

Urological Supplies

For any item to be covered by The Health Plan, it must:

1. Be eligible for a defined Medicare or The Health Plan benefit category
2. Be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member
3. Meet all other applicable Medicare and/or The Health Plan statutory and regulatory requirements

For the items addressed in this medical policy, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity. *Please refer to individual product lines certificates of coverage for possible exclusions of benefit.*

For an item to be covered by The Health Plan, the supplier must receive a written, signed, and dated order before a claim is submitted to The Health Plan. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

Suppliers are to follow The Health Plan requirements for precertification, as applicable.

Urological supplies, above the allowable listed below, require precertification.

National Coverage Determination Policy	None
Local Coverage Determination Policy	J- B/C
Effective Date	For services performed on or after 10/31/13
Revision/Review Date	01/19, 11/18, 6/8/18, 10/23/17, 04/21/17, 09/01/16, 05/01/16, 10/01/15, 10/31/13
The Health Plan	Plans will follow Coverage Determination posted on the CGS website unless otherwise indicated in sections of this policy, contractual agreements, or benefit plan documents. Please refer to WV Medicaid Coverage guidelines where indicated in this policy

DESCRIPTION

Items or supplies that assist with the care and treatment of urinary tract and the urogenital system.

COVERAGE GUIDELINES

Urinary catheters and external urinary collection devices are covered to drain or collect urine for a member who has permanent urinary incontinence or permanent urinary retention.

INDWELLING CATHETERS (A4311 - A4316, A4338 - A4346)

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:

1. Catheter is accidentally removed (e.g., pulled out by member)
2. Malfunction of catheter (e.g., balloon does not stay inflated, hole in catheter)
3. Catheter is obstructed by encrustation, mucous plug, or blood clot
4. 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

When a specialty indwelling catheter (A4340) or an all silicone catheter (A4344, A4312, or A4315) is used, there must be documentation in the member's medical record of the medical necessity for that catheter (such as recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex etc). 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 medically necessary. Documentation of medical necessity may be requested. If documentation is requested and does not substantiate medical necessity for A4340, A4344, A4312, or A4315 requests will be denied as not meeting coverage guidelines.

A three way indwelling catheter either alone (A4346) or with other components (A4313 or A4316) will be covered only if continuous catheter irrigation is medically 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 meeting coverage guidelines.

CATHETER INSERTION TRAY (A4310 - A4316, A4353, and A4354)

One insertion tray will be covered per episode of indwelling catheter insertion. More than one tray per episode will be denied as not meeting coverage guidelines.

One intermittent catheter with insertion supplies (A4353) will be covered per episode of medically necessary sterile intermittent catheterization. Refer to intermittent catheterization section for coverage guidelines.

URINARY DRAINAGE COLLECTION SYSTEM (A4314 - A4316, A4354, A4357, A4358, A5102, and A5112)

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 denied as not meeting coverage guidelines.

Usual Maximum Quantity of Supplies

CODE	NUMBER/MONTH	CODE	NUMBER/MONTH
A4314	1	A4357	2
A4315	1	A4358	2
A4316	1	A5112	1
A4354	1		

CODE	NUMBER/3 MONTH
A5102	1

Additional charges will be allowed for medically necessary non-routine changes when the documentation substantiates the medical necessity, (e.g., obstruction, sludge, clotting of blood, or chronic, recurrent urinary tract infection).

If there is a catheter change (A4314 - A4316, A4354) and an additional drainage bag (A4357) change within a month, the combined utilization for A4314 - A4316, A4354, and A4357 should be considered when determining if additional documentation should be submitted with the claim. For example, if one unit of A4314 and one 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 medically 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 medically 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 member's medical record of the presence of acute catheter obstruction may be requested when irrigation supplies are billed.

Covered supplies for medically 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 medically 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 meeting coverage guidelines.

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 medically necessary catheter changes. Continuous irrigation as a primary preventative measure (i.e., no history of obstruction) will be denied as not medically 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 medically necessary continuous bladder irrigation include a three-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 meeting coverage guidelines.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as noncovered. 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 two weeks is rarely medically 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 covered when basic coverage criteria are met and the member or caregiver can perform the procedure.

For each episode of covered catheterization, The Health Plan, following Medicare's position, will cover:

- A. One catheter (A4351, A4352) and an individual packet of lubricant (A4332); or
- B. One sterile intermittent catheter kit (A4353) if additional coverage criteria are met.

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

1. A resident of a nursing facility,
2. There is immunosuppression, 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. There is radiologically documented vesico-ureteral reflux occurring while on a program of intermittent catheterization,
4. A spinal cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),
5. History of 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.

