Disclaimer: Draft articles are works in progress and not necessarily a reflection of the current billing and coding practices. The draft article information contained in this document does not represent nor does it include all information found in an active LCD-related Policy Article. For example, abridged ICD-10-CM code information relevant to the proposed LCD may be included; unchanged ICD-10-CM code information may not be included. Please refer to the active LCD-related Policy Article in effect on the Medicare Coverage Database, if applicable, for current billing and coding information.

Contractor Information:

Contractor Name	Contract Type	Contract Number	Jurisdiction
CGS Administrators, LLC	DME MAC	17013 - DME MAC	Jurisdiction B
CGS Administrators, LLC	DME MAC	18003 - DME MAC	Jurisdiction C
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	Jurisdiction A
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	Jurisdiction D

DRAFT

Urological Supplies - Policy Article

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 provide a list

of the specified codes, which is periodically updated. The required Face-to-Face Encounter and Written Order Prior to Delivery List is available here .

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. 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, the test of permanence is considered met.

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 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 (A4297, 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.

An intermittent catheter with hydrophilic coating (A4295, A4296) is a single use catheter with a hydrophilic coating that, with the addition of water or 0.9% sterile saline, allows for smooth insertion and removal of the catheter without the use of a separate lubricating gel.

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 (A4297, A4353) is a kit, which includes a catheter and all supplies necessary for a single, sterile insertion (see below). Code A4297 or 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 (A4297, A4353) described in #1 and #2 above contains an intermittent urinary catheter (packaged separately from the other components in #2), lubricant (if applicable), 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, codes A4297 or 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 (A4297, A4353) containing a catheter and the additional components as described in the previous paragraph. In order to be coded as A4297 or 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 through March 31, 2023, 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).

For claims with DOS on or after April 1, 2023, the inFlow Intraurethral Valve-Pump system (Vesiflo, Inc.) must be billed using HCPCS code A4341 (INDWELLING INTRAURETHRAL DRAINAGE DEVICE WITH VALVE, PATIENT INSERTED, REPLACEMENT ONLY, EACH).

The initial sizing and insertion of the inFlow device is performed by the treating practitioner in their office. Claims for these services must be billed to the Part B MAC. Replacement of the indwelling intraurethral drainage device with valve is done by a trained caregiver or the beneficiary at home and may be billed on a monthly basis. If a replacement of the indwelling intraurethral drainage device with valve is performed by the treating practitioner, claims for this service must be billed to the Part B MAC.

Since the activator and charging base are provided at the time of initial issue in the treating practitioner's office to the beneficiary, these may only be billed to the DME MAC as a replacement using HCPCS code A4342 (ACCESSORIES FOR PATIENT INSERTED INDWELLING INTRAURETHRAL DRAINAGE DEVICE WITH VALVE, REPLACEMENT ONLY, EACH).

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

ICD-10-CM Codes that Support Medical Necessity
[no change]

ICD-10-CM Codes that DO NOT Support Medical Necessity
[no change]

Associated Documents

This draft document is an attachment to the proposed Urological Supplies LCD (DL33803) that has a Proposed LCD Posting Date of 08/28/2025.