facility,
2. The member is immunosuppressed, for example (not all-inclusive):
  - o on a regimen of immunosuppressive drugs post-transplant,
  - o on cancer chemotherapy,
  - o has AIDS,
  - o has a drug-induced state such as chronic oral corticosteroid use.
3. The member has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,
4. The member is a spinal cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),
5. The member has had distinct, recurrent urinary tract infections, while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant A4332, twice within the 12-month prior to the initiation of sterile intermittent catheter kits.

A member would be considered to have a urinary tract infection if they have a urine culture with greater than 10,000 colony forming units of a urinary pathogen **AND** concurrent presence of **ONE OR MORE** of the following signs, symptoms or laboratory findings:

- Fever (oral temperature greater than 38° C [100.4° F])
- Systemic leukocytosis
- Change in urinary urgency, frequency, or incontinence
- Appearance of new or increase in autonomic dysreflexia (sweating, bradycardia, blood pressure elevation)
- Physical signs of prostatitis, epididymitis, orchitis
- Increased muscle spasms
- Pyuria (greater than 5 white blood cells [WBCs] per high-powered field).

### Usual Maximum Quantity of Supplies

Code	Code Description	Number per month
A4332	Lubricant, individual sterile packet, each	200
A4351	Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each	200
A4352	Intermittent urinary catheter; Coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each	200
A4353	Intermittent urinary catheter, with insertion supplies	200

Refer to Coding Guidelines section of the related [Policy Article](#) for contents of the kit (A4353). A4353 should not be used for billing if the components are packaged separately rather than together as a kit. Separately provided components do not provide the equivalent degree of sterility achieved with an A4353. If separate components are provided instead of a kit (A4353) they will be denied as **NOT MEDICALLY NECESSARY**.

Use of a Coude (curved) tip catheter (A4352) in female beneficiaries is rarely reasonable and necessary. When a Coude tip catheter is used (either male or female members), there must be documentation in the member's medical record of the medical necessity for that catheter. An example would be the inability to catheterize with a straight tip catheter. This documentation must be available upon request. If documentation is requested and does not substantiate medical necessity, claims will be denied as **NOT MEDICALLY NECESSARY**.

### **External Catheters/Urinary Collection Devices**

Male external catheters (condom-type) or female external urinary collection devices are considered **MEDICALLY NECESSARY** for members who have permanent urinary incontinence when used as an alternative to an indwelling catheter.

The utilization of male external catheters (A4349) generally **should not exceed 35 per month**. Greater utilization of these devices must be accompanied by documentation of medical necessity.

Male external catheters (condom-type) or female external urinary collection devices will be denied **NOT MEDICALLY NECESSARY** when ordered for members who also use an indwelling catheter.

Specialty type male external catheters (A4326) such as those that inflate or that include a faceplate or extended wear catheter systems are considered **MEDICALLY NECESSARY** only when documentation substantiates the medical necessity for such a catheter. If documentation does not justify the medical need claims will be denied as **NOT MEDICALLY NECESSARY**.

For female external urinary collection devices, more than one meatal cup (A4327) per week or more than one pouch (A4328) per day will be denied as **NOT MEDICALLY NECESSARY**.

### **Initial Coverage for Inflow Device**

The inFlow device is considered **MEDICALLY NECESSARY** as an alternative to intermittent catheterization for members with Permanent Urinary Retention (PUR) due to Impaired Detrusor Contractility (IDC).

One (1) inFlow device may be considered **MEDICALLY NECESSARY** no more than once every 29 days. Claims for the inFlow device billed more than once every 29 days will be denied as **NOT MEDICALLY NECESSARY**.

### **Continued Coverage for Inflow Device Beyond the First Three Months of Therapy**

Continued coverage of the inFlow device 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 member continues to use and is benefiting from the inFlow device.

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 member'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 denied as **NOT MEDICALLY NECESSARY**.

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

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.

