curative

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1. PURPOSE

This policy will be used to inform medical necessity decisions related to authorization requests for Urological Supplies.

2. SCOPE

Medical UM Department

3. DEFINITIONS

- Urinary drainage systems are used to replace the urine collection, urine retention function and bladder emptying function in individuals with permanent urinary incontinence, urinary obstruction or neurogenic bladder dysfunction resulting from disease, accidental injury, or surgery.
- External systems are worn by incontinent male patients in situations where injury to the urethra prohibits use of an indwelling catheter. The external system consists of a latex sheath fitted over the penis and connects directly or with a drainage tube to a urine collection bag strapped to the patient's leg.
- Internal systems consist of an indwelling urethral catheter attached to a bag for collection and retention of urine. This system requires flushing or irrigation of the catheter.
- Intermittent systems are used for intermittent catheterization of patients who require regularly performed, periodic bladder catheterizations as an alternative to indwelling catheters. An example of one type of intermittent system is a catheter enclosed in a plastic bag permitting lubrication and insertion without touching. The urine is collected in a calibrated lower chamber eliminating the need for a sterile field and gloves. Intermittent systems are identical for male and female patients. When the bladder is emptied, the catheter is withdrawn, and the kit is discarded after emptying the urine into a urinal or toilet.
- Sterile catheterization technique involves the use of a new, sterile packaged catheter and sterile lubricant for each catheterization. It may also involve the use of sterile gloves and drapes and use of an antiseptic solution to cleanse the peri-urethral area. Clean, non-sterile intermittent catheterization technique involves the use of soap and water for cleansing of the periurethral area, a reusable catheter that is cleansed between episodes, and non-sterile lubricant.

Ureteral Stents

- An UpToDate review on “Placement and management of indwelling ureteral stents” (Nakada and Patel, 2019) states that “Ureteral stents are indicated for the management of ureteral obstruction, to protect a ureteral anastomosis prophylactically prior to extracorporeal shock wave lithotripsy (ESWL), following complicated ureteroscopy, or prior to surgery to assist with intraoperative identification of the ureter”.

The inFlow Device

- The inFlow Intra-urethral valve pump system is a urinary “prosthesis” comprised of the inFlow device, and the Activator. The inFlow device is a sterile, single-use, intra-urethral valve-pump that is inserted into the female urethra. As a prosthetic device, the inFlow compensates for the inability of women with impaired detrusor contractility (IDC) to generate bladder pressure by pumping the urine out of the urinary bladder, allowing almost normal use of a toilet. Other benefits include reduced rates of infection and encrustation, as well as improved quality of life (QOL). The inFlow urinary prosthesis device is indicated for use by women with permanently impaired detrusor contractility of neurologic origin - a condition where patients care unable to empty their bladder. The inFlow device is a 3- to 7-cm long magnetic pump encased in a silicone tube that has flexible stays to anchor the device at the bladder neck. The pump is packaged with a disposable introducer. Device sizing and initial insertion is performed by a physician. Device insertion is similar to that of a urinary catheter. The device is replaced every 29 days (essentially monthly) by the patient or a caregiver. The activator is a hand-held, patient-operated remote control that operates the internal valve-pump mechanism in the InFlow device. The activator comes with a base station for charging its internal battery. The user sits on the commode, uses the remote-control activator to activate the valve-pump, which pumps urine from the bladder through the urethra to empty the bladder.
- In a prospective, single-arm, cross-over, multi-center study, Chen and colleagues (2005) compared the safety, effectiveness and patient satisfaction of an intra-urethral valve-pump catheter (In-Flow) versus the current standard of care, clean intermittent catheterization (CIC), for women with hypo-contractile or a-contractile bladder. Eligible patients underwent a 1-week In-Flow tolerability trial. Successful patients then continued through an 8-week baseline phase using CIC, followed by a 16-week In-Flow treatment phase, and a final 4-week treatment withdrawal phase. Outcome measures included post-void residual (PVR), Wagner incontinence-specific QOL (I-QOL), rate of urinary tract infection and adverse events (AEs). At study completion, open enrollment was offered. A total of 273 women with a mean age of 48.9 years using CIC entered the study in 18 centers under either the original (n = 88) or revised protocols (n = 185). The revised protocol included the addition of a 1-week tolerability trial. The reasons for the large early withdrawal of subjects (169/273) were mainly related to initial discomfort and leakage. A total of 77 patients completed the In-Flow treatment phase. PVR was comparable during baseline CIC phase and In-Flow treatment phase (20.3 ml versus 16.1 ml), with significantly improved QOL (mean improvement of I-QOL score +25.9; $p < 0.001$). The authors concluded that the In-Flow catheter appeared to be a viable alternative to CIC. A subgroup of patients, mainly those unsatisfied with the currently available treatments, was more likely to tolerate In-Flow catheters, and they may achieve enhanced independence and QOL.
- Bayrak and Dmochowski (2019) noted that the inflow Intra-urethral Valve-Pump and Activator (collectively called inFlow) device was approved by the Food and Drug

