Medical Policy

Northwood

Urological Supplies

Description

Urinary catheters and external urinary collection devices are designed to drain or collect urine for an individual 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 an individual within three months.

Policy

Urological supplies are covered as long as they are **medically necessary,** and the member meets coverage criteria.

Policy Guidelines

Medicare Member Coverage Criteria:

Refer to Medicare policy (L33803) and article (A52521) for coverage criteria.

Non-Medicare Member Coverage Criteria:

Coverage Criteria:

1. Must be ordered by the member's treating practitioner.
2. General:
    a. The medical necessity for use of a greater quantity of supplies than the amounts specified in this policy must be well documented and available upon request.

Indwelling Catheters (A4311, A4312, A4313, A4314, A4315, A4316, A4338, A4340, A4344, and A4346):

No more than one catheter per month is considered reasonable and necessary for routine catheter maintenance. Non-routine catheter changes are considered reasonable and necessary when documentation substantiates medical necessity, such as for the following indications:

a. Catheter is accidentally removed (e.g., pulled out by member),
b. Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter),
c. Catheter is obstructed by encrustation, mucous plug, or blood clot,

d. 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 considered reasonable and necessary when the criteria for an indwelling catheter (above) are met and there is documentation in the member'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 member. For example, use of a Coude (curved) tip indwelling catheter (A4340) in female members is rarely reasonable and necessary. If documentation is requested and does not substantiate medical necessity requests for A4340, A4344, A4312, or A4315 will be considered not reasonable and necessary.

A three-way indwelling catheter either alone (A4346) or with other components (A4313 or A4316) will be considered reasonable and necessary 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 considered not reasonable and necessary.

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Catheter Insertion Tray (A4310, A4311, A4312, A4313, A4314, A4315, A4316, A4353, and A4354):

One insertion tray will be considered reasonable and necessary per episode of indwelling catheter insertion. More than one tray per episode will be considered not reasonable and necessary.

A urinary intermittent catheter with insertion supplies (A4353) is a kit, which includes a catheter and all supplies necessary for sterile insertion. Code A4353 may be used if either 1 or 2 is supplied:

1. A sterile intermittent urinary catheter plus a separately packaged sterile kit of insertion/collection supplies; or,
2. A single sterile package containing both a catheter and all insertion/collection supplies.

The insertion kit (A4353) contains a catheter, (may be packaged separately from the other components), lubricant, gloves antiseptic solution, applicators, drape, and a tray or bag in a sterile package intended for single use. The collection tray/bag is a separate item included as part of the kit; therefore, materials that serve as non-sterile packaging to

contain all of the items in the kit do not meet this requirement. Except as noted in 1 above, code (A4353) must not be billed if individual insertion kit components are provided as separate items. When providing a sterile kit, the individual components must not be separately billed.

Urinary Drainage Collection System (A4314, A4315, A4316, A4354, A4357, A4358, A5102, and A5112):

a. Payment will be made for routine changes of the urinary drainage collection system as noted below. Additional charges will be allowed for reasonable and necessary non-routine changes when the documentation substantiates the medical necessity, (e.g., obstruction, sludging, clotting of blood, or chronic, recurrent urinary tract infection.
b. **Leg bags** are indicated for members who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden members would be considered not reasonable and necessary.

Usual Maximum Quantity of Supplies

Procedure Code	Quantity per Month
A4314	1 or per specific state guidelines
A4315	1 or per specific state guidelines
A4316	1 or per specific state guidelines
A4354	1 or per specific state guidelines
A4357	2 or per specific state guidelines
A4358	2 or per specific state guidelines
A5112	1 or per specific state guidelines

Procedure Code	Quantity Every 3 Months
A5102	1 or per specific state guidelines

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. 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 gel matrix or other material which are intended to be disposed of on a daily basis has not been established. Requests for this type of bag will be considered not reasonable and necessary.