Medicare describes a urinary tract infection as having 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 five white blood cells [WBCs] per high-powered field)

The following table represents the usual maximum number of supplies:

Code	Number/month	Code	Number/month
A4332	200	A4352	200
A4351	200	A4353	200

Refer to the billing guidelines section for contents of the kit. The kit code should be used for billing even if the components are packaged separately rather than together as a kit.

If sterile catheterization is not medically necessary, sterile supplies will be denied as not meeting coverage guidelines.

A coude (curved) tip catheter (A4352) is rarely medically necessary for use in females. When a coude tip catheter is used (either for a male or female member), there must be documentation in the medical record of the medical necessity for that catheter rather than a straight tip catheter (A4351) and why a straight tip catheter could not be used. This documentation must be available with claim or precertification.

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. Greater utilization of these devices must be accompanied by documentation of medical necessity.

Male external catheters (condom-type) or female external urinary collection devices are not covered 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 covered only when documentation substantiates the medical necessity for such a catheter.

For female external urinary collection devices, more than one metal cup (A4327) per week or more than one pouch (A4328) per day will be denied as not meeting coverage guidelines.

COVERAGE GUIDELINES FOR 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 medically necessary.

One external urethral clamp or compression device (A4356) is covered every three months or sooner if the rubber/foam casing deteriorates.

Tape (A4450, A4452) which is used to secure an indwelling catheter to the body is covered. More than 10 units (1 unit = 18 sq. in.; 10 units = 180 sq. in. = 5 yds. of 1 in. tape) per month will be denied as not covered.

Adhesive catheter anchoring devices (A4333) and catheter leg straps (A4334) for indwelling urethral catheters are covered. More than three per week of A4333 or 1 per month of A4334 will be denied as not medically 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/precertification will be denied as not reasonable or necessary.

Urethral inserts (A4336) are covered for adult females with stress incontinence (N39.3) when basic coverage criteria are met and the member or caregiver can perform the procedure. They are not indicated for women;

1. With bladder or other urinary tract infections
2. With a history of urethral stricture, stricture, bladder augmentation, pelvic radiation, or other conditions where urethral catheterization is not clinically advisable.
3. Who are immunocompromised, at significant risk from UTI, interstitial, cystitis, or pyelonephritis, or who have severely compromised urinary mucosa
4. Unable to tolerate antibiotic therapy
5. On anticoagulants
6. With overflow incontinence or neurogenic bladder

The Health Plan has adopted the above Medicare policy across all lines of business, unless specifically addressed in a contract or benefit document.

NONCOVERAGE STATEMENT

Catheters and related supplies will be denied as noncovered in situations in which it is expected that the condition will be temporary. See Medicare definitions and description section below for what is considered a permanent condition.

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. Requests for this type of bag will be denied as not meeting coverage guidelines.

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

1. Creams, salves, lotions, barriers (liquid, spray, wipes, powder, paste) or other skin care products (A6250)
2. Catheter care kits (A9270)
3. Adhesive remover (A4455, A4456) (Coverage remains for use with ostomy supplies)
4. Catheter clamp or plug (A9270)
5. Non-Disposable Underpads, all sizes (A4553)
6. Disposable underpads, e.g., Chux (A4554)*
7. Diapers, or incontinent garments, disposable or reusable (A4520) *
8. Drainage bag holder or stand (A9270)
9. Urinary suspensory without leg bag (A9270)
10. Measuring container (A9270)
11. Urinary drainage tray (A9270)
12. Gauze pads (A6216 - A6218) and other dressings (coverage remains under other benefits, e.g., surgical dressings)
13. Other incontinence products not directly related to the use of a covered urinary catheter or external urinary collection device (A9270)
14. Disposable external urethral clamp or compression device, with pad or pouch (A4360)

Note: * For WV Medicaid members concerning disposable underpads (A4554) and Diapers/incontinent garments (A4520), please refer to WV Medicaid Coverage guidelines for individuals older than 3 years of age as they may be covered. Refer to page 18 for BMS incontinence guidelines.

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 noncovered.

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 noncovered. Since the member's urinary system is functioning, the criteria for coverage under the prosthetic benefit provision are not met.

Irrigation supplies that are used for care of the skin or perineum of incontinent members are noncovered.

Routine (non-billable): Supplies that are customarily used in small quantities during the usual course of most home visits. They are usually included in the staff's supplies and are not designated for a specific member. These supplies, such as alcohol swabs or gloves, are included in the cost per visit of home health care services.

Non-Covered: Supplies that are not covered under the Medicare home health benefit. Home health agencies cannot bill for these supplies and the cost of the supplies cannot be included as a part of the services provided. Comfort and convenience items are non-covered as well as program exclusions such as over the counter medications; prescription drugs and biologicals (e.g. blood components).

