**UROLOGICAL SUPPLIES**

**Guideline Number:** MPG359.06  
**Approval Date:** July 8, 2020

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**POLICY SUMMARY**

**Overview**

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.

**Guidelines**

**Indwelling Catheters**

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:

- Catheter is accidentally removed (e.g., pulled out by beneficiary)
- Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter)
- Catheter is obstructed by encrustation, mucous plug, or blood clot
- 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 or an all silicone catheter 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 in a female beneficiary is rarely reasonable and necessary. If documentation is requested and does not substantiate medical necessity payment for the specialty catheter will be denied as not reasonable and necessary.

A three way indwelling catheter either alone or with other components 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.) Other situations will be denied as not reasonable and necessary.

**Catheter Insertion Tray**

Refer to the related CMS Local Coverage Determination (LCD) and/or Local Coverage Article for coverage indications, limitations, and/or medical necessity. Catheter insertion trays 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.

**Urinary Drainage Collection System**

Refer to the related CMS Local Coverage Determination (LCD) and/or Local Coverage Article for limitations.

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.

Payment will be made for either a vinyl leg bag or a latex leg bag. The use of both is not reasonable and necessary. Extension tubing will be covered for use with a latex urinary leg bag. If it is included in the allowance for another code, it should not be separately billed.

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.

For additional information, please reference the UnitedHealthcare Medicare Advantage Policy Guideline titled Urinary Drainage Bags (NCD 230.17).

**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, irrigation tubing set, and sterile water/saline.

Irrigation solutions containing antibiotics and chemotherapeutic agents 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.

Irrigation supplies that are used for care of the skin or perineum of incontinent beneficiaries are non-covered.
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 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 or an irrigation syringe, and sterile water/saline. 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 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, will be denied as not reasonable and necessary.

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

**Intermittent Catheterization**
Intermittent catheterization using a sterile intermittent catheter kit 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 and sterile lubricant, 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)

Refer to the related CMS Local Coverage Article for Coding Guidelines addressing the contents of the kit for intermittent catheter with insertion supplies. A kit 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 a kit. If separate components are provided instead of a kit they will be denied as not reasonable and necessary.

Use of a Coude (curved) tip catheter 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**
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.
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.

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 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.

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

A meatal cup female external urinary collection device 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 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.

**Initial Coverage for the inFLOW Device**

The inFlow™ device (A4335) [Incontinence supply; miscellaneous (Bundled)] 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.

The inFlow Intraurethral Valve-Pump (Vesiflo, Inc.) must be billed using HCPCS code A4335. Code A4335 is billed as 1 unit of service (UOS) at initial issue, and is all inclusive (catheter, activator). Code A4335 must also be used on separate claim lines for replacement of any of the individual components of the inFlow Intraurethral Valve-Pump (catheter, activator). In addition, claims for replacement catheters, batteries, or wands must also use HCPCS code A4335.

Refer to the related CMS LCD and/or Local Coverage Article for limitations.

**Miscellaneous Supplies**

Appliance cleaner is covered when used to clean the inside of certain urinary collecting appliances.

One external urethral clamp or compression device is covered every 3 months or sooner if the rubber/foam casing deteriorates.

Tape which is used to secure an indwelling catheter to the beneficiary’s body is covered.
Adhesive catheter anchoring devices and catheter leg straps for indwelling urethral catheters are covered. A catheter/tube anchoring device is covered and separately payable when it is used to anchor a covered suprapubic tube or nephrostomy tube.

Claims for initial issue or replacement of any of the components (catheter, battery, wand) of the inFlow™ Intraurethral Valve-Pump shall be denied as not reasonable and necessary.

Urethral inserts are covered for adult females with stress incontinence (Reference Diagnosis Codes that Support Medical Necessity) 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

Refer to the related CMS LCD and/or Local Coverage Article for limitations.

**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.

**Non-Medical Necessity Coverage and Payment Rules**

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.

**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.

Suppliers must add a KX modifier to a code for the inFlow device (A4335), 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.

