

Medicare Coverage of the inFlow

(Complete Urological Supplies LCD and Policy Article start on the next page)

Local Coverage Determination (LCD): Urological Supplies (L33803)

Revision Effective Date: For services performed on or after 04/01/2021

INITIAL COVERAGE FOR THE INFLOW DEVICE. The inFlow device is considered to be reasonable and necessary as an alternative to intermittent catheterization for beneficiaries with Permanent Urinary Retention (PUR) due to Impaired Detrusor Contractility (IDC).

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 FOR THE 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 beneficiary 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 beneficiary'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 reasonable and necessary.

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. 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.

Local Coverage Article: Urological Supplies - Policy Article (A52521)

Revision Effective Date: For services performed on or after 04/01/2021

When inserting an inFlow device or using urological supplies in a treating practitioner's office as part of a professional service that is billed to Medicare, the supplies are considered incident to the professional services of the health care practitioner and are not separately payable. Claims for these devices must not be submitted. Claims for the professional service, which includes the device, must be submitted to the A/B MAC.

If additional inFlow devices or urological supplies are sent home with the beneficiary, claims for these devices may be billed to the DME MAC only if the beneficiary's condition meets the definition of permanence as defined in the Prosthetic Device benefit. In this situation, use the place of service corresponding to the beneficiary's residence; Place of Service Office (POS) 11 must not be used.

For claims with DOS April 1, 2021 and after, the inFlow Intraurethral Valve-Pump system (Vesiflo, Inc.) must be billed using HCPCS code A4335 (INCONTINENCE SUPPLY; MISCELLANEOUS). Code A4335 is billed as 1 unit of service (UOS) at initial issue (see below), and is all-inclusive (catheter, activator, charging base). For replacement of individual components, code A4335 must be used on separate claim lines for any of the individual components of the inFlow Intraurethral Valve-Pump system (catheter, activator, charging base).

The initial sizing and insertion of the inFlow device is performed by the treating practitioner in their office. Claims for these services, billed to the DME MAC, will be denied as wrong jurisdiction. Replacement of the indwelling intraurethral drainage device with valve is typically done by a trained caregiver at home and may be billed on a monthly basis. Since the activator and charging base are provided at the time of initial issue to the beneficiary, these may only be billed to the DME MAC as a replacement.

Local Coverage Determination (LCD): Urological Supplies (L33803)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

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L33803

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LCD Title

Urological Supplies

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For services performed on or after 04/01/2021

Proposed LCD in Comment Period

N/A

Revision Ending Date

N/A

Source Proposed LCD

DL33803

Retirement Date

N/A

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Notice Period Start Date

06/11/2020

Notice Period End Date

07/25/2020

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CMS National Coverage Policy

None

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

The statutory coverage criteria for coverage of urological supplies are specified in the related Policy Article.

The medical necessity for use of a greater quantity of supplies than the amounts specified in the policy must be well documented in the beneficiary'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 covered for routine catheter maintenance. Non-routine catheter changes are covered when documentation substantiates medical necessity, such as for the following indications:

1. Catheter is accidentally removed (e.g., pulled out by beneficiary)
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 covered when the criteria for an indwelling catheter (above) are met and there is documentation in the beneficiary'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 beneficiary. For example, use of a Coude (curved) tip indwelling catheter (A4340) in a female beneficiary 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 reasonable and 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 the section "Continuous Irrigation of Indwelling Catheters" for indications for continuous catheter irrigations.) In other situations, A4346, A4313 and A4316 will be denied as not reasonable and necessary.

CATHETER INSERTION TRAY (A4310, A4311, A4312, A4313, A4314, A4315, A4316, A4353, and A4354)

One insertion tray will be covered per episode of indwelling catheter insertion. More than one tray per episode will be

denied as not reasonable and necessary.

One intermittent catheter with insertion supplies (A4353) will be covered per episode of reasonable and necessary sterile intermittent catheterization (see below).

