

Catheters and Urological Supplies

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Introduction and general information

This guideline addresses catheters and urological supplies.

Criteria

Urinary catheters and urinary collection devices are considered medically necessary to drain or collect urine for an individual who has permanent urinary incontinence **or** permanent urinary retention.

If the catheter or the urinary collection device meets the coverage criteria, then the related supplies that are necessary for their effective use are also considered medically necessary.

Indwelling catheters (HCPCS A4311, A4312, A4313, A4314, A4315, A4316, A4340, A4344, A4346)

One catheter per month is considered medically necessary for routine catheter maintenance. Non-routine catheter changes are considered medically necessary when there is documentation, such as:

- catheter is accidentally removed
- malfunction of catheter
- catheter is obstructed (e.g., encrustation, mucous plug, or blood clot)
- the establishment that more frequent scheduled changes can prevent multiple obstructions or urinary tract infections

Catheter insertion tray (HCPCS A4310, A4311, A4312, A4313, A4314, A4315, A4316, A4353, A4354)

One insertion tray is considered medically necessary per episode of indwelling catheter insertion.

Urinary drainage collection system (HCPCS A4314, A4315, A4316, A4354, A4357, A4358, A5102, A5112)

The quantity of supplies considered medically necessary for routine changes of the urinary drainage collection system are listed in Table 1. Additional supplies for non-

routine changes of the urinary drainage collection system may be considered medically necessary when there is documentation including, such as:

- obstruction
- sludging
- blood clots
- chronic urinary tract infection

Table 1. Usual Maximum Medically Necessary Quantity of Supplies

Code	Number per month
A4314	1
A4315	1
A4316	1
A4354	1
A4357	2
A4358	2
A5112	1

Code	Number per 3 months
A5102	1

Leg bags are considered medically necessary for individuals who are ambulatory or are wheelchair bound. Either a vinyl leg bag (HCPCS A4358) or a latex leg bag (HCPCS A5112) is considered medically necessary; the use of both is not considered medically necessary. The use of drainage bags containing absorbent material (e.g., gel matrix) that are intended to be disposed of on a daily basis has not been established as medically necessary.

Intermittent irrigation of indwelling catheters

Supplies for intermittent irrigation of an indwelling catheter are considered medically necessary when used on an as needed (non-routine) basis to address acute catheter obstruction.

Medically necessary supplies for medically necessary non-routine irrigation of a catheter include either an irrigation tray (HCPCS A4320) or an irrigation syringe (HCPCS A4322), and sterile saline or sterile water.

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

Continuous irrigation of indwelling catheters

Supplies for continuous irrigation of a catheter are considered medically necessary if there is a history of obstruction of the catheter. Documentation is required to substantiate the medical necessity of continuous irrigation as opposed to intermittent irrigation. More than one irrigation tubing set per day for continuous catheter irrigation is not considered medically necessary.

Continuous irrigation is considered a temporary measure. Continuous irrigation for more than two weeks is rarely considered medically necessary. Documentation is required to substantiate the medical necessity of continuous irrigation for greater than two weeks.

Intermittent catheterization

Intermittent catheterization is covered when basic medical necessity criteria are met and the individual or caregiver can perform the procedure.

For each episode of medically necessary catheterization, the following are considered medically necessary:

- one catheter (HCPCS A4351, A4352) and an individual packet of lubricant (HCPCS A4332) **or**
- one catheter (HCPCS A4295, A4296) **or**
- one intermittent catheter kit (A4297, A4353) if there is documentation of **any** of the following:
 - the individual is immunosuppressed
 - the individual has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization
 - the individual has had distinct, recurrent urinary tract infections, while on a program of sterile intermittent catheterization, twice within the 12-months prior to the initiation of sterile intermittent catheter kits
 - an individual 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 taken from the catheter **and** presence of one or more of the following signs:
 - 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 per high-powered field)

Table 2. Medical Necessary Supply Quantities for Intermittent Catheterization

Code	Number per Month
A4295	200
A4296	200
A4297	200
A4332	200
A4351	200
A4352	200
A4353	200

If a Coude tip catheter (HCPCS A4296, A4352) is considered medically necessary, there must be documentation in the individual's medical record for the necessity of that catheter.