KX Modifier:

Suppliers must add a KX modifier to a code for a catheter, an external urinary collection device, or a supply used with one of these items only if all of the criteria in the "Coverage Indications, Limitations and/or Medical Necessity" section of the related CMS Local Coverage Determination (LCD) have been met and evidence of such is maintained in the
supplier's files. This information must be available upon request. For additional information, please reference the UnitedHealthcare Medicare Advantage Policy Guideline titled KX Modifier.

Miscellaneous
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:
- Creams, salves, lotions, barriers (liquid, spray, wipes, powder, paste) or other skin care products
- Catheter care kits
- Adhesive remover (Coverage remains for use with ostomy supplies.)
- Catheter clamp or plug
- Disposable underpads, e.g., Chux
- Diapers, or incontinent garments, disposable or reusable
- Drainage bag holder or stand
- Urinary suspensory without leg bag
- Measuring container
- Urinary drainage tray
- Gauze pads and other dressings (coverage remains under other benefits, e.g., surgical dressings)
- Other incontinence products not directly related to the use of a covered urinary catheter or external urinary collection device
- Disposable external urethral clamp or compression device, with pad and/or pouch

Coding Guidelines
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.

APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tr>
<td>A4217</td>
<td>Sterile water/saline, 500 ml</td>
</tr>
<tr>
<td>A4310</td>
<td>Insertion tray without drainage bag and without catheter (accessories only) (Bundled)</td>
</tr>
<tr>
<td>A4311</td>
<td>Insertion tray without drainage bag with indwelling catheter, Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer or hydrophilic, etc.) (Bundled)</td>
</tr>
<tr>
<td>A4312</td>
<td>Insertion tray without drainage bag with indwelling catheter, Foley type, two-way, all silicone (Bundled)</td>
</tr>
<tr>
<td>A4313</td>
<td>Insertion tray without drainage bag with indwelling catheter, Foley type, three-way, for continuous irrigation (Bundled)</td>
</tr>
<tr>
<td>A4314</td>
<td>Insertion tray with drainage bag with indwelling catheter, Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer or hydrophilic, etc.) (Bundled)</td>
</tr>
<tr>
<td>A4315</td>
<td>Insertion tray with drainage bag with indwelling catheter, Foley type, two-way, all silicone (Bundled)</td>
</tr>
<tr>
<td>A4316</td>
<td>Insertion tray with drainage bag with indwelling catheter, Foley type, three-way, for continuous irrigation (Bundled)</td>
</tr>
<tr>
<td>A4320</td>
<td>Irrigation tray with bulb or piston syringe, any purpose (Bundled)</td>
</tr>
<tr>
<td>A4321</td>
<td>Therapeutic agent for urinary catheter irrigation</td>
</tr>
<tr>
<td>A4322</td>
<td>Irrigation syringe, bulb or piston, each (Bundled)</td>
</tr>
<tr>
<td>A4326</td>
<td>Male external catheter with integral collection chamber, any type, each (Bundled)</td>
</tr>
<tr>
<td>A4327</td>
<td>Female external urinary collection device; meatal cup, each (Bundled)</td>
</tr>
<tr>
<td>A4328</td>
<td>Female external urinary collection device; pouch, each (Bundled)</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Description</td>
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<tr>
<td>------------</td>
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</tr>
<tr>
<td>A4331</td>
<td>Extension drainage tubing, any type, any length, with connector/adaptor, for use with urinary leg bag or urostomy pouch, each</td>
</tr>
<tr>
<td>A4332</td>
<td>Lubricant, individual sterile packet, each</td>
</tr>
<tr>
<td>A4333</td>
<td>Urinary catheter anchoring device, adhesive skin attachment, each</td>
</tr>
<tr>
<td>A4334</td>
<td>Urinary catheter anchoring device, leg strap, each</td>
</tr>
<tr>
<td>A4335</td>
<td>Incontinence supply; miscellaneous (Bundled)</td>
</tr>
<tr>
<td>A4336</td>
<td>Incontinence supply, urethral insert, any type, each</td>
</tr>
<tr>
<td>A4338</td>