Claims for initial issue or replacement of any of the components (catheter, battery, wand) of the **InFlow™ Intraurethral Valve-Pump** (A4335) shall be denied as not reasonable and necessary.

CODING INFORMATION

CPT/HCPCS codes: The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS

AU	ITEM FURNISHED IN CONJUNCTION WITH A UROLOGICAL, OSTOMY, OR TRACHEOSTOMY SUPPLY
EY	NO PHYSICIAN OR OTHER LICENSED HEALTH CARE PROVIDER ORDER FOR THIS ITEM OR SERVICE
GA	WAIVER OF LIABILITY STATEMENT ISSUED AS REQUIRED BY PAYOR POLICY, IND CASE
GY	ITEM OR SERVICE STATUTORILY EXCLUDED OR DOES NOT MEET THE DEFINITION OF ANY MEDICARE BENEFIT
GZ	ITEM OR SERVICE EXPECTED TO BE DENIED AS NOT REASONABLE OR NECESSARY
KX	REQUIREMENTS SPECIFIED IN MEDICAL POLICY HAVE BEEN MET

HCPCS CODES

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, EG; COUDE, MUSHROOM, WING, ETC.), EACH
A4344	INDWELLING CATHETER, FOLEY TYPE, TWO-WAY, ALL SILICONE, EACH
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
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
A4553	NON-DISPOSABLE UNDERPADS, ALL SIZES
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
A9270	NON-COVERED ITEM OR SERVICE

ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY FOR A4336

N39.3	STRESS INCONTINENCE FEMALE/MALE
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There are no specified diagnoses or ICD-10 codes that do not support medical necessity for other HCPCS codes listed above.

DOCUMENTATION REQUIREMENTS

For the purposes of this policy it is expected that the medical record will support the need for the care provided. It is generally understood that the medical record includes the physician's office records, hospital records, nursing home records, home health agency records, records from other health care professionals and test reports.

The following information must be submitted at the time of precertification.

1. Physician detailed written order. Order must include the following:
 - a. Member's name
 - b. Date
 - c. Description of item. The medical record must contain the information that supports the request for each item, and must be submitted with the precertification, if the item requires precertification, or with the claim, if no precertification was required. Clinical documentation of the medical condition and surgical procedure performed, if any, is also required
 - d. Order must include diagnosis code
 - e. Physician signature - with date. Date stamps are not appropriate
 - f. Quantity of items required and duration. A new order is required if there is an increase in the quantity of the supply used per month and/or the type of supply used

The supplier is to contact The Health Plan in this instance to update referral

2. There must be documentation in the supplier's records to support the medical necessity of that item. This information must be available upon request usually with precertification per The Health Plan policy.
3. Proof of delivery to be kept on file by the provider of the item.

Note: If templates or forms are submitted, (e.g. A Medicare Certificate of Medical Necessity, and /or a provider created form), and all of the required information is not included, The Health Plan

reserves the right to request the medical record that may include, but not limited to, the physician office notes, hospital and nursing facility records, home health records.

Note: Template provider forms, prescriptions, and attestation letters are not considered part of the medical record, even if signed by the ordering physician.

The provider is to have the order prior to dispensing the item.

The Health Plan will accept clinical documentation from the member's chart with a signed order, if all the criteria is included with that documentation.

UROLOGICAL SUPPLIES PROVIDED WHILE MEMBER IN A PART A COVERED STAY

Reimbursement for urological supplies provided to a member while the member is covered in a Part A facility is based on specific contract information with the individual facility. Urological supplies are usually included in the per diem for Part A facilities.

UROLOGICAL SUPPLIES PROVIDED WHILE MEMBER ENROLLED IN HOME HEALTH

Non-Routine (billable): Supplies that are needed to treat a member's specific illness or injury in accordance with the physician's plan of care. The item must be directly identifiable to the member, the cost of the item can be identified and accumulated in a separate cost center, and the item is furnished at the direction of the member's physician and is specifically identified in the plan of care, i.e., the item is needed to treat a member's specific illness. The home health agency must also follow a consistent charging practice for Medicaid and non-Medicaid members receiving the item.

Home health agencies must use reasonable quantities of the least costly product which will adequately meet the needs of the member. Limited amounts of medical supplies may be left with the member between visits where repeated applications are required and rendered by the member or other caregivers.

SEE NONCOVERAGE STATEMENT

BILLING GUIDELINES

The medical necessity for use of a greater quantity of supplies than the amounts specified in the policy must be well documented in the medical record and must be available with precertification.