### Miscellaneous Supplies

Appliance cleaner (A5131) is considered **MEDICALLY NECESSARY** when used to clean the inside of certain urinary collecting appliances (A5102, A5105, A5112). More than one unit of service (16 oz.) per month is rarely reasonable and necessary.

One external urethral clamp or compression device (A4356) is considered **MEDICALLY NECESSARY** every 3 months or sooner if the rubber/foam casing deteriorates.

Tape (A4450, A4452) which is used to secure an indwelling catheter to the member's body is considered **MEDICALLY NECESSARY**. More than 10 units (1 unit = 18 sq. in.; 10 units = 180 sq. in. = 5 yds. of 1 inch tape) per month will be denied as **NOT MEDICALLY NECESSARY**.

Adhesive catheter anchoring devices (A4333) and catheter leg straps (A4334) for indwelling urethral catheters are considered **MEDICALLY NECESSARY**. More than 3 per week of A4333 or 1 per month of A4334 will be denied as **NOT MEDICALLY NECESSARY**.

A catheter/tube anchoring device (A5200) is considered **MEDICALLY NECESSARY** and separately payable when it is used to anchor a covered suprapubic tube or nephrostomy tube. If code A5200 is used to anchor an indwelling urethral catheter, the claim will be denied as **NOT MEDICALLY NECESSARY**.

Urethral inserts (A4336) are considered **MEDICALLY NECESSARY** for adult females with stress incontinence (refer to the ICD-10 Codes section in the [Policy Article](#) for applicable diagnoses) when basic coverage criteria are met and the member or caregiver can perform the procedure. They are not indicated for women:

- With bladder or other urinary tract infections (UTI)
- With a history of urethral stricture, bladder augmentation, pelvic radiation or other conditions where urethral catheterization is not clinically advisable
- Who are immunocompromised, at significant risk from UTI, interstitial cystitis, or pyelonephritis, or who have severely compromised urinary mucosa
- Unable to tolerate antibiotic therapy
- On anticoagulants
- With overflow incontinence or neurogenic bladder.

### Prior Authorization Information

#### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

#### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

*The following codes are included below for informational purposes only; this is not an all-inclusive list.*

**The above medical necessity criteria **MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:**

### HCPCS Codes

HCPCS codes:	Code Description
A4217	Sterile water/saline, 500 ml
A4310	Insertion tray without drainage bag and without catheter (accessories only)
A4311	Insertion tray without drainage bag with indwelling catheter, foley type, two-way latex with coating (teflon, silicone, silicone elastomer or hydrophilic, etc.)
A4312	Insertion tray without drainage bag with indwelling catheter, foley type, two-way, all silicone
A4313	Insertion tray without drainage bag with indwelling catheter, foley type, three-way, for continuous irrigation
A4314	Insertion tray with drainage bag with indwelling catheter, foley type, two-way latex with coating (teflon, silicone, silicone elastomer or hydrophilic, etc.)
A4315	Insertion tray with drainage bag with indwelling catheter, foley type, two-way, all silicone
A4316	Insertion tray with drainage bag with indwelling catheter, foley type, three-way, for continuous irrigation
A4320	Irrigation tray with bulb or piston syringe, any purpose
A4321	Therapeutic agent for urinary catheter irrigation
A4322	Irrigation syringe, bulb or piston, each
A4326	Male external catheter with integral collection chamber, any type, each
A4327	Female external urinary collection device; meatal cup, each
A4328	Female external urinary collection device; pouch, each
A4331	Extension drainage tubing, any type, any length, with connector/adaptor, for use with urinary leg bag or urostomy pouch, each
A4332	Lubricant, individual sterile packet, each
A4333	Urinary catheter anchoring device, adhesive skin attachment, each
A4334	Urinary catheter anchoring device, leg strap, each
A4335	Incontinence supply; miscellaneous
A4336	Incontinence supply, urethral insert, any type, each
A4338	Indwelling catheter; foley type, two-way latex with coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each
A4340	Indwelling catheter; specialty type, (e.g., coude, mushroom, wing, etc.), each
A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
A4344	Indwelling catheter, foley type, two-way, all silicone, each
A4346	Indwelling catheter; foley type, three way for continuous irrigation, each
A4349	Male external catheter, with or without adhesive, disposable, each

