

LCD for UROLOGICAL Supplies (L11566)

Contractor Information

Contractor Name

CIGNA Government Services

Contractor Number

18003

Contractor Type

DME MAC

LCD Information

LCD ID Number

L11566

LCD Title

UROLOGICAL Supplies

Contractor's Determination Number

URO

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CMS National Coverage Policy

CMS Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Section 230.17

Primary Geographic Jurisdiction

Alabama

Arkansas

Colorado

Florida

Georgia

Louisiana

Mississippi

North Carolina

New Mexico

Oklahoma

Puerto Rico

South Carolina

Tennessee
Texas
Virginia
Virgin Islands
West Virginia

Oversight Region

Region VI

DME Region LCD Covers

Jurisdiction C

Original Determination Effective Date

For services performed on or after 10/01/1993

Original Determination Ending Date

Revision Effective Date

For services performed on or after 04/01/2008

Revision Ending Date

Indications and Limitations of Coverage 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 an illness or injury or to improve the functioning of a malformed body member, and (3) meet all other applicable Medicare 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.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. 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.

GENERAL

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 patient's medical record and must be available upon request.

INDWELLING CATHETERS (A4311 - A4316, A4338 - 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 patient)
- 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 patient's medical record of the medical necessity for that catheter rather than a straight Foley type catheter with coating (such as recurrent encrustation, inability to pass a straight catheter, or sensitivity to latex). In addition, the particular catheter must be necessary for the patient. For example, use of a Coude (curved) tip indwelling catheter (A4340) in female patients is rarely medically necessary. Documentation of medical necessity may be requested. If documentation is requested and does not substantiate medical necessity, payment for A4340 will be based on the least costly medically appropriate alternative (A4338) and payment for A4344, A4312, or A4315 will be based on the least costly medically appropriate alternative (A4338, A4311, or A4314, respectively).

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, payment will be based on the least costly medically appropriate alternative (A4338, A4311, or A4314, respectively).

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 medically necessary.

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

URINARY DRAINAGE COLLECTION SYSTEM (A4314-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 medically 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 (#/mo.)

A4314 (1)

A4315 (1)

A4316 (1)

A4354 (1)

A4357 (2)

A4358 (2)

A5112 (1)

Code (#/3mo.)

A5102 (1)

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

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 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 medically necessary.

The medical necessity for drainage bags containing gel matrix or other material which are intended to be disposed of on a daily basis has not been established. Payment for this type of bag will be based on the allowance and usual frequency of change for the least costly medically appropriate alternative, code A4357.

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 patient'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 noncovered. 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 medically 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 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 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 medically necessary.

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 2 weeks is rarely medically necessary. The patient'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 patient 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 patient requires catheterization and the patient meets one of the following criteria (1-5):

1. The patient resides in a nursing facility,
2. The patient 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 patient has radiologically documented vesico-ureteral reflux while on a program of intermittent catheterization,
4. The patient is a spinal cord injured female with neurogenic bladder who is pregnant (for duration of pregnancy only),
5. The patient 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 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 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 5 white blood cells [WBCs] per high-powered field)

The following table represents the usual maximum number of supplies:

Code (#/mo.)
A4332 (200)

A4351 (200)

A4352 (200)

A4353 (200)

Refer to Coding Guidelines section of the related Policy Article 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.

Use of a Coude (curved) tip catheter (A4352) in female patients is rarely medically necessary. When a Coude tip catheter is used (either male or female patients), there must be documentation in the patient's medical record of the medical necessity for that catheter rather than a straight tip catheter (A4351). 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, payment will be based on the least costly medically appropriate alternative - (A4351).

EXTERNAL CATHETERS/URINARY COLLECTION DEVICES

Male external catheters (condom-type) or female external urinary collection devices are covered for patients 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 medically necessary when ordered for patients 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. Payment will be based on the least costly medically appropriate alternative if documentation does not substantiate medical necessity.

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 medically necessary.

MISCELLANEOUS SUPPLIES

Appliance cleaner (A5131) is covered when used to clean the inside of certain urinary collecting appliances (A5102, 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 3 months or sooner if the rubber/foam casing deteriorates.

Tape (A4450, A4452) which is used to secure an indwelling catheter to the patient'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 medically necessary unless the claim is accompanied by documentation justifying a larger quantity in the individual case.

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 medically necessary unless the claim is accompanied by documentation justifying a larger quantity in the individual case. 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, payment will be based on the allowance for the least costly medically appropriate alternative, A4333.

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; METAL 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

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

A4365 ADHESIVE REMOVER WIPES, ANY TYPE, PER 50

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

A4520 INCONTINENCE GARMENT, ANY TYPE, (E.G. BRIEF, DIAPER), EACH

A4554 DISPOSABLE UNDERPADS, ALL SIZES

A5102 BEDSIDE DRAINAGE BOTTLE WITH OR WITHOUT TUBING, RIGID OR EXPANDABLE, EACH

A5105 URINARY SUSPENSORY WITH LEG BAG, WITH OR WITHOUT TUBE, EACH

A5112 URINARY LEG BAG; LATEX

A5113 LEG STRAP; LATEX, REPLACEMENT ONLY, PER SET

A5114 LEG STRAP; FOAM OR FABRIC, REPLACEMENT ONLY, PER SET

A5131 APPLIANCE CLEANER, INCONTINENCE AND OSTOMY APPLIANCES, PER 16 OZ.