Administration (FDA) since 2014. inFlow assists urine drainage in patients who have urinary retention due to underactive bladder (UAB). It is inserted into the urethra and replaced after 29 days. It is a short self-retaining silicone catheter including an internal valve and pump mechanism that uses a miniature magnetically coupled pump activated by a hand-held remote control. When the patient activates the remote control by holding it over her pelvis and pushing the button, urine is actively pumped from the bladder to mimic normal voiding. When the button is released at the end of micturition, a valve is engaged within the device that stops further flow of urine. In a multi-center study of intra-urethral valve-pump catheter in women with a hypo-contractile or a-contractile bladder, Chen et al (2005) compared inFlow versus CIC. A total of 273 women performing CIC were included in the study in 18 centers; with 77 patients completed the inFlow treatment phase. This study showed that inFlow was significantly superior to CIC in its effect on QOL. More importantly, urinary tract infections (UTIs) rates for inFlow started off slightly lower than those for CIC and reduced with continued usage. inFlow has already been in use in Europe for more than 20 years. It is possible that the decreased UTI rate related to the ability of the inFlow to mimic normal micturition acts by providing periodic, powerful, and total emptying of urine. Furthermore, inFlow is a sterile device that is placed only once monthly, whereas CIC requires 4 to 6 times daily, each of which increases the risk of bacterial infection.

PureWick Urine Collection System

- The PureWick system 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’s soiled with feces or blood.
- 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.

4. RESPONSIBILITIES

Medical UM Department

5. POLICY

Medical Necessity

Curative considers urinary catheters and external urinary collection devices medically necessary prosthetics for patients who have 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 person within 3 months.

Note: 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.

Indwelling Catheters

- Curative considers 1 catheter per month medically necessary for routine catheter maintenance. Non-routine catheter changes are considered medically necessary in exceptional circumstances, such as the following:

a. Catheter is accidentally removed (e.g., pulled out by the patient); *or*

- Catheter is obstructed by encrustation, mucous plug, or blood clot; *or*
- Catheter malfunctions (e.g., balloon does not stay inflated, hole in catheter); *or*
- The patient has a history of recurrent obstruction or urinary tract infection for which it has been established that an acute event is prevented by a scheduled change at intervals of less than once per month.
  - Tuck Specialty indwelling catheters and all silicone catheters are considered medically necessary where the patient is unable to use a straight Foley type catheter with coating (such as recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex). For example, use of a Coude (curved) tip indwelling catheter in female patient's is rarely medically necessary.
  - A 3-way indwelling catheter either alone or with other components is considered medically necessary only if continuous catheter irrigation is medically necessary.

Catheter Insertion Trays

One insertion tray is considered medically necessary per episode of indwelling catheter insertion. One intermittent catheter with insertion supplies is considered medically necessary per episode of medically necessary sterile intermittent catheterization (see below). Catheter insertion trays are of no proven benefit for clean, non-sterile intermittent catheterization.

Catheter insertion trays that contain component parts of the urinary collection system, (e.g., drainage bags and tubing) are inclusive sets and additional component parts are considered medically necessary only per the stated criteria in each section of this policy.