URINARY DRAINAGE COLLECTION SYSTEM (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	Number per month
A4314	1
A4315	1
A4316	1
A4354	1
A4357	2
A4358	2
A5112	1

Code	Number per 3 month
A5102	1

Leg bags are indicated for beneficiaries who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden beneficiaries would be denied as not reasonable and 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 reasonable and 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 reasonable and necessary.

INTERMITTENT IRRIGATION OF INDWELLING CATHETERS

Supplies for the intermittent irrigation of an indwelling catheter are covered 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 reasonable and 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 beneficiary'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 reasonable and 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 reasonable and necessary.

CONTINUOUS IRRIGATION OF INDWELLING CATHETERS

Supplies for continuous irrigation of a catheter are covered 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 reasonable and 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 reasonable and necessary.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as non-covered. 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 beneficiary's medical records should indicate this medical necessity and these medical records must be available upon request.

INTERMITTENT CATHETERIZATION

Intermittent catheterization is covered when basic coverage criteria are met and the beneficiary or caregiver can perform the procedure.

For each episode of covered catheterization, Medicare will cover:

- 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 covered when the beneficiary requires catheterization and the beneficiary meets one of the following criteria (1-5):

1. The beneficiary resides in a nursing facility,
2. The beneficiary is immunosuppressed, for example (not all-inclusive):
 - on a regimen of immunosuppressive drugs post-transplant,
 - on cancer chemotherapy,
 - has AIDS,
 - has a drug-induced state such as chronic oral corticosteroid use.
3. The beneficiary has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,
4. The beneficiary is a spinal cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),
5. The beneficiary 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 beneficiary 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	Number per Month
A4332	200
A4351	200
A4352	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 reasonable and 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 beneficiaries), there must be documentation in the beneficiary'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 reasonable and necessary.

EXTERNAL CATHETERS/URINARY COLLECTION DEVICES

Male external catheters (condom-type) or female external urinary collection devices are covered for beneficiaries 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 as not reasonable and necessary when ordered for beneficiaries 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 covered 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 reasonable and 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 reasonable and necessary.

INITIAL COVERAGE FOR THE INFLOW DEVICE

The inFlow device is considered to be reasonable and necessary as an alternative to intermittent catheterization for beneficiaries with Permanent Urinary Retention (PUR) due to Impaired Detrusor Contractility (IDC).

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 FOR THE 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 beneficiary 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 beneficiary'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 reasonable and necessary.

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.

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 covered 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 covered every 3 months or sooner if the rubber/foam casing deteriorates.

Tape (A4450, A4452) which is used to secure an indwelling catheter to the beneficiary's body is covered. 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 reasonable and necessary.

Adhesive catheter anchoring devices (A4333) and catheter leg straps (A4334) for indwelling urethral catheters are covered. More than 3 per week of A4333 or 1 per month of A4334 will be denied as not reasonable and necessary. A catheter/tube anchoring device (A5200) is covered 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 reasonable and necessary.

Urethral inserts (A4336) are covered for adult females with stress incontinence (refer to the ICD-10 Codes section in the LCD-related Policy Article for applicable diagnoses) when basic coverage criteria are met and the beneficiary 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

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a three (3) - month quantity at a time.

Summary of Evidence

Background

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.^{1,2}

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

Summary of Evidence

Seven clinical studies that included a total of 501 participants have been published on the inFlow device.⁵⁻¹¹ The pivotal multicenter trial⁵ 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 studies⁶⁻¹¹ 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 article¹ 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.¹² 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."¹³

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 – Moderate

Strength – Moderate

Weight – 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.

Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

AU – Item furnished in conjunction with a urological, ostomy, or tracheostomy supply

EY - No physician or other licensed health care provider order for this item or service

GA – Waiver of liability statement issued as required by payer policy, individual case

GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefit

GZ – Item or service expected to be denied as not reasonable and necessary

KX - Requirements specified in the medical policy have been met

HCPCS CODES

Group 1 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

CODE	DESCRIPTION
	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
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

CODE	DESCRIPTION
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

CODE	DESCRIPTION
	ATTACHMENT
A9270	NON-COVERED ITEM OR SERVICE

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS

APPENDICES

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations, and/or Medical Necessity

Sources of Information

Reserved for future use

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
04/01/2021	R8	Revision Effective Date: 04/01/2021 COVERAGE INDICATIONS, LIMITATIONS AND/OR	<ul style="list-style-type: none">• Revisions Due To CPT/HCPCS Code

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>MEDICAL NECESSITY: Removed: Trademark symbol from first use of inFlow</p> <p>HCPCS CODES: Removed: K1010, K1011 and K1012 (effective for DOS on or after 04/01/2021)</p> <p><i>04/29/2021: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.</i></p>	Changes
10/01/2020	R7	<p>Revision Effective Date: 10/01/2020 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: HCPCS A4335 from inFlow device reference due to new HCPCS codes as of 10/01/2020</p> <p>HCPCS CODES: Added: K1010, K1011 and K1012 (effective DOS on or after 10/01/2020)</p> <p><i>10/15/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates to add CMS HCPCS coding determinations.</i></p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes
07/26/2020	R6	<p>Revision Effective Date: 07/26/2020 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Format of HCPCS code references, from code `spans` to individually-listed Added: Billing and coverage information for the inFlow device (HCPCS Code A4335) Removed: Denial statement for inFlow device (A4335)</p> <p>GENERAL: Added: References to Standard Written Order (SWO)</p> <p>REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners"</p> <p>SUMMARY OF EVIDENCE:</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Reconsideration Request • Other

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>Added: Information related to inFlow device ANALYSIS OF EVIDENCE: Added: Information related to inFlow device CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information" DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "practitioner's" GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO" BIBLIOGRAPHY: Added: Section related to inFlow device RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments (A58231)</p>	
01/01/2019	R5	<p>Revision History Effective Date: 01/01/2019 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Removed: Statement to refer to diagnosis code section below Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Moved: Statement about noncovered diagnosis codes moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction</p>	<ul style="list-style-type: none"> • Other (ICD-10 code relocation per CMS instruction)
01/01/2017	R4	<p>Revision History Effective Date: 01/01/2017 COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Revised: Refill Requirements</p>	<ul style="list-style-type: none"> • Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		HCPCS Code: Added: A4553 DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Information under Miscellaneous and Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
07/01/2016	R3	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	<ul style="list-style-type: none"> • Change in Assigned States or Affiliated Contract Numbers
01/01/2016	R2	Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Non-reimbursement language for the inFlow™ Intraurethral Valve-Pump system (A4335) DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)	<ul style="list-style-type: none"> • Provider Education/Guidance
10/01/2015	R1	Revision Effective Date: 08/01/2015 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD (Note: Standard Documentation Language updates noted above are effective for DOS on or after 10/31/2014)	<ul style="list-style-type: none"> • Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		Added: Language for HCPCS codes A4217, A4450, A4452 when submitted without correct modifier	

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A58231 - Response to Comments: Urological Supplies (DL33803)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

A52521 - Urological Supplies - Policy Article

Related National Coverage Documents

N/A

Public Version(s)

Updated on 04/22/2021 with effective dates 04/01/2021 - N/A

Updated on 10/09/2020 with effective dates 10/01/2020 - 03/31/2021

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Updated on 02/15/2019 with effective dates 01/01/2019 - 07/25/2020

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article: Urological Supplies - Policy Article (A52521)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

Article ID

A52521

Original Effective Date

10/01/2015

Original ICD-9 Article ID

[A25230](#)

[A25620](#)

[A47236](#)

[A25377](#)

Revision Effective Date

04/01/2021

Revision Ending Date

N/A

Article Title

Urological Supplies - Policy Article

Retirement Date

N/A

Article Type

Article

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Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be

reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Urological supplies are covered under the Prosthetic Device benefit (Social Security Act § 1861(s)(8)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provides a list of the specified codes, which is periodically updated, the link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD prior to delivery, it will be eligible for coverage.

GENERAL

Urinary catheters and external urinary collection devices are covered to drain or collect urine for a beneficiary who has permanent urinary incontinence or permanent urinary retention. Permanent urinary retention is defined as retention that is not expected to be medically or surgically corrected in that beneficiary within 3 months.