A5200

PERCUTANEOUS CATHETER/TUBE ANCHORING
DEVICE, ADHESIVE SKIN ATTACHMENT

A9270

NON-COVERED ITEM OR SERVICE

ICD-9 Codes that Support Medical Necessity

Not specified.

XX000

Not Applicable

Diagnoses that Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity

Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Not specified.

General 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 patient's medical records will reflect the need for the care provided. The patient's medical records include the physician'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.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order must include the type of supplies ordered and the approximate quantity to be used per unit of time.

If a supplier is billing for items, which are noncovered, this must be indicated on the claim. The recommended way of doing this is to add the GY modifier to the code.

Suppliers must add a KX modifier to a code only if the order indicates patient has permanent urinary incontinence or urinary retention, and if the item is a catheter, an external urinary collection device, or a supply used with one of these items. If the requirements for the KX modifier are not met, the KX modifier must not be used.

When billing for quantities of supplies greater than those described in the policy as the usual maximum amounts, the supplier must obtain information supporting the medical necessity for the higher utilization. This information must be retained in the supplier's file and be available upon request.

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

Appendices

Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision

Reserved for future use

Advisory Committee Meeting Notes

Start Date of Comment Period

04/30/1993

End Date of Comment Period

06/14/1993

Start Date of Notice Period

08/01/1993

Revision History Number

018

Revision History Explanation

Revision Effective Date: 04/01/2008

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised: Indications for intermittent catheterization

HCPCS CODES:

Revised: A5105 (Effective 01/01/2008)

APPENDICES:

Removed: Definitions.

Revision Effective Date: 03/01/2008

In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC CIGNA Government Services (18003) LCD L11517 from DME PSC TrustSolutions (77012) LCD L11517.

Revision Effective Date: 06/01/2007

In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007

INDICATIONS AND LIMITATIONS OF COVERAGE:

Removed: DMERC references

Removed: Reference to A4348

HCPCS CODES:

Revised: A4326, A5105

Deleted: A4348, A4359

DOCUMENTATION REQUIREMENTS:

Removed: DMERC references

Revision Effective Date: 03/01/2006

In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TrustSolutions (77012) from DMERC Palmetto GBA (00885).

Revision Effective Date: 01/01/2006

DOCUMENTATION REQUIREMENTS:

Revised: Requirements for high utilization.

Revision Effective Date: 04/01/2005

LMRP converted to LCD and Policy Article

HCPCS CODES AND MODIFIERS:

Deleted: A4324, A4325, A4347, A4521-A4538

Added: A4349, A4520

Revised: A4332

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added references to new codes and removed deleted codes.

Revision Effective Date: 04/01/2004

HCPCS CODES AND MODIFIERS:

Added: A4217

Deleted: A4319, A4323

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added references to new code and removed deleted codes.

CODING GUIDELINES:

Added: A4217 to codes requiring AU modifier.

Revision Effective Date: 04/01/2003

HCPCS CODES AND MODIFIERS:

Added: AU, EY modifiers, A4450, A4452, A4521-A4538

Deleted: K0572, K0573, A4360

INDICATIONS AND LIMITATIONS OF COVERAGE:

Adds standard language concerning coverage of items without an order and use of the AU modifier

CODING GUIDELINES:

Added: coding definitions from "LMRP Description" section

DOCUMENTATION REQUIREMENTS:

Adds standard language concerning use of EY modifier for items without an order

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

04/01/2002 - Added HCPCS codes A4319, A4324, 4325, A4331-A4333, A4348, A4360, K0572, K0573. Deleted from policy HCPCS codes A4329, A4359, A4554, A5149, A6265, K0280, K0281, K0407-K0409, K0411. Added use of GY modifier for non-covered conditions. Replaced ZX with KX modifier.

04/01/2000 - In the Winter 1999 Region D Supplier Manual update, verbiage was inadvertently omitted from the Urological Supplies regional medical review policy (RMRP) revision. The verbiage below was present in previous versions of the policy but was absent in the latest revision published. Coverage and Payment Rules for indwelling catheters (IX-37), indications #3 and #4 for non-routine changes should read:

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 at intervals of less than one per month

The revision also reflects updates to the Coding Guidelines (IX - 37.5) which clarify the previously published payment policy for HCPCS code A5200 (Percutaneous catheter/tube anchoring device, adhesive skin attachment). (See Winter 1998 DMERC Dialogue, page 12.)

01/01/2000 – Added HCPCS codes A5200 and A6265. Added reasonable and necessary language in Coverage and Payment Rules section. Added language for A4340 in Coverage and Payment Rules section.

03/01/1998 – Deleted certain HCPCS K and XX codes.

04/01/1996 – Updated utilization table.

07/01/1995 – Added HCPCS codes. Renamed policy from Incontinence Appliances and Care Supplies to Urological Supplies. Entire policy revised.

Reason for Change

Last Reviewed On Date

Related Documents

Article(s)

A25620 - Urological Supplies - Policy Article - Effective January 2008

LCD Attachments

There are no attachments for this LCD.