Urinary Drainage Collection Systems

- The following table indicates the quantity of supplies that are considered medically necessary for routine changes of the urinary drainage collection system. Additional supplies for non-routine changes are considered medically necessary only under exceptional circumstances (e.g., for obstruction, sludging, clotting of blood, or chronic, recurrent urinary tract infections).

Table: Usual Maximum Medically Necessary Quantity of Supplies

Description	Number per month	Number per 3 months
Insertion tray with drainage bag with indwelling catheter, Foley-type, 2-way, latex with coating	1	
Insertion tray with drainage bag with indwelling catheter, Foley-type, 2-way, all silicone	1	
Insertion tray with drainage bag with indwelling catheter, Foley-type, 3-way, for continuous irrigation	1	
Insertion tray with drainage bag but without catheter	1	

Bedside drainage bag, day or night, with or without anti-reflux device, with or without tube, each	2	
Urinary leg bag; vinyl, with or without tube, each	2	
Bedside drainage bottle with or without tubing, rigid or expandable, each		1
Urinary leg bag; latex	1	

- Leg bags are considered medically necessary for patients who are ambulatory or are chair- or wheelchair-bound. The use of leg bags for bedridden patients is not considered medically necessary.
- Either a vinyl leg bag or a latex leg bag is considered medically necessary; the use of both is not considered medically necessary.
- If there is a catheter change and an additional drainage bag change within a month, the combined utilization for catheters and drainage bags should be considered when determining if additional documentation should be submitted with the claim. For example, if one insertion tray with drainage bag and indwelling foley-type catheter and one bedside drainage bag are provided, this should be considered as two drainage bags, which is the usual maximum quantity of drainage bags needed for routine changes.
- The value 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 proven.

Intermittent Irrigation of Indwelling Catheter

Supplies for the intermittent irrigation of an indwelling catheter are considered medically necessary when they are used on as needed (non-routine) basis in the presence of acute obstruction of the catheter. Routine intermittent irrigations of a catheter (i.e., catheterizations performed at pre-determined intervals) are of no proven value.

Medically necessary supplies for medically necessary non-routine irrigation of a catheter include either an irrigation tray or an irrigation syringe, and sterile saline or sterile water. When syringes, trays, sterile saline, or water are used for routine irrigation, they will be considered not medically necessary.

Note: Irrigation supplies that are used for care of the skin or perineum of incontinent patients are not covered.

Continuous Irrigation of Indwelling Catheter

Supplies for continuous irrigation of a catheter are considered medically necessary if there is a history of obstruction of the catheter and the patency of the catheter can not be maintained by intermittent irrigation and catheter changes. Continuous irrigation has not been proven to be of benefit as a primary preventive measure (i.e., no history of obstruction).

Medically necessary supplies for medically necessary continuous bladder irrigation include a 3-way Foley catheter, irrigation tubing set, and sterile saline or sterile water. More than one irrigation tubing set per day for continuous catheter irrigation is not considered medically necessary.

Sterile water or sterile saline are considered medically necessary for use as irrigation solutions.

Continuous irrigation is a temporary measure; continuous irrigation for more than 2 weeks is rarely considered medically necessary.

Intermittent Catheterization

Intermittent catheterization is considered medically necessary when basic medical necessity criteria are met, and the patient or caregiver can perform the procedure.

- Intermittent catheterization using sterile technique is considered medically necessary when the patient requires catheterization, and the patient meets any of the following criteria:

- The patient resides in a nursing facility; *or*
- The patient is immunosuppressed, for example (not all inclusive):
    - Has AIDS,
    - Has a drug-induced state such as chronic oral corticosteroid use,
    - On a regimen of immunosuppressive drugs post-transplant,
    - On cancer chemotherapy; *or*
- The patient has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization; *or*
- The patient is a spinal cord-injured female with neurogenic bladder who is pregnant (for duration of pregnancy only); *or*
- The patient has had distinct, recurrent urinary tract infections, while on a program of clean intermittent catheterization with sterile lubricant, twice within the 12-month period prior to the initiation of sterile intermittent catheterization.