Intermittent Irrigation of indwelling Catheters:

Supplies for the intermittent irrigation of an indwelling catheter are considered reasonable and necessary 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 considered not reasonable and necessary since they are of no proven value. Routine irrigations are defined as those performed at predetermined intervals. In individual cases, a copy of the order for irrigation and documentation in the member's medical record of the presence of acute catheter obstruction may be requested when irrigation supplies are requested. 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 considered not reasonable and necessary since routine intermittent irrigations are not reasonable and necessary since they are of no proven value. Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) are considered experimental and investigational since their value is unproven. Irrigating solutions such as acetic acid or hydrogen peroxide, which are used for the treatment or prevention of urinary obstruction (A4321), will be considered not reasonable and necessary since they are of no proven value.

Continuous Irrigation of Indwelling Catheters:

Supplies for continuous irrigation of a catheter are reasonable and necessary 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 preventive measure (i.e., no history of obstruction) will be considered not reasonable and necessary since it has not been proven to be of benefit. 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 considered not reasonable and necessary.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) are considered experimental and investigational since their value is unproven. Sterile water or sterile saline (A4217) are considered medically necessary for use as irrigation solutions.

Continuous irrigation is a temporary measure. Continuous irrigation for more than two weeks is rarely reasonable and necessary. The member's medical records should indicate this medical necessity and these medical records must be available upon request.

Intermittent Catheterization:

Intermittent catheterization is reasonable and necessary when basic coverage criteria are met, and the member or caregiver can perform the procedure.

For each episode of covered catheterization,

a. One catheter (A4351, A4352) and an individual packet of lubricant (A4332); or
b. One sterile intermittent catheter kit (A4353) if additional coverage criteria (see below) are met.

Intermittent catheterization using sterile intermittent catheter kit (A4353) is covered when the member requires catheterization, and the member meets one of the following criteria (1-5):

1. The member resides in a nursing facility.
2. The member is immunosuppressed, for example (not all-inclusive):
    i. on a regimen of immunosuppressive drugs post-transplant,
    ii. on cancer chemotherapy,
    iii. has AIDS,
    iv. has a drug-induced state such as chronic oral corticosteroid use
3. The member has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,
4. The member is a spinal cord injured female with neurogenic bladder that is pregnant (for duration of pregnancy only)
5. The member 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 member 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 38º C [100.4º 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 five white blood cells [WBCs] per high-powered field)

Usual Maximum Quantity of Supplies:

HCPC CODE	NUMBER PER MONTH
A4332	200 or per specific state guidelines
A4351	200 or per specific state guidelines
A4352	200 or per specific state guidelines

Use of a Coude (curved) tip catheter (A4352) in female members is rarely medically necessary. When a Coude tip catheter is used, (either male or female members), there must be documentation in the member's medial record of the medical necessity for that catheter rather than a straight tip 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, requests will be considered as not reasonable and necessary.

External Catheters/Urinary Collection Devices:
Male external catheters (condom-type) or female external urinary collection devices are covered for members 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, or specific state guidelines. 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 considered not reasonable and necessary when ordered for members 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 considered reasonable and necessary only when documentation substantiates the medical necessity for such a catheter. If documentation does not justify the medical need requests will be considered 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 considered not reasonable and necessary.

The PureWick Urine Collection System (K1006) is considered unproven and not medically necessary for the management of urinary incontinence.

Initial Coverage for the InFlow Device

The inFlow device (A4341) is considered to be reasonable and necessary as an alternative to intermittent catheterization for members 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 reevaluation and document that the member 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.

PureWick Urine Collection System (K1006)

The PureWick System (K1006) is a urine collection system that includes the PureWick female external catheter, a flexible, disposable "wick", which is attached to a continuous low-pressure pump, the PureWick Urine Collection System. The system is designed to gently pull the urine from the external catheter into the sealed collection canister. The female external catheter works outside the body to absorb and wick urine. The wick is replaced every 8-12 hours or if it is soiled with feces or blood.

Effective for dates of service on or after April 1, 2023, the HCPCS codes for use when billing the accessories for the PureWick Urine Collection System are the (A6590) external urinary catheters; disposable, with wicking material, for use with suction pump, per month, (A7001) canister, non-disposable, used with suction pump, each, and the (A7002) tubing, used with suction pump, each.

