Local Coverage Determination (LCD)

Urological Supplies

L33803

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

LCD ID
L33803

LCD Title
Urological Supplies

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL33803

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 01/01/2024

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
06/11/2020

Notice Period End Date
07/25/2020

Issue

Issue Description

The LCD is revised to align refill requirements with CMS Final Rule CMS-1780-F. This revision allows contact with the beneficiary regarding refills to take place no sooner than 30 calendar days prior to the end of the current supply and to document an affirmative response.

Issue - Explanation of Change Between Proposed LCD and Final LCD

No proposed LCD issued.

CMS National Coverage Policy

None

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

The statutory coverage criteria for coverage of urological supplies are specified in the related Policy Article.

The medical necessity for use of a greater quantity of supplies than the amounts specified in the policy must be well documented in the beneficiary's medical record and must be available upon request.

INDWELLING CATHETERS (A4311, A4312, A4313, A4314, A4315, A4316, A4338, A4340, A4344, and A4346)

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

1. Catheter is accidentally removed (e.g., pulled out by beneficiary)
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

A specialty indwelling catheter (A4340) or an all silicone catheter (A4344, A4312, or A4315) is covered when the criteria for an indwelling catheter (above) are met and there is documentation in the beneficiary's medical record to justify the medical need for that catheter (such as recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex(not all-inclusive)). In addition, the particular catheter must be necessary for the beneficiary. For example, use of a Coude (curved) tip indwelling catheter (A4340) in a female beneficiary is rarely reasonable and necessary. If documentation is requested and does not substantiate medical necessity payment for A4340, A4344, A4312, or A4315 will be denied as not reasonable and necessary.

A three way indwelling catheter either alone (A4346) or with other components (A4313 or A4316) will be covered only if continuous catheter irrigation is reasonable and necessary. (Refer to the section "Continuous Irrigation of Indwelling Catheters" for indications for continuous catheter irrigations.) In other situations, A4346, A4313 and A4316 will be denied as not reasonable and necessary.

CATHETER INSERTION TRAY (A4310, A4311, A4312, A4313, A4314, A4315, 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 reasonable and necessary.

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

URINARY DRAINAGE COLLECTION SYSTEM (A4314, A4315, A4316, A4354, A4357, A4358, A5102, and A5112)

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).

Usual Maximum Quantity of Supplies:

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

Code	Number per 3 month
A5102	1

Leg bags are indicated for beneficiaries who are ambulatory or are chair or wheelchair bound. The use of leg bags for bedridden beneficiaries would be denied as not reasonable and necessary.

If there is a catheter change (A4314, A4315, A4316, A4354) and an additional drainage bag (A4357) change within a month, the combined utilization for A4314, A4315, A4316, A4354, and A4357 should be considered when determining if additional documentation should be submitted with the claim. For example, if 1 unit of A4314 and 1 unit of A4357 are provided, this should be considered as two drainage bags, which is the usual maximum quantity of drainage bags needed for routine changes.

Payment will be made for either a vinyl leg bag (A4358) or a latex leg bag (A5112). The use of both is not reasonable and necessary.

The medical necessity for drainage bags containing absorbent material such as gel matrix or other material, which are intended to be disposed of on a daily basis has not been established. Claims for this type of bag will be denied as not reasonable and necessary.

INTERMITTENT IRRIGATION OF INDWELLING CATHETERS

Supplies for the intermittent irrigation of an indwelling catheter are covered when they are used on an as needed (non-routine) basis in the presence of acute obstruction of the catheter. Routine intermittent irrigations of a catheter will be denied as not reasonable and necessary. Routine irrigations are defined as those performed at predetermined intervals. In individual cases, a copy of the order for irrigation and documentation in the beneficiary's medical record of the presence of acute catheter obstruction may be requested when irrigation supplies are billed.

Covered supplies for reasonable and necessary non-routine irrigation of a catheter include either an irrigation tray (A4320) or an irrigation syringe (A4322), and sterile water/saline (A4217). When syringes, trays, sterile saline, or water are used for routine irrigation, they will be denied as not reasonable and necessary. Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as non-covered. Irrigating solutions such as acetic acid or hydrogen peroxide, which are used for the treatment or prevention of urinary obstruction (A4321), will be denied as not reasonable and necessary.

