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.
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 (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

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

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:

- One catheter (A4351, A4352) and an individual packet of lubricant (A4332); or
- 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)
Refer to the 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.

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

**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

**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 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 (A6250)
• Catheter care kits (A9270)
• Adhesive remover (A4455, A4456) (Coverage remains for use with ostomy supplies.)
• Catheter clamp or plug (A9270)
• Disposable underpads, e.g., Chux (A4554)
• Diapers, or incontinent garments, disposable or reusable (A4520)
• Drainage bag holder or stand (A9270)
• Urinary suspensory without leg bag (A9270)
• Measuring container (A9270)
• Urinary drainage tray (A9270)
• Gauze pads (A6216, A6217, A6218) 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 (A9270)
• Disposable external urethral clamp or compression device, with pad and/or pouch (A4360)

**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.

All references for the inFlow™ device have been moved to the NCD 230.10 Incontinence Control Devices policy guideline.

### Applicable Codes

The following list(s) of procedure and/or diagnosis 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.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</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 (Bundled)</td>
</tr>
<tr>
<td>A4358</td>
<td>Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with straps, each (Bundled)</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 (Bundled)</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 (Bundled)</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>
</tr>
<tr>
<td>------------</td>
<td>-------------</td>
</tr>
<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 (Non covered)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Modifier</th>
<th>Description</th>
</tr>
</thead>
<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>

**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>
</tr>
</thead>
<tbody>
<tr>
<td>L33803</td>
<td>A52521 Urological Supplies - Policy Article</td>
<td>CGS</td>
<td>AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, WI, WV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Noridian</td>
<td>AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WI, WV</td>
</tr>
<tr>
<td>N/A</td>
<td>A55426 Standard Documentation Requirements for All Claims Submitted to DME MACs</td>
<td>CGS</td>
<td>AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, WI, WV</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Noridian</td>
<td>AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WI, WV</td>
</tr>
</tbody>
</table>

**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

**UnitedHealthcare Commercial Policies**
- Durable Medical Equipment, Orthotics and Prosthetics Policy, Professional
- Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies, and Repairs/Replacements

**Other(s)**
- Medicare Program Integrity Manual: Chapter 5 Items and Services Having Special DME Review Considerations
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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Policy Summary</th>
<th>Summary of Changes</th>
</tr>
</thead>
</table>
| 5/12/2021| Indwelling Catheters | • Replaced language indicating “if documentation is requested and does not substantiate medical necessity, payment for the specialty catheter will be denied as not reasonable and necessary” with “if documentation is requested and does not substantiate medical necessity, payment for HCPCS code A4340, A4344, A4312, or A4315 will be denied as not reasonable and necessary”  
• Added language to clarify A4346, A4313, and A4316 will be denied as not reasonable and necessary in situations other than those listed as covered |
|          | Urinary Drainage Collection System | • Added language to indicate:  
  o If there is a catheter change (HCPCS codes A4314, A4315, A4316, and A4354) and an additional drainage bag change (HCPCS code A4357) within a month, the combined utilization for HCPCS codes A4314, A4315, A4316, A4354, and A4357 should be considered when determining if additional documentation should be submitted with the claim  
  o For example, if 1 unit of HCPCS code A4314 and 1 unit of HCPCS code A4357 are provided, this should be considered as two drainage bags, which is the usual maximum quantity of drainage bags needed for routine changes  
• Removed instruction to refer to the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs) for coverage limitations  
• Removed language indicating 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 |
|          | Intermittent Irrigation of Indwelling Catheters | • Removed language indicating irrigation supplies that are used for care of the skin or perineum of incontinent beneficiaries are non-covered |
|          | Continuous Irrigation of Indwelling Catheters | • Added language to indicate more than one irrigation tubing set per day for continuous catheter irrigation will be denied as not reasonable and necessary  
• Removed language indicating irrigation supplies that are used for care of the skin or perineum of incontinent beneficiaries are non-covered |
|          | Intermittent Catheterization | • Added language to indicate:  
  o Intermittent catheterization is covered when basic coverage criteria are met, and the beneficiary or caregiver can perform the procedure  
  o For each episode of covered catheterization, Medicare will cover:  
    ▪ One catheter (HCPCS codes A4351 and A4352) and an individual packet of lubricant (A4332); or  
    ▪ One sterile intermittent catheter kit (HCPCS code A4353) if additional coverage criteria [in the policy] are met  
• Revised language addressing intermittent catheter kit content to indicate:  
  o Refer to the Coding Guidelines section of the related Policy Article for contents of the kit (HCPCS code A4353)  
  o HCPCS code A4353 should not be used for billing if the components are packaged separately rather than together as a kit |
Summary of Changes

- Separately provided components do not provide the equivalent degree of sterility achieved with HCPCS code A4353
- If separate components are provided instead of a kit (HCPCS code A4353), they will be denied as not reasonable and necessary

External Catheters/Urinary Collection Devices

- Added language to indicate:
  - The utilization of male external catheters (HCPCS code A4349) generally should not exceed 35 per month; greater utilization of these devices must be accompanied by documentation of medical necessity
  - For female external urinary collection devices, more than one meatal cup (HCPCS code A4327) per week or more than one pouch (HCPCS code A4328) per day 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

- Removed language indicating:
  - 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 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
  - Refer to the CMS LCDs and LCAs for coverage limitations

Miscellaneous Supplies

- Updated coverage guidelines for:
  - Appliance cleaner; added language to indicate more than one unit of service (16 oz.) per month is rarely reasonable and necessary
  - Tape; added language to indicate 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 and catheter leg straps; added language to indicate more than 3 per week of HCPCS code A4333 or 1 per month of HCPCS code A4334 will be denied as not reasonable and necessary
  - Catheter/tube anchoring device; added language to indicate if HCPCS code A5200 is used to anchor an indwelling urethral catheter, the claim will be denied as not reasonable and necessary
  - Urethral inserts; added instruction to refer to the Diagnosis Codes section in the LCD-related Policy Article for applicable diagnoses

- Removed instruction to refer to the CMS LCDs and LCAs for coverage limitations

Applicable Codes

- Added notation to indicate HCPCS codes A4357, A4358, A5102, and A5112 are “bundled”

Supporting Information

- Updated References section to reflect the most current information
- Archived previous policy version MPG359.07

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 NCDs, LCDs, LCAs, 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.

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.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*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.