There are no peer-reviewed published literature specific to the PureWick System, or external urinary collection system using a continuous low-pressure pump. Thus, there is no evidence to show the PureWick System to be an equally effective alternative in managing urinary incontinence.

The PureWick Urine Collection System (K1006) is **considered unproven and not medically necessary** for the management of urinary incontinence.

Miscellaneous Supplies:

Appliance cleaner (A5131) is considered reasonable and necessary 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 considered reasonable and necessary every 3 months or sooner if the rubber/foam casing deteriorates.

Tape (A4450, A4452) which is used to secure an indwelling catheter to the member's body is considered reasonable and necessary. More than 10 units (1 unit = 18 sq. in.; 10

units = 180 sq. in. = 5 yds. of 1-inch tape) per month (or per specific state guidelines) will be considered not reasonable and necessary.

Adhesive catheter anchoring devices (A4333) and catheter leg straps (A4334) for indwelling urethral catheters are considered reasonable and necessary. More than 3 per week of (A4333) or 1 per month of (A4334) (or per specific state guidelines) will be considered not reasonable and necessary.

Urethral inserts (A4336) are considered reasonable and necessary for adult females with stress incontinence (ICD-10 N39.3) when basic coverage criteria are met, and the member 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

Limitations:

1. The treating practitioner's order must include the type of supplies ordered and the approximate quantity to be used per unit of time.
2. When requesting quantities of supplies greater than those described in the policy as the usual maximum amounts, the provider must obtain information supporting the medical necessity for the higher utilization. The medical necessity documentation must be submitted with the request.
3. General:

    a. 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 considered reasonable and necessary. 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 considered not reasonable and necessary.
    b. The member must have a permanent impairment of urination. This does not require a determination that there is no possibility that the member'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 considered not reasonable and necessary in situations in which it is expected that the condition will be temporary.

c. 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 is generally not reasonable or necessary.
d. When inserting an inFlow™ device or using urological supplies in a treating practitioner's office as part of a professional service that is billed as a professional service, the supplies are considered incident to the professional services of the health care practitioner and are not separately payable.
    i. If additional inFlow devices or urological supplies are sent home with the beneficiary, claims for these devices may be billed separately only if the member's condition meets the definition of permanence as defined above. If the member'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.

Exclusions (for Commercial and Medicare members – may or may not be applicable to NH Medicaid which is determined by state guidelines):

Other supplies used in the management of incontinence, including but not limited to the following items, will be considered not reasonable and necessary because they are not prosthetic devices nor are they required for the effective use of a prosthetic device:

i. Creams, salves, lotions, barriers (liquid, spray, wipes, powder, paste) or other skin care products (A6250)
ii. Catheter care kits (A9270)
iii. Adhesive remover or solvent (for tape, cement or other adhesive) per ounce. (A4455). Adhesive remover, wipes, any type, each (A4456).
iv. Catheter clamp or plug (A9270)
v. Non-disposable under pads (A4553)
vi. Disposable underpads, e.g., Chux (A4554)
vii. Diapers, or incontinent garments, disposable or reusable (A4520)
viii. Drainage bag holder or stand (A9270)
ix. Urinary suspensory without leg bag (A9270)
x. Measuring container (A9270)
xi. Urinary drainage tray (A9270)

xii. Gauze pads (A6216 - A6218) and other dressings when used with urological supplies.
xiii. Other incontinence products not directly related to the use of a covered urinary catheter or external urinary collection device (A9270)
xiv. Disposable external urethral clamp or compression device, with pad and/or pouch (A4360).

Coding Guidelines

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

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

HCPCS Level II Codes and 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
A4332	Lubricant, individual sterile packet, each
A4333	Urinary catheter anchoring device, adhesive skin attachment, each
A4334	Urinary catheter anchoring device, leg strap, each
A4335	Incontinence supply; miscellaneous
A4336	Incontinence supply, urethral insert, any type, each
A4338	Indwelling catheter; Foley type, two-way latex with coating (Teflon, silicone, silicone elastomer, or hydrophilic, etc.), each
A4340	Indwelling catheter; specialty type, (e.g., coude, mushroom, wing, etc.), each
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
A4344	Indwelling catheter, foley type, two-way, all silicone or polyurethane, each