CONTINUOUS IRRIGATION OF INDWELLING CATHETERS

Supplies for continuous irrigation of a catheter are covered if there is a history of obstruction of the catheter and the patency of the catheter cannot be maintained by intermittent irrigation in conjunction with reasonable and necessary catheter changes. Continuous irrigation as a primary preventative measure (i.e., no history of obstruction) will be denied as not reasonable and necessary. Documentation must substantiate the medical necessity of catheter irrigation and in particular continuous irrigation as opposed to intermittent irrigation. The records must also indicate the rate of solution administration and the duration of need. This documentation must be available upon request.

Covered supplies for reasonable and necessary continuous bladder irrigation include a 3-way Foley catheter (A4313, A4316, and A4346), irrigation tubing set (A4355), and sterile water/saline (A4217). More than one irrigation tubing set per day for continuous catheter irrigation will be denied as not reasonable and necessary.

Irrigation solutions containing antibiotics and chemotherapeutic agents (A9270) will be denied as non-covered. Payment for irrigating solutions such as acetic acid or hydrogen peroxide will be based on the allowance for sterile water/saline (A4217).

Continuous irrigation is a temporary measure. Continuous irrigation for more than 2 weeks is rarely reasonable and necessary. The beneficiary's medical records should indicate this medical necessity and these medical records must be available upon request.

INTERMITTENT CATHETERIZATION

Intermittent catheterization is covered when basic coverage criteria are met and the beneficiary or caregiver can perform the procedure.

For each episode of covered catheterization, Medicare will cover:

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

1. The beneficiary resides in a nursing facility,
2. The beneficiary is immunosuppressed, for example (not all-inclusive):
    - on a regimen of immunosuppressive drugs post-transplant,
    - on cancer chemotherapy,
    - has AIDS,
    - has a drug-induced state such as chronic oral corticosteroid use.
3. The beneficiary has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,

4. The beneficiary is a spinal cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),
5. The beneficiary has had distinct, recurrent urinary tract infections, while on a program of sterile intermittent catheterization with A4351/A4352 and sterile lubricant A4332, twice within the 12-month prior to the initiation of sterile intermittent catheter kits.

A beneficiary would be considered to have a urinary tract infection if they have a urine culture with greater than 10,000 colony forming units of a urinary pathogen AND concurrent presence of one or more of the following signs, symptoms or laboratory findings:

- Fever (oral temperature greater than 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 5 white blood cells [WBCs] per high-powered field)

Usual Maximum Quantity of Supplies:

Code	Number per Month
A4332	200
A4351	200
A4352	200
A4353	200

Refer to Coding Guidelines section of the related Policy Article for contents of the kit (A4353). A4353 should not be used for billing if the components are packaged separately rather than together as a kit. Separately provided components do not provide the equivalent degree of sterility achieved with an A4353. If separate components are provided instead of a kit (A4353) they will be denied as not reasonable and necessary.

Use of a Coude (curved) tip catheter (A4352) in female beneficiaries is rarely reasonable and necessary. When a Coude tip catheter is used (either male or female beneficiaries), there must be documentation in the beneficiary's medical record of the medical necessity for that catheter. An example would be the inability to catheterize with a straight tip catheter. This documentation must be available upon request. If documentation is requested and does not substantiate medical necessity, claims will be denied as not reasonable and necessary.

EXTERNAL CATHETERS/URINARY COLLECTION DEVICES

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

The utilization of male external catheters (A4349) generally should not exceed 35 per month. Greater utilization of these devices must be accompanied by documentation of medical necessity.

Male external catheters (condom-type) or female external urinary collection devices will be denied as not reasonable and necessary when ordered for beneficiaries who also use an indwelling catheter.

Specialty type male external catheters (A4326) such as those that inflate or that include a faceplate or extended wear catheter systems are covered only when documentation substantiates the medical necessity for such a catheter. If documentation does not justify the medical need claims will be denied as not reasonable and necessary.

For female external urinary collection devices, more than one meatal cup (A4327) per week or more than one pouch (A4328) per day will be denied as not reasonable and necessary.

INITIAL COVERAGE FOR THE INFLOW DEVICE

The inFlow device (A4341) is considered to be reasonable and necessary as an alternative to intermittent catheterization for beneficiaries 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 re-evaluation and document that the beneficiary 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.

MISCELLANEOUS SUPPLIES

Appliance cleaner (A5131) is covered when used to clean the inside of certain urinary collecting appliances (A5102, A5105, A5112). More than one unit of service (16 oz.) per month is rarely reasonable and necessary.

One external urethral clamp or compression device (A4356) is covered every 3 months or sooner if the rubber/foam casing deteriorates.