Note: A patient 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 any of the following signs, symptoms, or laboratory findings:

- Appearance of new or increase in autonomic dysreflexia (sweating, bradycardia, blood pressure elevation)
- Change in urinary urgency, frequency, or incontinence.
- Fever (oral temperature over 38º C [100.4º F])
- Increased muscle spasms
- Physical signs of prostatitis, epididymitis, orchitis
- Pyuria (greater than 5 white blood cells (WBCs) per high-powered field)
- Systemic leukocytosis

Intermittent catheterization using sterile technique is of no proven benefit for other indications. Requests for sterile intermittent catheterization for patients who fail to meet the above criteria are subject to medical review.

- The following table lists the usual medically necessary quantity of supplies for intermittent catheterization.

Table: Medically Necessary Quantity of Supplies for Intermittent Catheterization

Description	Number per month

Lubricant, individual sterile packet, each	200
Intermittent urinary catheter; straight tip, with or without coating (teflon, silicone, silicone elastomer, or hydrophilic, etc.), each	200
Intermittent urinary catheter; coude (curved) tip, with or without coating (teflon, silicone, silicone elastomeric, or hydrophilic, etc.), each	200
Intermittent urinary catheter, with insertion supplies	200

- **Note**: The code for an intermittent urinary catheter with insertion supplies 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 intermittent urinary catheter with insertion supplies kit.
- For each episode of medically necessary sterile catheterization, Curative considers medically necessary either.
  - catheter plus an individual packet of lubricant, or
  - an intermittent catheter kit if medical necessity criteria above are met.
  - catheter plus an individual packet of lubricant, or
  - an intermittent catheter kit if medical necessity criteria above are met.

A urinary intermittent catheter with insertion supplies 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.

Use of a Coude (curved) tip catheter in female patients is rarely medically necessary. A Coude tip catheter is considered medically necessary for either male or female patients only when a straight tip catheter cannot be used. An example would be the inability to catheterize with a straight tip catheter.

External Catheters/Urinary Collection Devices

Male external catheters (condom-type) or female external urinary collection devices are considered medically necessary for patients who have permanent urinary incontinence when used as an alternative to an indwelling catheter.

- Generally, no more than 35 male external catheters are considered medically necessary per month.
- **Note**: Adhesive strips or tape used with male external catheters with adhesive strips or adhesive coating are included in the allowance for that code and are not separately payable.
- Male external catheters (condom-type) or female external urinary collection devices are not considered medically necessary when ordered for patients who also use an indwelling catheter.
- Specialty-type male external catheters such as those that inflate or that include a faceplate are considered medically necessary where the clinical situation justifies their need.
- For female external urinary collection devices, more than 1 meatal cup per week or more than 1 pouch per day are not considered medically necessary.
- 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 peri-urethral area with adhesive and which can be connected to a urinary drainage container such as a bag or bottle.

- Curative considers the PureWick urine collection system unproven and not medically necessary for the management of urinary incontinence.

The inFlow Device

Curative considers the inFlow device medically necessary as an alternative to intermittent catheterization for patients with permanent urinary retention (PUR) due to impaired detrusor contractility. (**Note**: One inFlow device is considered medically necessary no more than once every 29 days).

Documentation of the continued medical necessity of the inFlow device beyond the first 3 months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating practitioner conducts a clinical re-evaluation and document that the patient continues to use and is benefiting from the inFlow device.

Documentation of use and clinical benefit is demonstrated by:

- An in-person encounter by the treating practitioner with documentation that urinary symptoms are improved; *and*
- The treating practitioner verifies the patient's adherence to use of the inFlow device.

If the above criteria are not met, continued use of the inFlow device and related accessories will be considered not medically necessary.

If the practitioner re-evaluation does not occur until after the 91st day but the evaluation demonstrates that the patient 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.

Note: 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.

Miscellaneous Supplies

- Appliance cleaner is considered medically necessary when used to clean the inside of certain urinary collecting appliances. More than 16 oz. per month is rarely considered medically necessary.
- One external urethral clamp or compression device is considered medically necessary every 3 months or sooner if the rubber/foam casing deteriorates.
- Tape that is used to secure an indwelling catheter to the patient's body is considered medically necessary. More than 5 yards of 1-inch tape per month is usually not considered medically necessary.
- Adhesive catheter anchoring devices and catheter leg straps for indwelling urethral catheters are considered medically necessary.