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A4346	Indwelling catheter; Foley type, three-way for continuous irrigation, each
A4349	Male external catheter, with or without adhesive, disposable, 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
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 (non-covered).
A4402	Lubricant, per ounce
A4450	Tape, non-waterproof, per 18 square inches
A4452	Tape, waterproof, per 18 square inches
A4455	Adhesive remover or solvent (for tape, cement or other adhesive), per ounce
A4456	Adhesive remover, wipes, any type, each
A4520	Incontinence garment, any type, (e.g., brief, diaper), each
A4554	Disposable underpads, all sizes
A5102	Bedside drainage bottle with or without tubing, rigid or expandable, each
A5105	Urinary suspensory; with leg bag, with or without tube, each
A5112	Urinary leg bag; latex
A5113	Leg strap; latex, replacement only, per set

A5114	Leg strap; foam or fabric, replacement only, per set
A5131	Appliance cleaner, incontinence and ostomy appliances, per 16 oz.
A5200	Percutaneous catheter/tube anchoring device, adhesive skin attachment
A6590	External urinary catheters, disposable, with wicking material, for use with suction pump, per month
A7001	Canister, non-disposable, used with suction pump, each
A7002	Tubing, used with suction pump, each
A9270	Non-covered item or service
K1006	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system (e.g., PureWick System)

ICD-10 Codes that Support Medical Necessity

For HCPCS Code A4336:

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

ICD-10 Codes that Do Not Support Medical Necessity

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

KX and GY Modifiers (if applicable):

If modifiers are utilized the provider must add a KX modifier to a code only if the order indicates that the member has permanent urinary incontinence or urinary retention, and if the item is a catheter, an external urinary collection device, or a supply used with one of these items.

If all the criteria in the related Policy Article are not met, the GY modifier must be added to the code.

Claims lines billed without a KX or GY modifier will be rejected as missing information.

Medical Policy

Urological Supplies

Important Note:

Northwood's Medical Policies are developed to assist Northwood in administering plan benefits and determining whether a particular DMEPOS product or service is reasonable and necessary. Equipment that is used primarily and customarily for a non-medical purpose is not considered durable medical equipment.

Coverage determinations are made on a case-by-case basis and are subject to all of the terms, conditions, limitations, and exclusions of the member's contract including medical necessity requirements.

The conclusion that a DMEPOS product or service is reasonable and necessary does not constitute coverage. The member's contract defines which DMEPOS product or service is covered, excluded or limited. The policies provide for clearly written, reasonable and current criteria that have been approved by Northwood's Medical Director.

The clinical criteria and medical policies provide guidelines for determining the medical necessity for specific DMEPOS products or services. In all cases, final benefit determinations are based on the applicable contract language. To the extent there are any conflicts between medical policy guidelines and applicable contract language, the contract language prevails. Medical policy is not intended to override the policy that defines the member's benefits, nor is it intended to dictate to providers how to direct care. Northwood Medical policies shall not be interpreted to limit the benefits afforded to Medicare or Medicaid members by law and regulation and Northwood will use the applicable state requirements to determine required quantity limit guidelines.

Northwood's policies do not constitute medical advice. Northwood does not provide or recommend treatment to members. Members should consult with their treating practitioner in connection with diagnosis and treatment decisions.

Northwood follows all CMS National coverage Determinations (NCD) and Local Coverage Determinations (LCD), as applicable.

References

1. Centers for Medicare and Medicaid Services, Medicare Coverage Database, National Coverage Documents. Last accessed December 6, 2022.

2. CGS Administrators, LLC; Urological Supplies. Local Coverage Determination No. L33803. Durable Medical Equipment Medicare

Administrative Carrier Jurisdiction B; revised April 1, 2021; Last accessed/reviewed December 12, 2023.

3. Noridian Healthcare Solutions, LLC; Urological Supplies. Local Carrier Determination (LCD) No. L33803. Durable Medical Equipment Medicare Administrative Contractor (DME MAC) Jurisdiction A. revised April 1, 2021; Last accessed/reviewed December 6, 2022.