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

Adhesive catheter anchoring devices (A4333) and catheter leg straps (A4334) for indwelling urethral catheters are covered. More than 3 per week of A4333 or 1 per month of A4334 will be denied as not reasonable and necessary. A catheter/tube anchoring device (A5200) is covered and separately payable when it is used to anchor a covered suprapubic tube or nephrostomy tube. If code A5200 is used to anchor an indwelling urethral catheter, the claim will be denied as not reasonable and necessary.

Urethral inserts (A4336) are covered for adult females with stress incontinence (refer to the ICD-10 Codes section in the LCD-related Policy Article for applicable diagnoses) when basic coverage criteria are met and the beneficiary or caregiver can perform the procedure. They are not indicated for women:

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

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary.

Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary, and document an affirmative response, prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee and document an affirmative response, prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request and an affirmative response from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a three (3) - month quantity at a time.

Summary of Evidence
N/A

Analysis of Evidence (Rationale for Determination)
N/A

Coding Information

CPT/HCPCS Codes

Group 1 (52 Codes)

Group 1 Paragraph
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 payer policy, individual 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 and necessary

KX - Requirements specified in the medical policy have been met

HCPCS CODES

Group 1 Codes

Code	Description
A4217	STERILE WATER/SALINE, 500 ML
A4310	INSERTION TRAY WITHOUT DRAINAGE BAG AND WITHOUT CATHETER (ACCESSORIES ONLY)
A4311	INSERTION TRAY WITHOUT DRAINAGE BAG WITH INDWELLING CATHETER, FOLEY TYPE, TWO-WAY LATEX WITH COATING (TEFLON, SILICONE, SILICONE ELASTOMER OR HYDROPHILIC, ETC.)
A4312	INSERTION TRAY WITHOUT DRAINAGE BAG WITH INDWELLING CATHETER, FOLEY TYPE, TWO-WAY, ALL SILICONE
A4313	INSERTION TRAY WITHOUT DRAINAGE BAG WITH INDWELLING CATHETER, FOLEY TYPE, THREE-WAY, FOR CONTINUOUS IRRIGATION
A4314	INSERTION TRAY WITH DRAINAGE BAG WITH INDWELLING CATHETER, FOLEY TYPE, TWO-WAY LATEX WITH COATING (TEFLON, SILICONE, SILICONE ELASTOMER OR HYDROPHILIC, ETC.)
A4315	INSERTION TRAY WITH DRAINAGE BAG WITH INDWELLING CATHETER, FOLEY TYPE, TWO-WAY, ALL SILICONE
A4316	INSERTION TRAY WITH DRAINAGE BAG WITH INDWELLING CATHETER, FOLEY TYPE, THREE-WAY, FOR CONTINUOUS IRRIGATION
A4320	IRRIGATION TRAY WITH BULB OR PISTON SYRINGE, ANY PURPOSE
A4321	THERAPEUTIC AGENT FOR URINARY CATHETER IRRIGATION
A4322	IRRIGATION SYRINGE, BULB OR PISTON, EACH
A4326	MALE EXTERNAL CATHETER WITH INTEGRAL COLLECTION CHAMBER, ANY TYPE, EACH
A4327	FEMALE EXTERNAL URINARY COLLECTION DEVICE; MEATAL CUP, EACH
A4328	FEMALE EXTERNAL URINARY COLLECTION DEVICE; POUCH, EACH
A4331	EXTENSION DRAINAGE TUBING, ANY TYPE, ANY LENGTH, WITH CONNECTOR/ADAPTOR, FOR USE WITH URINARY LEG BAG OR UROSTOMY POUCH, EACH
A4332	LUBRICANT, INDIVIDUAL STERILE PACKET, EACH
A4333	URINARY CATHETER ANCHORING DEVICE, ADHESIVE SKIN ATTACHMENT, EACH

Code	Description
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
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

Code	Description
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 DRAINAGE BAG, LEG OR ABDOMEN, LATEX, WITH OR WITHOUT TUBE, WITH STRAPS, EACH
A5113	LEG STRAP; LATEX, REPLACEMENT ONLY, PER SET
A5114	LEG STRAP; FOAM OR FABRIC, REPLACEMENT ONLY, PER SET
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

General Information

Associated Information

DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner’s office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS

APPENDICES

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations, and/or Medical Necessity