If the catheter or the external urinary collection device meets the coverage criteria then the related supplies that are necessary for their effective use are also covered. Urological supplies that are used for purposes not related to the covered use of catheters or external urinary collection devices (i.e., drainage and/or collection of urine from the bladder) will be denied as non-covered.

The beneficiary must have a permanent impairment of urination. This does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the medical record, including the judgment of the treating practitioner, indicates the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Catheters and related supplies will be denied as non-covered in situations in which it is expected that the condition will be temporary.

The use of a urological supply for the treatment of chronic urinary tract infection or other bladder condition in the absence of permanent urinary incontinence or retention is non-covered. Since the beneficiary's urinary system is functioning, the criteria for coverage under the prosthetic benefit provision are not met.

When inserting an inFlow device or using urological supplies in a treating practitioner's office as part of a professional service that is billed to Medicare, the supplies are considered incident to the professional services of the health care

practitioner and are not separately payable. Claims for these devices must not be submitted. Claims for the professional service, which includes the device, must be submitted to the A/B MAC.

If additional inFlow devices or urological supplies are sent home with the beneficiary, claims for these devices may be billed to the DME MAC only if the beneficiary's condition meets the definition of permanence as defined in the Prosthetic Device benefit. In this situation, use the place of service corresponding to the beneficiary's residence; Place of Service Office (POS) 11 must not be used. If the beneficiary's condition is expected to be temporary, urological supplies may not be billed. In this situation, they are considered as supplies provided incident to a treating practitioner's service and payment is included in the allowance for the treating practitioner services, which are processed by the A/B MAC.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

When the prescribing practitioner is also the supplier, and is permitted to furnish specific items of DMEPOS, a separate order is not required; however, the medical record must still contain all of the required order elements.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered, therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription. Once initial medical need is established, unless continued coverage requirements are specified in the LCD, ongoing need for urological supplies is assumed to drain or collect urine for a beneficiary who has permanent urinary incontinence or permanent urinary retention. There is no requirement for further documentation of continued medical need as long as the beneficiary continues to meet the Prosthetic Devices benefit.

MODIFIERS

AU MODIFIER:

When codes A4217, A4450, and A4452 are used with Urological Supplies, they must be billed with the AU modifier. For this policy, codes A4217, A4450, and A4452 are the only three codes for which the AU modifier may be used. Claim lines for codes A4217, A4450 and A4452 billed for urological supplies without an AU modifier will be rejected as missing information.

KX, GA, GY and GZ MODIFIERS:

Suppliers must add a KX modifier to a code for the inFlow device, a catheter, an external urinary collection device, or a supply used with one of these items only if both 1 and 2 are met.

1. The statutory benefit criteria described in the NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section above are met, and
2. The applicable reasonable and necessary (R&N) criteria described in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section of the related LCD are met.

If all of the criteria in the NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES section above are not met, a GY modifier must be added to the code.

If all of the applicable R&N criteria in the COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY section in the related LCD have not been met, a GA or GZ modifier must be added to the code. When there is an expectation of a medical necessity (R&N) denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Claim lines billed without a KX, GA, GY or GZ modifier will be rejected as missing information.

MISCELLANEOUS

Adhesive strips or tape used with male external catheters are included in the allowance for the code and are not separately payable.

Catheter insertion trays (A4310, A4311, A4312, A4313, A4314, A4315, A4316, A4353, and A4354) that contain component parts of the urinary collection system, (e.g., drainage bags and tubing) are inclusive sets and payment for additional component parts will be allowed only per the stated criteria in each section of the policy.

Irrigation supplies that are used for care of the skin or perineum of incontinent beneficiaries are non-covered.

Claims for sterile water/saline (A4217) and tape (A4450 or A4452) that are billed without an AU modifier or another modifier indicating coverage under a different policy will be rejected as missing information.