A4351	Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each
A4352	Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each
A4353	Intermittent urinary catheter, with insertion supplies
A4354	Insertion tray with drainage bag but without catheter
A4355	Irrigation tubing set for continuous bladder irrigation through a three-way indwelling foley catheter, each
A4356	External urethral clamp or compression device (not to be used for catheter clamp), each
A4357	Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each
A4358	Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with straps, each
A4360	Disposable external urethral clamp or compression device, with pad and/or pouch, each
A4402	Lubricant, per ounce
A4450	Tape, non-waterproof, per 18 square inches
A4452	Tape, waterproof, per 18 square inches
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
A4456	Adhesive remover, wipes, any type, each
A4520	Incontinence garment, any type, (e.g., brief, diaper), each
A4553	Non-disposable underpads, all sizes
A4554	Disposable underpads, all sizes
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each
A5105	Urinary suspensory with leg bag, with or without tube, each
A5112	Urinary drainage bag, leg or abdomen, latex, with or without tube, with straps, each
A5113	Leg strap; latex, replacement only, per set
A5114	Leg strap; foam or fabric, replacement only, per set
A5131	Appliance cleaner, incontinence and ostomy appliances, per 16 oz.
A5200	Percutaneous catheter/tube anchoring device, adhesive skin attachment
A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591	External urinary catheter; non-disposable, for use with suction pump, per month
A9270	Non-covered item or service

## Description

Impaired detrusor contractility (IDC) is defined by the International Continence Society (ICS) as “a contraction of reduced strength and/or duration, resulting in prolonged bladder emptying and/or failure to achieve complete bladder emptying within a normal time span.” IDC may also be referred to as atonic bladder or detrusor underactivity. IDC most commonly develops due to neurologic disease or injury, such as multiple sclerosis, stroke, spinal cord injury, diabetic neuropathy, and Parkinson’s disease. Clean intermittent catheterization (CIC) is most commonly used to drain the bladder in patients with IDC. The average frequency of self-catheterizations is four to six times daily. In patients who cannot self-catheterize or do not have a caregiver to assist with catheterization, an indwelling (“Foley”) catheter or suprapubic tube may be used.<sup>1,2</sup>

The inFlow device (Intraurethral Valve-Pump and Activator), is a urinary catheter intended to be used as an alternative to CIC in patients with IDC. The inFlow device consists of a silicone tube containing a miniature valve and pump, and a separate remote control “activator” wand. The tube is inserted with a disposable introducer and remains inside the urethra for about a month. To empty the bladder, the patient sits on the toilet, holds the remote-control wand over the lower pelvic area, and presses a button, which magnetically activates a small valve-pump in the inserted urethral tube. Once the pump is activated, the bladder drains at a normal rate. Once the button is released, a valve closes, and urine flow stops. The inFlow device is sized and initially inserted by a treating practitioner; and it must be replaced every 29

days. Generally, the user or caregiver can replace the inFlow device, since insertion is similar to a urinary catheter.

In 2014, the Food and Drug Administration (FDA) issued approval for the inFlow device via the De Novo pathway. [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/DEN130044.pdf](https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130044.pdf)

## Summary

Seven clinical studies that included a total of 501 participants have been published on the inFlow device.<sup>5-</sup>