Sources of Information

Reserved for future use

Bibliography

N/A

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2024	R11	**Revision Effective Date: 01/01/2024** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: “and document an affirmative response” to language that pertains to contact with the beneficiary or caregiver/designee for DMEPOS products supplied as refills Revised: “approaching exhaustion” to “expected to end” in regard to existing supplies Revised: “Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date.” to “Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply.” Revised: “For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product.” to “For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply.” *12/14/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates to refill requirement information per CMS Final Rule CMS-1780-F.*	• Provider Education/Guidance • Other (CMS Final Rule CMS-1780-F)
10/01/2023	R10	**Revision Effective Date: 10/01/2023** HCPCS CODES: Revised: Description of HCPCS code A4344 to “INDWELLING CATHETER, FOLEY TYPE, TWO-WAY, ALL SILICONE OR POLYURETHANE, EACH” *10/12/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.*	• Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
04/01/2023	R9	**Revision Effective Date: 04/01/2023** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Reference to inFlow device to include HCPCS code A4341 SUMMARY OF EVIDENCE: Removed: Summary of evidence information, due to not being applicable to the non-discretionary changes ANALYSIS OF EVIDENCE (RATIONALE FOR DETERMINATION): Removed: Analysis of evidence information, due to not being applicable to the non-discretionary changes HCPCS CODES: Added: HCPCS codes A4341 and A4342 BIBLIOGRAPHY: Removed: Bibliography information, due to not being applicable to the non-discretionary changes *04/27/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.*	• Revisions Due To CPT/HCPCS Code Changes
04/01/2021	R8	**Revision Effective Date: 04/01/2021** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Trademark symbol from first use of inFlow HCPCS CODES: Removed: K1010, K1011 and K1012 (effective for DOS on or after 04/01/2021) *04/29/2021: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.*	• Revisions Due To CPT/HCPCS Code Changes
10/01/2020	R7	**Revision Effective Date: 10/01/2020** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: HCPCS A4335 from inFlow device reference due to new HCPCS codes as of 10/01/2020 HCPCS CODES: Added: K1010, K1011 and K1012 (effective DOS on or after 10/01/2020) *10/15/2020: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates to add CMS HCPCS coding determinations.*	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
07/26/2020	R6	**Revision Effective Date: 07/26/2020** COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Format of HCPCS code references, from code 'spans' to individually-listed Added: Billing and coverage information for the inFlow device (HCPCS Code A4335) Removed: Denial statement for inFlow device (A4335) GENERAL: Added: References to Standard Written Order (SWO) REFILL REQUIREMENTS: Revised: "ordering physicians" to "treating practitioners" SUMMARY OF EVIDENCE: Added: Information related to inFlow device ANALYSIS OF EVIDENCE: Added: Information related to inFlow device CODING INFORMATION: Removed: Field titled "Bill Type" Removed: Field titled "Revenue Codes" Removed: Field titled "ICD-10 Codes that Support Medical Necessity" Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity" Removed: Field titled "Additional ICD-10 Information" DOCUMENTATION REQUIREMENTS: Revised: "physician's" to "practitioner's" GENERAL DOCUMENTATION REQUIREMENTS: Revised: "Prescriptions (orders)" to "SWO" BIBLIOGRAPHY: Added: Section related to inFlow device RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments (A58231)	• Provider Education/Guidance • Reconsideration Request • Other
01/01/2019	R5	**Revision History Effective Date: 01/01/2019** COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Removed: Statement to refer to diagnosis code section below Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Moved: Statement about noncovered diagnosis codes moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction	• Other (ICD-10 code relocation per CMS instruction)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2017	R4	**Revision History Effective Date: 01/01/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements Revised: Refill Requirements HCPCS Code: Added: A4553 DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Information under Miscellaneous and Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes
07/01/2016	R3	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	• Change in Assigned States or Affiliated Contract Numbers
01/01/2016	R2	Revision Effective Date: 01/01/2016 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Added: Non-reimbursement language for the inFlow™ Intraurethral Valve-Pump system (A4335) DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to remove start date verbiage from Prescription Requirements (Effective 11/05/2015)	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
10/01/2015	R1	Revision Effective Date: 08/01/2015 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD (Note: Standard Documentation Language updates noted above are effective for DOS on or after 10/31/2014) Added: Language for HCPCS codes A4217, A4450, A4452 when submitted without correct modifier	• Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A58231 - Response to Comments: Urological Supplies (DL33803)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

A52521 - Urological Supplies - Policy Article

Related National Coverage Documents

NCDs

N/A

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12/07/2023	01/01/2024 - N/A	Currently in Effect	You are here

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Keywords

N/A