When urological supplies are furnished in a physician's office, they may be billed only if the member's condition meets the definition of permanence. (In this situation, the catheters and related supplies are covered under the prosthetic device benefit). 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 physician's service and payment is included in the allowance for the physician services).

Physician's supplying urological supplies for permanent impairment will need to follow above policies and are subject to contractual stipulations.

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

Catheter insertion trays (A4310 - A4316, A4353, and A4354) that contain component parts of the urinary collection system, (e.g., drainage bags and tubing) are inclusive sets and payment for additional component parts will be allowed only per the stated criteria in each section of the policy.

A urinary intermittent catheter with insertion supplies (**A4353**) is a kit, which includes a catheter, 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. Materials that serve as packaging for the kit do not meet this requirement. **A4353** must not be billed if individual components (i.e. insertion tray, lubricant, and catheter) are provided as separate items, rather than in a single sterile package. When providing a sterile kit, the individual components must not be separately billed.

A4353 may be used in the following two scenarios;

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.
3. A sterile “no-touch” type of catheter system.

Payment for code A4353 includes both the catheter and all supplies required for insertion and collection of urine. Separate billing for the catheter and or any insertion supplies is incorrect.

In order for a no–touch system to be billed as A4353 it must be a sterile, all inclusive, self-contained system, Able to be used for sterile intermittent catheterization without the use of additional supplies (gloves, lubricant etc). Separate billing for additional supplies will be denied as not separately payable.

Correct Coding - inFlow™ Intraurethral Valve-Pump (Vesiflo, Inc.): The inFlow™ Intraurethral Valve-Pump is a urinary device for women with incomplete bladder emptying due to impaired detrusor contractility (IDC). The inFlow™ is promoted as an alternative to urinary catheters. The device consists of a small catheter with an internal, magnetically-activated pump-valve mechanism. The inFlow™ is placed in the female urethra for up to 30 days. It is activated by a battery-powered wand which, when held low over the pubic area, the valve opens and the pump induces urine flow. **Effective 1/1/2016**, the **inFlow™ Intraurethral Valve-Pump** was assigned Healthcare Common Procedure Coding System (HCPCS) code **A4335** (Incontinence supply, miscellaneous). This HCPCS code must be used for all requests for initial issue of inFlow™, and **is all-inclusive** (catheter, wand and batteries). In addition, requests for replacement catheters, batteries, or wands must also use HCPCS code A4335.

Manufacturer and product name must be provided. **See noncoverage section.**

SpeediCath® Flex Coudé Catheter (Coloplast) - It has been determined that this is a straight catheter that is thinner and more flexible than other staright tip catheters, but it is not considered a coudé catheter- therefore should be billed as a straight catheter. <https://cgsmedicare.com/jb/pubs/news/2017/08/cope4199.html>

Claims for tape (A4450 or A4452) that are billed without an AU modifier or another modifier indicating coverage under a different policy will be denied as non-covered.

Extension tubing (A4331) will be covered for use with a latex urinary leg bag (A5112). It is included in the allowance for codes A4314, A4315, A4316, A4354, A4357, A4358, and A5105 and should not be separately billed with these codes.

In the following table, the Column I code includes the items identified by the codes in Column II. The Column I code must be used instead of multiple Column II codes when the items are provided at the same time.

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

If a code exists that includes multiple products, that code should be used in lieu of the individual codes.

Code A5105 should be used when billing for a urinary suspensory with leg bag.

Irrigation solutions containing antibiotics and chemotherapeutic agents should be coded A9270. Irrigating solutions, such as acetic acid or hydrogen peroxide, which is used for the treatment or prevention of urinary obstruction, should be coded A4321.

Adhesive strips or tape used with code A4349 (MALE EXTERNAL CATHETER, WITH OR WITHOUT ADHESIVE, DISPOSABLE, EACH) should not be billed separately.

Adhesive catheter anchoring devices that are used with indwelling urethral catheters are billed using codes A4333 and A4334, respectively. An anchoring device used with a percutaneous catheter/tube (e.g., suprapubic tube, nephrostomy tube) is billed using code A5200.

Replacement leg straps (A5113, A5114) are used with a urinary leg bag (A4358, A5105, or A5112). These codes are not used for a leg strap for an indwelling catheter.

When codes A4217, A4450, and A4452 are used with urological supplies, they must be billed with the AU modifier. For this policy, codes A4217, A4450, and A4452 are the only three codes for which the AU modifier may be used.

An external catheter that contains a barrier for attachment should be coded using A4335.

Codes for ostomy barriers (A4369-A4371) should not be used for skin care products used in the management of urinary incontinence.