4. Aetna: Urological Supplies http://www.aetna.com/cpb/medical/data/500_599/0533.html; Last accessed/reviewed December 12, 2023.

5. Becton, Dickinson and Company (BD). PureWick Urine Collection System. BD [website]. Available at: https://www.purewickathome.com/purewick-how-it-works/.

6. Cravens DD, Zweig S. Urinary catheter management. Am Fam Physician. 2000;61(2):369-376.

7. Winn C, Thompson J. Urinary catheters for intermittent use. Prof Nurse. 1999;14(12):859-865.

8. U.S. Department of Health and Human Services, Agency for Healthcare Policy and Research (AHCPR). Urinary incontinence in adults: Acute and chronic management. Clinical Practice Guideline No. 2. Rockville, MD: AHCPR; March 1996.

9. Warren JW. Catheter-associated urinary tract infections. Infect Dis Clin North Am. 1997;11(3):609-622.

10. Shandera KC, Thompson IM. Urologic prostheses. Emerg Med Clin North Am. 1994;12(3):729-748.

11. Johnson JR. Safer urinary catheterization. Contemp Intern Med. 1992;4(1):47-54.

12. Belsfield PW. Urinary catheters. Br Med J. 1988;296(6625):837-837.

13. Warren JW. Catheters and catheter care. Clin Geriatr Med. 1986;2(4):857-871.

14. U.S. Department of Health and Human Services, Health Care Financing Administration (HCFA). Prosthetic devices. Medicare Carriers Manual §2130. Baltimore, MD: HCFA; 1999.

15. White HM. Choosing continence aids. Br J Nurs. 1994;3(22):1158, 1160, 1162-1163.

16. Resnick NM. Geriatric incontinence. Urol Clin North Am. 1996;23(1):55-74.

17. Niel-Weise BS, Arend SM, van den Broek PJ. Is there evidence for recommending silver-coated urinary catheters in guidelines? J Hosp Infect. 2002;52(2):81-87.

18. Wyndaele JJ. Complications of intermittent catheterization: Their prevention and treatment. Spinal Cord. 2002;40(10):536-541.

SPECIAL COVERAGE INFORMATION PER PLAN:

Health New England (Medicaid and Commercial Plans – Pediatrics Only – up to age 21 years)	**For (A4357) Bedside Drainage Bag:** **Indications:** Used with SPT for Bladder Outlet Obstruction. **Exceptions:** Both 1 large capacity and 1 leg bag. **Initial Fulfillment:** 4-5 each large capacity, 4-5 each leg bags **Maintenance Requests:** Up to 4 each per month ********** **For (A4358) Urinary Drainage Bag:** **Indications:** Used with SPT for Neurogenic Bladder **Exceptions:** Both 1 large capacity and 1 leg bag. **Initial Fulfillment:** 4-5 each - large capacity **and** 4-5 each - leg bags **Maintenance Requests:** Up to 4 each per month.

	********** **For (A4358) Urinary Drainage Bag:** **Indications:** Used with G-tube with Lopez enteral valve **Initial Fulfillment:** 4-5 each large capacity and 4-5 each leg bags **Maintenance Requests:** Up to 2 per month. ********** **For (B9998) Lopez Enteral Valve:** **Initial Fulfillment:** 1 per month **Maintenance Requests:** Up to 2 per month. ********** **For (B4088) Button G-Tube:** **Initial Fulfillment:** 3 (initial insertion, home and school) **Maintenance Requests:** 1 per month.

Change/Authorization History

Revision Number	Date	Description of Change	Prepared / Reviewed by	Approved by	Review Date:	Effective Date:
A	11-20-06	Initial Release	Rosanne Brugnoni	Ken Fasse	n/a	
01		Changed HCPC code description for A5105	Susan Glomb	Ken Fasse	01	