External catheters/urinary collection devices

Male or female external urinary collection devices are considered medically necessary for individuals who have permanent urinary incontinence when used as an alternative to an indwelling catheter. Male or female external urinary collection devices are considered not medically necessary when ordered for individuals who also use an indwelling catheter.

Specialty type male external catheters (HCPCS A4326) such as those that inflate or that include a faceplate or extended wear catheter systems are covered only when considered medically necessary. For female external urinary collection devices, more than one meatal cup (HCPCS A4327) per week or more than one pouch (HCPCS A4328) per day are considered not medically necessary.

inFlow device (HCPCS A4341)

The inFlow device (HCPCS A4341), is considered medically necessary as an alternative to intermittent catheterization for individuals with permanent urinary retention due to Impaired Detrusor Contractility. One (1) inFlow device may be considered medically necessary no more than once every 30 days.

Continued coverage of the inFlow device beyond the initial 3-month period requires a clinical re-evaluation by the treating healthcare provider between day 31 and day 91 of

therapy. The provider must document that the patient is actively using the device and deriving clinical benefit

Evidence Discussion

Urinary incontinence may present as an isolated condition or may occur secondary to, or be exacerbated by, underlying neurological disorders such as myelomeningocele, Parkinson's disease, cerebrovascular accidents (stroke), multiple sclerosis, or peripheral neuropathies. The incidence of urinary incontinence is also expected to rise with the increase in the aging population. The incidence rate is higher in women, with the prevalence increasing with age, from 19% in women younger than 45 years of age to 29% in women 80 years or older. It is also estimated that 12% to 17% of men are also affected by urinary incontinence, and this prevalence increases with age.¹

The use of indwelling urinary catheters results in continuous bladder drainage, preventing normal bladder filling and voiding cycles. This persistent decompression can lead to diminished bladder wall tension, thereby increasing the patient's vulnerability to catheter-associated urinary tract infections (CAUTIs), urinary retention, and other complications following catheter removal. In a meta-analysis of 17 studies (n=3908), Ma et al. (2023) reported that clamping indwelling urinary catheters in patients with a catheterization duration of ≤ 7 days was associated with a significantly increased incidence of urinary tract infections and a prolonged time to first spontaneous voiding. Allowing free drainage is safer and more effective based on these data.²

Detrusor underactivity (DUA) is a condition where the bladder muscle does not contract with enough strength or duration to empty the bladder effectively. According to the International Continence Society, it is diagnosed through urodynamic testing and is typically associated with symptoms such as slow or incomplete urination. The condition is characterized by low bladder pressure or brief contractions during urination, along with a weak urine stream, which can lead to prolonged or incomplete bladder emptying. When women with detrusor underactivity (DUA) are unable to urinate or cannot empty their bladder well enough to prevent complications like urinary tract infections, overflow incontinence, bladder stones, or kidney damage, common treatments include using a urinary catheter or performing a clean intermittent catheterization. The inFlow™ urinary prosthesis is a device designed to help women who have DUA. The inFlow™ system includes a small valve-pump placed in the urethra and a remote control that the user activates by positioning it over the pelvis. While some hand coordination is needed to use the device, it requires less dexterity than performing clean intermittent

¹ Živković D, Franić D, Kojić V. Urinary Incontinence - From Childhood Onwards. *Acts Clin Croat.* 2022;61(1):115-123. doi:10.20471/acc.2022.61.01.14

² Ma S, Gu J, Fan X. Need to clamp indwelling urinary catheters before removal after different durations: a systematic review and meta-analysis. *BMJ Open.* 2023;13(2):e064075. Published 2023 Feb 15. doi:10.1136/bmjopen-2022-064075

catheterization. Hartigan and Dmochowski (2020) found that the inFlow™ urinary prosthesis is an effective alternative for women with DUA.³