A4358 (URINARY DRAINAGE BAG, LEG OR ABDOMEN, VINYL, WITH OR WITHOUT TUBE, WITH STRAPS, EACH) is a urinary collection bag that includes straps which hold the bag securely to the body.

Manufacturers of urinary collection bags have notified the PDAC contractor that some collection bags do not contain straps. While manufacturers may offer these products without straps, DME prosthetics, orthotics and supplies (DMEPOS) suppliers are reminded they MUST supply straps with the urinary drainage bag to the Medicare beneficiary.

Suppliers are reminded that A4358 includes both the drainage bag and straps. If the drainage bag from a particular manufacturer does not contain a leg strap, suppliers must provide a leg strap but should not bill using the miscellaneous code A4335 (INCONTINENCE SUPPLY; MISCELLANEOUS) and A5113 (LEG STRAP; LATEX, REPLACEMENT ONLY, PER SET) or A5114 (LEG STRAP; FOAM OR FABRIC, REPLACEMENT ONLY, PER SET).

DISPENSING SUPPLIES

The Health Plan is following Medicare's guidelines for supplies provided on a reoccurring basis.

Authorization of urological supplies should be limited to a one-month supply for a member in a nursing facility. For home use it will be based on information submitted above in the Documentation Requirement section of this policy

Providers are not to automatically dispense supplies according to allowable limits. Providers are required to reorder supplies based on actual usage of each member. There must be a specific request for the supplies from the member, caregiver, or physician prior to dispensing the supplies. Supplies should be shipped/delivered no sooner than 10 days prior to end of usage. Please refer to CMS Program Integrity Manual for more information. (CMS Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

The DME supplier is responsible to monitor utilization of covered frequently purchased supplies for members.

KX, GA, and GZ MODIFIERS

Suppliers may submit a claim with a KX modifier only if all the criteria for that item are met.

If coverage criteria are not met, the GA or GZ modifier must be used. When there is an expectation of a medical denial, suppliers must enter the GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN) or the GZ modifier if they have not obtained a valid ABN.

Providers are to include all appropriate modifiers, as applicable.

ADVANCED BENEFICIARY NOTICE

The Health Plan expects providers to follow the Medicare policy on ABN across all Medicare, Medicaid, and Commercial plans.

NOTE: Providers may be held financially responsible if they furnish the above items without notifying the member, verbally and in writing, that the specific service being provided is not covered. This must be

done prior to the dispensing of the device. The provider must submit the waiver or Advanced Beneficiary Notification (ABN) to The Health Plan with the claim showing the member agreed to pay for the device. Generalized statements on waivers or ABN are not acceptable.

PRICING, DATA ANALYSIS, AND CODING (PDAC)

The Health Plan has implemented use of Medicare's PDAC contractor for review of authorizations. Please refer to PDAC website for the appropriate product classification list. dmepdac.com/

<https://www.dmepdac.com/dmecsapp/>

For questions about correct coding, contact the PDAC contractor.

MEDICARE DEFINITIONS AND DESCRIPTION

Permanent urinary retention is defined as retention that is not expected to be medically or surgically corrected in that patient within three months. The patient must have a permanent impairment of urination. This does not require a determination that there is no possibility that the patient's condition may improve sometime in the future. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration (ordinarily at least three months), the test of permanence is considered met.

The general term "external urinary collection devices" used in this policy includes male external catheters and female pouches or metal cups. This term does not include diapers or other types of absorptive pads.

A metal cup female external urinary collection device (A4327) is a plastic cup, which is held in place around the female urethra by suction or pressure and is connected to a urinary drainage container such as a bag or bottle.

A pouch type female external collection device (A4328) is a plastic pouch which is attached to the periurethral area with adhesive and which can be connected to a urinary drainage container such as a bag or bottle.

A urinary catheter-anchoring device described by code A4333 has an adhesive surface, which attaches to the patient's skin and a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

A urinary catheter-anchoring device described by code A4334 is a strap, which goes around a patient's leg and has a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

Therapeutic agent for urinary irrigation (A4321) is defined as a solution containing agents in addition to saline or sterile water (for example acetic acid or hydrogen peroxide) which is used for the treatment or prevention of urinary catheter obstruction.

A4326 is a male external catheter with an integrated collection chamber that does not require the use of an additional leg bag.

A percutaneous catheter/tube anchoring device (A5200) is a dressing with adhesive that is designed to be applied directly over the cutaneous opening through which the catheter/tube passes. This dressing

has a hole through which the catheter/tube passes and a mechanism for firmly anchoring the catheter/tube to the dressing.

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INTERNET LINKS AND SOURCES

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