<td>Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each (Bundled)</td>
</tr>
<tr>
<td>A4340</td>
<td>Indwelling catheter; specialty type, (e.g., coude, mushroom, wing, etc.), each (Bundled)</td>
</tr>
<tr>
<td>A4344</td>
<td>Indwelling catheter, Foley type, two-way, all silicone, each (Bundled)</td>
</tr>
<tr>
<td>A4346</td>
<td>Indwelling catheter; Foley type, three way for continuous irrigation, each (Bundled)</td>
</tr>
<tr>
<td>A4349</td>
<td>Male external catheter, with or without adhesive, disposable, each</td>
</tr>
<tr>
<td>A4351</td>
<td>Intermittent urinary catheter; straight tip, with or without coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each (Bundled)</td>
</tr>
<tr>
<td>A4352</td>
<td>Intermittent urinary catheter; coude (curved) tip, with or without coating (Teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each (Bundled)</td>
</tr>
<tr>
<td>A4353</td>
<td>Intermittent urinary catheter, with insertion supplies</td>
</tr>
<tr>
<td>A4354</td>
<td>Insertion tray with drainage bag but without catheter (Bundled)</td>
</tr>
<tr>
<td>A4355</td>
<td>Irrigation tubing set for continuous bladder irrigation through a three-way indwelling Foley catheter, each (Bundled)</td>
</tr>
<tr>
<td>A4356</td>
<td>External urethral clamp or compression device (not to be used for catheter clamp), each (Bundled)</td>
</tr>
<tr>
<td>A4357</td>
<td>Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each</td>
</tr>
<tr>
<td>A4358</td>
<td>Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with straps, each</td>
</tr>
<tr>
<td>A4360</td>
<td>Disposable external urethral clamp or compression device, with pad and/or pouch, each</td>
</tr>
<tr>
<td>A4402</td>
<td>Lubricant, per ounce (Bundled)</td>
</tr>
<tr>
<td>A4450</td>
<td>Tape, non-waterproof, per 18 square inches</td>
</tr>
<tr>
<td>A4452</td>
<td>Tape, waterproof, per 18 square inches</td>
</tr>
<tr>
<td>A4455</td>
<td>Adhesive remover or solvent (for tape, cement or other adhesive), per ounce (Bundled)</td>
</tr>
<tr>
<td>A4456</td>
<td>Adhesive remover, wipes, any type, each</td>
</tr>
<tr>
<td>A4520</td>
<td>Incontinence garment, any type, (e.g., brief, diaper), each (Not covered)</td>
</tr>
<tr>
<td>A4553</td>
<td>Non-disposable underpads, all sizes (Not covered)</td>
</tr>
<tr>
<td>A4554</td>
<td>Disposable underpads, all sizes (Not covered)</td>
</tr>
<tr>
<td>A5102</td>
<td>Bedside drainage bottle with or without tubing, rigid or expandable, each</td>
</tr>
<tr>
<td>A5105</td>
<td>Urinary suspensory with leg bag, with or without tube, each (Bundled)</td>
</tr>
<tr>
<td>A5112</td>
<td>Urinary drainage bag, leg or abdomen, latex, with or without tube, with straps, each</td>
</tr>
<tr>
<td>A5113</td>
<td>Leg strap; latex, replacement only, per set (Bundled)</td>
</tr>
<tr>
<td>A5114</td>
<td>Leg strap; foam or fabric, replacement only, per set (Bundled)</td>
</tr>
<tr>
<td>A5131</td>
<td>Appliance cleaner, incontinence and ostomy appliances, per 16 oz. (Bundled)</td>
</tr>
<tr>
<td>A5200</td>
<td>Percutaneous catheter/tube anchoring device, adhesive skin attachment</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Description</td>
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<tr>
<td>A9270</td>
<td>Non-covered item or service Including but not limited to the following items: Irrigation solutions containing antibiotics and chemotherapeutic agents, Catheter care kits, Catheter clamp or plug, Drainage bag holder or stand, Urinary suspensory without leg bag, Measuring container, Urinary drainage tray, Other incontinence products not directly related to the use of a covered urinary catheter or external urinary collection device (Not covered)</td>
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<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
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<tbody>
<tr>
<td>AU</td>
<td>Item furnished in conjunction with a urological, ostomy, or tracheostomy supply</td>
</tr>
<tr>
<td>KX</td>
<td>Requirements specified in the medical policy have been met</td>
</tr>
</tbody>
</table>