02	12-08	Annual Review	Susan Glomb	Ken Fasse	Dec.2008	
03	12-01-09	Revised: additional quantity statements for tape, anchoring devices and leg bag straps. Removed instructions for additional quantity. Clarified: A4353. (Catheter with insertion tray and supplies. One per episode).	Susan Glomb	Ken Fasse		
04		Annual Review/ no changes	Susan Glomb	Ken Fasse	12-22-09	
05	01-05-10	Added :A4336; incontinent supply, urethral insert, any type, each . A4360; Disposable external urethral clamp or compression device, with pad and/or pouch, each (non-covered) A4456; Adhesive remover, wipes, any type, each Discontinued codes: A4365; adhesive remover wipes, any type per 50	Susan Glomb	Ken Fasse		
06		Annual Review – No changes	Susan Glomb	Ken Fasse	12-08-10	
07	01-20-11	Deleted: Least costly alternative language for multiple codes. Revised: Coverage of A4336. Added: A5105 to list of codes used with A5131. ICD-9 codes that support medical necessity Added: 625.6 for HCPCS A4336	Susan Glomb	Dr. B. Almasri	Jan.2011	
08	02-15-11	Revised A4353 definition. Deleted: A4353 from table.	Susan Glomb	Dr. B. Almasri	Feb.2011	
09	07-20-11	Added Important Note to all Medical Policies	Susan Glomb	Dr. B. Almasri		
10	12-09-11	Annual Review. Added References to Policy	Susan Glomb	Dr. B. Almasri	Dec. 2011	
11	12.29.11	Added additional references to policy	Susan Glomb	Dr. B. Almasri	Dec. 2011	

12	12-3-12	Annual Review – No changes	Susan Glomb	Dr. B. Almasri	Dec 12	
13	12-30-13	Annual review. No changes	Susan Glomb	Dr. B. Almasri		
14	12-03-15	Annual Review. Updated Medicare reference and ICD-10 code. Added coding guidelines.	Lisa Wojno	Dr. B. Almasri	December 2015	
15	12-02-16	Annual Review. No Changes.	Lisa Wojno	Dr. B. Almasri	December 2016	
16	12-11-17	Annual review. Added A4553 to non-covered list.	Carol Dimech	Dr. C. Lerchin	December 2017	
17	12-4-18	Annual review. Updated Medicare references.	Carol Dimech	Dr. C. Lerchin	December 2018	
18	12-13-19	Annual review. Added: ICD-10 codes that are not covered - notation excluding all unlisted diagnosis codes from coverage.	Carol Dimech	Dr. C. Lerchin	December 2019	December 2019
19	6-17-20	Added HNE Peds box noting indications and quantity for codes A4357, A4358, B9998, B4088.	Carol Dimech	Dr. C. Lerchin	June 2020	June 24,2020
20	12-10-20	Annual Review. Updated 'physician' to 'treating practitioner'. Per CMS: Added HCPCS codes K1010, K1011 and K1012 related to the inFlow Device and corresponding criteria for Initial and Continuing coverage. Revised format of HCPCS code references, from code 'spans' to individually-listed. Changed header from "ICD-10 Codes that are Covered" to "ICD-10 Codes that Support Medical Necessity". Changed header from "ICD-10 Codes that are not Covered" to "ICD-10 Codes that Do Not Support Medical Necessity".	Lisa Wojno	Dr. C. Lerchin	December 2020	December 2020
21	3-2-21	HCPCS code K1006 PureWick System information added to policy.	Carol Dimech	Dr. C. Lerchin	March 2, 2021	March 2, 2021

22	12-07-21	Annual review. Refer to 3-2-21 entry. Codes K1010, K1011 and K1012 will be replaced with code A4335 after 4-1-21. Also, added NCD/LCD verbiage to "Important Note".	Carol Dimech/Susan Glomb	Dr. C. Lerchin	December 7, 2021	
23	12-6-22	Annual review. Deleted references to codes K1010, K1011 and K1012.	Lisa Wojno	Dr. C. Lerchin	December 6, 2022	December 2022
24	4-19-23	Per CMS, added HCPCS supply codes A6590, A7001, A7002 for the PureWick Urine Collection System.	Carol Dimech	Dr. C. Lerchin	4-19-23	4-19-23
25	12-12-23	Annual review. Per CMS, revised reference to inFlow device to include HCPCS code A4341; added HCPCS codes A4341 and A4342 to code list; revised description of HCPCS code A4344.	Carol Dimech	Dr. C. Lerchin	12-12-23	12-12-23