Extension tubing (A4331) will be covered for use with a latex urinary leg bag (A5112). It is included in the allowance for codes A4314, A4315, A4316, A4354, A4357, A4358, and A5105 and should not be separately billed with these codes.

Other supplies used in the management of incontinence, including but not limited to the following items, will be denied as non-covered because they are not prosthetic devices nor are they required for the effective use of a prosthetic device:

1. Creams, salves, lotions, barriers (liquid, spray, wipes, powder, paste) or other skin care products (A6250)
2. Catheter care kits (A9270)
3. Adhesive remover (A4455, A4456) (Coverage remains for use with ostomy supplies.)
4. Catheter clamp or plug (A9270)
5. Non-Disposable underpads (A4553)
6. Disposable underpads, e.g., Chux (A4554)
7. Diapers, or incontinent garments, disposable or reusable (A4520)
8. Drainage bag holder or stand (A9270)
9. Urinary suspensory without leg bag (A9270)
10. Measuring container (A9270)

11. Urinary drainage tray (A9270)
12. Gauze pads (A6216, A6217, A6218) and other dressings (coverage remains under other benefits, e.g. surgical dressings)
13. Other incontinence products not directly related to the use of a covered urinary catheter or external urinary collection device (A9270)
14. Disposable external urethral clamp or compression device, with pad and/or pouch, (A4360)

CODING GUIDELINES

The general term "external urinary collection devices" used in this policy includes male external catheters and female pouches or meatal cups. This term does not include diapers or other types of absorptive pads.

A meatal cup female external urinary collection device (A4327) is a plastic cup, which is held in place around the female urethra by suction or pressure and is connected to a urinary drainage container such as a bag or bottle.

A pouch type female external collection device (A4328) is a plastic pouch which is attached to the periurethral area with adhesive and which can be connected to a urinary drainage container such as a bag or bottle.

A urinary catheter-anchoring device described by code A4333 has an adhesive surface, which attaches to the beneficiary's skin and a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

A urinary catheter-anchoring device described by code A4334 is a strap, which goes around a beneficiary's leg and has a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

An intermittent urinary catheter with insertion supplies (A4353) is a kit, which includes a catheter and all supplies necessary for a single, sterile insertion (see below). Code A4353 may be used if any of the following 1, 2 or 3 is supplied:

1. A single sterile package containing both an intermittent urinary catheter and all necessary insertion/collection supplies; or
2. A sterile intermittent urinary catheter plus a separately-packaged sterile kit containing all necessary insertion/collection supplies; or
3. A sterile "no-touch" type of catheter system.

The insertion kit (A4353) described in #1 and #2 above contains an intermittent urinary catheter (packaged separately from the other components in #2), lubricant, gloves, antiseptic solution, applicators, a drape, and a collection tray/bag in a sterile package intended for single use. The collection tray/bag is a separate item included within the kit; therefore, materials that serve as non-sterile packaging to contain all of the items in the kit do not meet this requirement. Except as noted in #2 above, code A4353 must not be billed if individual insertion kit components are provided as separate items. When providing a sterile kit, all components are included and packaged as a kit. Separate billing of individual components is considered as unbundling.

The product described in #3 is a single-catheter system that is functionally equivalent to a complete sterile insertion kit (A4353) containing a catheter and the additional components as described in the previous paragraph. In order to be coded as A4353, a "no-touch" type of catheter system must be a sterile, all-inclusive, self-contained system capable of accomplishing intermittent catheterization with sterile technique without the use of additional supplies such as gloves, lubricant, collection chamber, etc. Additional individual components must not be separately billed.

Separate billing of additional supply items is considered as unbundling.

Therapeutic agent for urinary irrigation (A4321) is defined as a solution containing agents in addition to saline or sterile water (for example acetic acid or hydrogen peroxide) which is used for the treatment or prevention of urinary catheter obstruction.

Code A5105 should be used when billing for a urinary suspensory with leg bag.

A4326 is a male external catheter with an integrated collection chamber that does not require the use of an additional leg bag.

Irrigation solutions containing antibiotics and chemotherapeutic agents should be coded A9270. Irrigating solutions, such as acetic acid or hydrogen peroxide, which is used for the treatment or prevention of urinary obstruction, should be coded A4321.