PURPOSE

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
Reference NCDs: [NCD 230.17 Urinary Drainage Bags](#); [NCD 280.1 Durable Medical Equipment Reference List](#)

CMS Local Coverage Determinations (LCDs) and Articles

<table>
<thead>
<tr>
<th>LCD</th>
<th>Article</th>
<th>Contractor</th>
<th>DME MAC</th>
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<td>L33803 (Urological Supplies)</td>
<td>A52521 (Urological Supplies - Policy Article)</td>
<td>CGS</td>
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<td>N/A</td>
<td>A55426 (Standard Documentation Requirements for All Claims Submitted to DME MACs)</td>
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CMS Benefit Policy Manual
[Chapter 15; § 110 Durable Medical Equipment - General](#)
[Chapter 15; § 120 Prosthetic Devices](#)

CMS Claims Processing Manual
[Chapter 20; § 30.9 Payment of DMEPOS Items Based on Modifiers](#)

MLN Matters
[Provider Compliance Tips for Urological Supplies, Date 2018-02](#)
[MM3714 Correction to Healthcare Common Procedure Coding System (HCPCS) Code A4217, Dated 03/04/2005](#)

UnitedHealthcare Commercial Policies
[Durable Medical Equipment, Orthotics and Prosthetics Policy, Professional](#)
[Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies, and Repairs/Replacements](#)
GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<tr>
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<td>07/08/2020</td>
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**Policy Summary**
- Replaced reference to “attending physician” with “treating practitioner”

**Overview**
- Revised language pertaining to claim submission/billing for urological supplies to indicate:
  - 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

**Guidelines**

**Initial Coverage for the inFLOW Device** (new to policy)
- Added language to indicate:
  - The inFlow™ device (A4335) [Incontinence supply; miscellaneous (Bundled)] 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** (new to policy)
- Added language to indicate:
  - 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:
    - An in-person encounter by the treating practitioner with documentation that urinary symptoms are improved; and,
    - 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
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<td>the evaluation demonstrates that the beneficiary is benefiting from the inFlow device as defined in the criteria above, continued coverage of the inFlow device will commence with the date of that re-evaluation</td>
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<td>o 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</td>
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<td>o The inFlow Intraurethral Valve-Pump (Vesiflo, Inc.) must be billed using HCPCS code A4335</td>
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<td>▪ Code A4335 is billed as 1 unit of service (UOS) at initial issue, and is all inclusive (catheter, activator)</td>
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<td>▪ Code A4335 must also be used on separate claim lines for replacement of any of the individual components of the inFlow Intraurethral Valve-Pump (catheter, activator)</td>
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<td>▪ In addition, claims for replacement catheters, batteries, or wands must also use HCPCS code A4335</td>
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**Modifiers**
- Added language to indicate suppliers must add a KX modifier to a code for the inFlow device (A4335), a catheter, an external urinary collection device, or a supply used with one of these items only if both [criteria] are met:
  - o The statutory benefit criteria described in the Nonmedical Necessity Coverage and Payment Rules section [of the policy] are met; and
  - o 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

**Applicable Codes**
- Removed notation pertaining to HCPCS codes A4357, A4358, A5102, and A5112 indicating code is "bundled"

**Supporting Information**
- Updated References section to reflect the most current information
- Archived previous policy version MPG359.05

**TERMS AND CONDITIONS**

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.
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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.