<sup>11</sup> The pivotal multicenter trial<sup>5</sup> upon which FDA approval was based included 273 participants from 18 sites (15 U.S., 3 international) and was a single-arm crossover design that evaluated the inFlow device compared with CIC in women with IDC who had been successfully using CIC. The primary endpoint was post-void residual urine (PVR) after the inFlow device use compared with PVR after CIC use. Quality of life (QOL) was evaluated as a secondary endpoint. Safety measures included UTI rates and other adverse events. Of the 273 participants, 77 women completed the study; the primary reason for withdrawal was discomfort. For the primary endpoint, 115 women had baseline and treatment PVR data available and were evaluable. The study exceeded its primary endpoint goal of 95% comparable PVRs; 98% of participants had comparable PVR values for inFlow device and CIC. Of the 85 patients with available baseline and treatment QOL data, QOL scores increased by a mean of 25 points when using the inFlow device ( $p < 0.0001$ ). The study authors considered these results statistically and clinically significant. For participants completing the study, UTI rate per month decreased with continued inFlow device use, and the authors found the inFlow device to be equivalent or superior to CIC for UTI rate. No serious adverse events were associated with the inFlow device. Reported adverse events included mild bladder inflammation, mild device awareness/discomfort, mild pain, and mild incontinence. The safety profile for participants that withdrew from the study was not significantly different from those who completed the study. The study authors noted that patients who were more likely to tolerate the inFlow device had lower voiding-related QOL, more ambulatory and manual dexterity limitations, and were more dependent on adult diapers. Of those who completed the study, 34.2% had spinal disease/injury, 25% had multiple sclerosis, 18.4% had spina bifida, and 17% had some paralysis.

The remaining six non-comparative studies<sup>6-11</sup> were published between 1997 and 2004 and reported on small groups of patients outside the United States. Improvements in QOL, low UTI rates, and no serious adverse events were reported in most studies.

A recent review article<sup>1</sup> noted that the inFlow device is a treatment alternative for women with detrusor underactivity.

## Professional Society Recommendations and Guidelines

In a 2016 consensus statement on treatments for chronic urinary retention (CUR), the American Urological Association (AUA) discussed IDC as one cause of CUR but did not mention the inFlow device.<sup>12</sup> In 2016 and 2017, the AUA endorsed the inFlow device as a potential management strategy for IDC.

In September 2017, the National Multiple Sclerosis Society, International Organization of Multiple Sclerosis Nurses, and Consortium for Multiple Sclerosis Centers collectively submitted a formal letter to CMS requesting coverage for the inFlow device.

## External Assessments

In a review of chronic urinary retention in women, *UpToDate* notes that, "An intraurethral valve-pump may be an alternate option to intermittent self-catheterization for women with DU and resultant CUR. The device does not remedy the DU itself. Women who may benefit include those with physical limitations that preclude self-catheterization or those who no longer wish to perform catheterization."<sup>13</sup>

The pivotal clinical trial data for FDA approval indicates that use of the inFlow device results in lower monthly UTI rates and significant QOL improvements for women with IDC who have been using CIC. Other than a high rate of discontinuation of the use of the inFlow device due to patient discomfort, no

serious adverse events were reported. More recent publications indicate that the inFlow device may be a treatment alternative for a subset of patients with detrusor underactivity.

### Analysis of Evidence: Rationale for Determination

#### Level of Evidence

Quality	Strength	Weight
Moderate	Moderate	Moderate

#### Conclusion

The inFlow device (HCPCS Code A4335) is an alternative to intermittent catheterization for a subset of beneficiaries with PUR due to IDC.

#### Other Technical Corrections

HCPCS Code Span Changes: In the Coverage Indications, Limitations, and/or Medical Necessity section, the DME MACs revised the Urological Supplies LCD to remove HCPCS code spans and list the applicable HCPCS codes individually. This change allows for flexibility and accuracy in coding and coverage when CMS creates new HCPCS codes or revises existing HCPCS codes. No changes in existing reasonable and necessary requirements are impacted by this change.

#### Policy History

Date	Action
4/2023	Clarified coding information.
10/2021	New medical policy describing medically necessary and not medically necessary urological supplies. Effective 10/1/2021.

### Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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## Endnotes

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<sup>1</sup> Based on Local Coverage Determination (LCD): Urological Supplies [L33803](#)  
Local Coverage Article: Urological Supplies - Policy Article [A52521](#)