Adhesive strips or tape used with code A4349 (MALE EXTERNAL CATHETER, WITH OR WITHOUT ADHESIVE, DISPOSABLE, EACH) should not be billed separately.

Adhesive catheter anchoring devices that are used with indwelling urethral catheters are billed using codes A4333 and A4334, respectively. An anchoring device used with a percutaneous catheter/tube (e.g., suprapubic tube, nephrostomy tube) is billed using code A5200.

Replacement leg straps (A5113, A5114) are used with a urinary leg bag (A4358, A5105, or A5112). These codes are not used for a leg strap for an indwelling catheter.

When codes A4217, A4450, and A4452 are used with Urological Supplies, they must be billed with the AU modifier. For this policy, codes A4217, A4450, and A4452 are the only three codes for which the AU modifier may be used.

An external catheter that contains a barrier for attachment should be coded using A4335.

Codes for ostomy barriers (A4369 and A4371) should not be used for skin care products used in the management of urinary incontinence.

A percutaneous catheter/tube anchoring device (A5200) is a dressing with adhesive that is designed to be applied directly over the cutaneous opening through which the catheter/tube passes. This dressing has a hole through which the catheter/tube passes and a mechanism for firmly anchoring the catheter/tube to the dressing.

For claims with date of service (DOS) July 26, 2020 through September 30, 2020, the inFlow Intraurethral Valve-Pump system (Vesiflo, Inc.) must be billed using HCPCS code A4335 (INCONTINENCE SUPPLY; MISCELLANEOUS). Code A4335 is billed as 1 unit of service (UOS) at initial issue, and is all inclusive (catheter, activator, charging base). Code A4335 must also be used on separate claim lines for replacement of any of the individual components of the inFlow Intraurethral Valve-Pump system (catheter, activator, charging base).

For claims with DOS October 1, 2020 through March 31, 2021, the inFlow system must be billed using HCPCS code(s): K1010 (Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each), K1011 (Activation device for intraurethral drainage device with valve, replacement only, each) and/or K1012 (Charger and base station for intraurethral activation device, replacement only).

For claims with DOS April 1, 2021 and after, the inFlow Intraurethral Valve-Pump system (Vesiflo, Inc.) must be billed using HCPCS code A4335 (INCONTINENCE SUPPLY; MISCELLANEOUS). Code A4335 is billed as 1 unit of service (UOS) at initial issue (see below), and is all-inclusive (catheter, activator, charging base). For replacement of individual components, code A4335 must be used on separate claim lines for any of the individual components of the inFlow Intraurethral Valve-Pump system (catheter, activator, charging base).

The initial sizing and insertion of the inFlow device is performed by the treating practitioner in their office. Claims for these services, billed to the DME MAC, will be denied as wrong jurisdiction. Replacement of the indwelling intraurethral drainage device with valve is typically done by a trained caregiver at home and may be billed on a monthly basis. Since the activator and charging base are provided at the time of initial issue to the beneficiary, these may only be billed to the DME MAC as a replacement.

Payment for items listed in Column II are included in the payment for the Column I code. In the following table, when providing the items listed in Column II, the Column I code must be used instead of billing separate Column II codes when the items are provided at the same time.

Column I	Column II
A4310	A4332
A4311	A4310, A4332, A4338
A4312	A4310, A4332, A4344
A4313	A4310, A4332, A4346
A4314	A4310, A4311, A4331, A4332, A4338, A4354, A4357
A4315	A4310, A4312, A4331, A4332, A4344, A4354, A4357
A4316	A4310, A4313, A4331, A4332, A4346, A4354, A4357
A4354	A4310, A4331, A4332, A4357
A4357	A4331
A4358	A4331, A5113, A5114
A5105	A4331, A4358, A5112, A5113, A5114
A5112	A5113, A5114

If a code exists that includes multiple products, that code should be used in lieu of the individual codes.

Suppliers should contact the Pricing, Data Analysis and Coding (PDAC) Contractor for guidance on the correct coding of these items.