Codes addressed in this guideline

HCPSC Code	Description
A4217	Sterile water/saline, 500 mL
A4310	Insertion tray without drainage bag and without catheter (accessories only)
A4311	Insertion tray without drainage bag with indwelling catheter, foley type, two-way latex with coating (teflon, silicone, silicone elastomer or hydrophilic, etc.)
A4312	Insertion tray without drainage bag with indwelling catheter, foley type, two-way, all silicone
A4313	Insertion tray without drainage bag with indwelling catheter, foley type, three-way, for continuous irrigation
A4314	Insertion tray with drainage bag with indwelling catheter, foley type, two-way latex with coating (teflon, silicone, silicone elastomer or hydrophilic, etc.)
A4315	Insertion tray with drainage bag with indwelling catheter, foley type, two-way, all silicone
A4316	Insertion tray with drainage bag with indwelling catheter, foley type, three-way, for continuous irrigation
A4320	Irrigation tray with bulb or piston syringe, any purpose
A4321	Therapeutic agent for urinary catheter irrigation
A4322	Irrigation syringe, bulb or piston, each
A4326	Male external catheter with integral collection chamber, any type, each
A4327	Female external urinary collection device; meatal cup, each
A4328	Female external urinary collection device; pouch, each
A4331	Extension drainage tubing, any type, any length, with connector/adaptor, for use with urinary leg bag or urostomy pouch, each

³ Hartigan SM, Dmochowski RR. The inFlow intraurethral valve-pump for women with detrusor underactivity: A summary of peer-reviewed literature. J Spinal Cord Med. 2022;45(4):489-497. doi:10.1080/10790268.2020.1829415

HCP Code	Description
A4332	Lubricant, individual sterile packet, each
A4333	Urinary catheter anchoring device, adhesive skin attachment, each
A4334	Urinary catheter anchoring device, leg strap, each
A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
A4336	Indwelling catheter; foley type, three way for continuous irrigation, each
A4337	Incontinence supply, rectal insert, any type, each
A4338	Indwelling catheter; foley type, two-way latex with coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each
A4340	Indwelling catheter; specialty type, (e.g., coude, mushroom, wing, etc.), each
A4344	Indwelling catheter, foley type, two-way, all silicone or polyurethane, each
A4346	Indwelling catheter; foley type, three way for continuous irrigation, each
A4351	Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each
A4352	Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each
A4353	Intermittent urinary catheter, with insertion supplies
A4354	Insertion tray with drainage bag but without catheter
A4355	Irrigation tubing set for continuous bladder irrigation through a three-way indwelling foley catheter, each
A4356	External urethral clamp or compression device (not to be used for catheter clamp), each
A4357	Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each

HCP Code	Description
A4358	Urinary drainage bag, leg or abdomen, vinyl, with or without tube, with straps, each
A4360	Disposable external urethral clamp or compression device, with pad and/or pouch, each
A4561	Pessary, reusable, rubber, any type
A4562	Pessary, reusable, non rubber, any type
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each
A5105	Urinary suspensory with leg bag, with or without tube, each
A5112	Urinary drainage bag, leg or abdomen, latex, with or without tube, with straps, each
A5113	Leg strap; latex, replacement only, per set
A5114	Leg strap; foam or fabric, replacement only, per set
A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591	External urinary catheter; non-disposable, for use with suction pump, per month
A7048	Vacuum drainage collection unit and tubing kit, including all supplies needed for collection unit change, for use with implanted catheter, each

References

1. Urological supplies. CMS.gov. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=40270&ver=19&keywordtype=starts&keyword=urological&bc=0>.
2. Urological Supplies - JD DME - Noridian. JD DME. Published 2020. <https://med.noridianmedicare.com/web/jddme/dmepos/urological-supplies>
3. Živković D, Franić D, Kojović V. Urinary Incontinence - From Childhood Onwards. *Acts Clin Croat*. 2022;61(1):115-123. doi:10.20471/acc.2022.61.01.14