A urinary catheter anchoring device with an adhesive skin attachment 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 device. A urinary catheter anchoring device with a leg strap has 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 device.

- More than 3 per week of adhesive catheter anchoring devices or 1 catheter leg strap per month is usually not considered medically necessary.
- A catheter/tube anchoring device is considered medically necessary when it is used to anchor a covered suprapubic tube or nephrostomy tube. A catheter/tube anchoring device is considered not medically necessary to anchor an indwelling catheter.
  - Urethral inserts are considered medically necessary for adult women with stress incontinence when basic medical necessity criteria are met, and the patient 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.
  - Extension tubing is considered medically necessary for use with a latex urinary leg bag. **Note**: Extension tubing is included in the allowance for insertion trays with drainage bags, bedside drainage bags, vinyl urinary drainage bags, and urinary suspensories with leg bags, and should not be separately billed with these items.
  - Curative considers ureteral stents medically necessary for the following indications:

- Before surgery (eg, gynecologic surgery, rectosigmoid surgery, aortoiliac surgery) to assist with intra-operative identification of the ureter; *or*
- Following ureteroscopy for ureteral stone disease, ureteral stricture, or treatment of transitional cell carcinoma of the ureter or kidney; *or*
- Management of ureteral obstruction due to nephrolithiasis, tumor, or retroperitoneal fibrosis; *or*
- Following the creation of a ureteral anastomosis (ie, ureteroureterostomy) for repair of ureteral injury (eg, trauma, iatrogenic), kidney surgery (eg, pyeloplasty), or renal transplant (ie, neo-ureterostomy); *or*
- Protection of a ureteral anastomosis prophylactically before extracorporeal shock wave lithotripsy.

Experimental and Investigational

The following procedures are considered experimental and investigational because the effectiveness of these approaches has not been established:

- Irrigation solutions containing antibiotics and chemotherapeutic agents.
- Irrigating solutions such as acetic acid or hydrogen peroxide, which are used for the treatment or prevention of urinary obstruction.

- Ureteral stents for all other indications (except for those listed in the "Medical Necessity" section above).

Policy Limitations and Exclusions

Notes on Non-Covered Supplies

The following supplies used in the management of incontinence are not covered, other than for home care suppliers who bill for the supplies as part of the home health care visit, because they are not prosthetic devices and are not required for the effective use of a prosthetic device:

1. Adhesive remover (**Note**: these are considered medically necessary for ostomy supplies)
2. Catheter care kits
3. Catheter clamp or plug
4. Creams, salves, lotions, barriers (liquid, spray, wipes, powder, paste) or other skin care products.
5. Diapers, drip collectors, or incontinent garments, disposable or reusable
6. Disposable under pads (e.g., Chux)
7. Drainage bag holder or stand.
8. Gauze pads and other dressings (maybe covered under other benefits, e.g., surgical dressings)
9. Measuring container
10. Urinary drainage tray
11. Urinary suspensory without leg bag
12. Other incontinence products that are not directly related to the use of medically necessary urinary catheter or external urinary collection device.

A. The following items are not covered other than for home care suppliers because they are not medical supplies and/or they could be used by the patient or the patient's family for purposes other than replacing the urine collection and retention function of the bladder:

1. Rubber bands
2. Rubber gloves
3. Scissors
4. Sheets.

Note: These lists are not all-inclusive.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

7.1. All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

Documentation, in the form of a prescription written by the physician, must include an estimate of the frequency, duration of use, duration of need, and cost.

REFERENCE DOCUMENTS AND MATERIALS

9.1. Regulatory Authority - N/A

10. COLLABORATING DEPARTMENTS

N/A

11. DOCUMENT CONTROL

APPROVED BY:		
Charles,Brandon	4/16/2024	DocuSigned by: Charles,Brandon DE2813BF834C49A...
(Printed Name)	**(Date)**	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A:

N/A