Coding Information

CPT/HCPCS Codes

N/A

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "**Coverage Indications, Limitations, and/or Medical Necessity**" for other coverage criteria and payment information.

For HCPCS Code A4336:

Group 1 Codes:

ICD-10 CODE	DESCRIPTION
N39.3	Stress incontinence (female) (male)

ICD-10 Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

For the specific HCPCS codes indicated above, all ICD-10 codes that are not specified in the preceding section.

Group 1 Codes:

N/A

Additional ICD-10 Information

N/A

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/01/2021	R9	<p>Revised Effective Date: 04/01/2021</p> <p>GENERAL: Removed: Trademark symbol from first use of inFlow</p> <p>CODING GUIDELINES: Revised: inFlow HCPCS billing directions for K1010, K1011 and/or K1012 for DOS 10/01/2020 through 03/31/2021 Added: Billing direction for inFlow under HCPCS A4335 for DOS on or after 04/01/2021 Revised: inFlow replacement language, to include product information instead of K1010, K1011, and K1012</p> <p><i>04/29/2021: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
10/01/2020	R8	<p>Revised Effective Date: 10/01/2020</p> <p>MODIFIERS: Removed: inFlow A4335 code from directions</p> <p>CODING GUIDELINES: Revised: inFlow HCPCS billing direction, HCPCS A4335 for DOS 07/26/2020 through 9/30/2020 and HCPCS K1010, K1011 and/or K1012 for DOS on or after 10/01/2020</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p>Added: Billing direction for K1010, K1011 and K1012</p> <p><i>10/15/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination</i></p>
07/26/2020	R7	<p>Revision Effective Date: 07/26/2020</p> <p>REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217):</p> <p>Added: Section and related information based on Final Rule 1713</p> <p>GENERAL:</p> <p>Revised: Billing direction for inFlow and urological supplies when inserted or used in a practitioner’s office</p> <p>Revised: “physician” updated to “treating practitioner”</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:</p> <p>Added: Directional statement regarding practitioner as supplier</p> <p>Added: Continued medical need language</p> <p>MODIFIER:</p> <p>Added: inFlow device to KX modifier directions</p> <p>MISCELLANEOUS:</p> <p>Revised: Format of HCPCS code references, from code ‘spans’ to individually-listed</p> <p>CODING GUIDELINES:</p> <p>Revised: Format of HCPCS code references, from code ‘spans’ to individually-listed</p> <p>Revised: inFlow device statement to replace battery and/or wand with “activator”</p> <p>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:</p> <p>Revised: Section header “ICD-10 Codes that are Covered” updated to “ICD-10 Codes that Support Medical Necessity”</p> <p>ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:</p> <p>Revised: Section header “ICD-10 Codes that are Not Covered” updated to “ICD-10 Codes that DO NOT Support Medical Necessity”</p> <p><i>06/11/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination</i></p>
01/01/2019	R6	<p>Revision History Effective Date: 01/01/2019</p> <p>ICD-10 CODES THAT ARE COVERED:</p> <p>Added: All diagnosis codes formerly listed in the LCD</p> <p>ICD-10 CODES THAT ARE NOT COVERED:</p> <p>Added: Notation excluding all unlisted diagnosis codes from coverage</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<i>02/21/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i>
01/01/2017	R5	Revision Effective Date: 01/01/2017 RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article
01/01/2017	R4	Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: Modifiers section Added: A4553 to non-covered list
07/01/2016	R3	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
01/01/2016	R2	Revision Effective Date: 01/01/2016 CODING GUIDELINES: Added: Coding guidelines for the inFlow™ Intraurethral Valve-Pump (A4335)
10/01/2015	R1	Revision Effective Date: 08/01/2015 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: KX modifier reference from this section Revised: Language for HCPCS codes A4217, A4450, A4452 when submitted without correct modifier

Associated Documents

Related Local Coverage Document(s)

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

L33803 - Urological Supplies

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

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Updated on 04/22/2021 with effective dates 04/01/2021 - N/A

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