Incontinence Control Devices (NCD 230.10)

Guideline Number: MPG153.06
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Terms and Conditions

Table of Contents Page

Related Medicare Advantage Coverage Summary

- Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments

Policy Summary

See Purpose

Overview

Mechanical/Hydraulic Incontinence Control Devices

Mechanical/hydraulic incontinence control devices are accepted as safe and effective in the management of urinary incontinence in patients with permanent neurologic and anatomic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. Such a device is covered when its use is reasonable and necessary for the individual patient. The materials used and the success rate may vary somewhat from device to device.

Collagen Implant

A collagen implant is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). Collagen implant is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra. ISD is a cause of stress urinary incontinence in which the urethral sphincter is unable to contract and generate sufficient resistance in the bladder, especially during stress maneuvers.

Prior to collagen implant therapy, a skin test for collagen sensitivity must be administered and evaluated over a 4 week period.

In male patients, the evaluation must include a complete history and physical examination and a simple cystometrogram to determine that the bladder fills and stores properly. The patient then is asked to stand upright with a full bladder and to cough or otherwise exert abdominal pressure on his bladder. If the patient leaks, the diagnosis of ISD is established.

In female patients, the evaluation must include a complete history and physical examination (including a pelvic exam) and a simple cystometrogram to rule out abnormalities of urethral support and abnormalities of bladder compliance. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H2O, is defined as the intra-abdominal pressure at which leakage occurs from the bladder (around a catheter) when the bladder has been filled with a minimum of 150 cc fluid. If the patient has an ALLP of less than 100 cm H2O, the diagnosis of ISD is established.

To use a collagen implant, physicians must complete a collagen implant training program and must have urology training in the use of a cystoscope.

inFlow Device

When inserting an inFlow™ device or using urological supplies in a treating practitioner's office as part of a professional service that is billed to Medicare, the supplies are considered incident to the professional services of the health care practitioner and are not separately payable. Claims for these devices must not be submitted. Claims for the professional service, which includes the device, must be submitted to the A/B MAC.

If additional inFlow devices or urological supplies are sent home with the beneficiary, claims for these devices may be billed to the DME MAC only if the beneficiary's condition meets the definition of permanence as defined in the Prosthetic Device benefit. In this situation, use the place of service corresponding to the beneficiary's residence; Place of Service Office (POS) 11 must not be used. If the beneficiary's condition is expected to be temporary, urological supplies may not be billed. In this situation, they are considered as supplies provided incident to a treating practitioner's service and payment is included in the allowance for the treating practitioner services, which are processed by the A/B MAC.

Guidelines

Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD:

- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H2O or less;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male or female patients with congenital sphincter weakness secondary to conditions such as Myelomeningocele or Epispadias; and
- Male patients following trauma, including prostatectomy and/or radiation.

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Patients who have a reoccurrence of incontinence following successful treatment with collagen implants in the past (e.g., 6-12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification.

Initial Covergae for the inFLOW Device

The inFlow™ device 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:

- An in-person encounter by the treating practitioner with documentation that urinary symptoms are improved; and,
- 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.

For claims with date of service (DOS) July 26, 2020 through September 30, 2020, the inFlow Intraurethral Valve-Pump system (Vesiflo, Inc.) must be billed using HCPCS code A4335 (Incontinence Supply; Miscellaneous). Code A4335 is billed as 1 unit of service (UOS) at initial issue, and is all inclusive (catheter, activator). Code A4335 must also be used on separate claim lines for replacement of any of the individual components of the inFlow Intraurethral Valve-Pump system (catheter, activator).

For claims with DOS on or after October 1, 2020 the inFlow system must be billed using HCPCS code(s): K1010 (Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each), K1011 (Activation device for intraurethral drainage device with valve, replacement only, each) and/or K1012 (Charger and base station for intraurethral activation device, replacement only).

The initial sizing and insertion of the inFlow device is typically performed by the treating practitioner in their office, as a service incident to the practitioner's office visit. Claims for these services, billed to the DME MAC, will be denied as wrong jurisdiction. Replacement of the K1010 device is typically done by a trained caregiver at home, and may be billed on a monthly basis. Since K1011 and K1012 are provided at the time of initial issue to the beneficiary, these may only be billed to the DME MAC as a replacement.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
K1010	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
K1011	Activation device for intraurethral drainage device with valve, replacement only, each
K1012	Charger and base station for intraurethral activation device, replacement only
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
Q3031	Collagen skin test (Bundled code)

Diagnosis Code	Description
N36.42	Intrinsic sphincter deficiency (ISD)

References

CMS National Coverage Determinations (NCDs)

NCD 230.10 Incontinence Control Devices

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	Medicare Part A	Medicare Part B
N/A	A52374 Collagen Implantation for Urinary Incontinence - Medical Policy Article	NGS	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI

LCD	Article	Contractor	DME MAC
L33803 Urological Supplies	A52521 Urological Supplies - Policy Article	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY

CMS Benefit Policy Manual

Chapter 15 § 120 Prosthetic Devices

CMS Claims Processing Manual

Chapter 20 § 10.1.2 Prosthetic Devices - Coverage Definition

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update • Reformatted policy; transferred content to new template

01/13/2021	Policy Summary
	inFlow Device (new to policy)
	• Added language to indicate:
	  ○ When inserting an inFlow™ device or using urological supplies in a treating practitioner's office as part of a professional service that is billed to Medicare, the supplies are considered incident to the professional services of the health care practitioner and are not separately payable; claims for these devices must not be submitted
	  ○ Claims for the professional service, which includes the device, must be submitted to the A/B MAC
	  ○ If additional inFlow devices or urological supplies are sent home with the beneficiary, claims for these devices may be billed to the DME MAC only if the beneficiary's condition meets the definition of permanence as defined in the Prosthetic Device benefit; in this situation, use the place of service corresponding to the beneficiary's residence; Place of Service Office (POS) 11 must not be used
	  ○ If the beneficiary's condition is expected to be temporary, urological supplies may not be billed; in this situation, they are considered as supplies provided incident to a treating practitioner's service and payment is included in the allowance for the treating practitioner services, which are processed by the A/B MAC
	Initial Coverage for the inFLOW Device (new to policy)
	• Added language to indicate the inFlow™ device (A4335) [incontinence supply; miscellaneous (bundled)] 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 (new to policy)
	• Added language to indicate:

Date	Summary of Changes
	○ 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: ▪ An in-person encounter by the treating practitioner with documentation that urinary symptoms are improved; and, ▪ 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 the criteria 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 ○ For claims with date of service (DOS) Jul. 26, 2020 through Sep. 30, 2020, the inFlow Intraurethral Valve-Pump system (Vesiflo, Inc.) must be billed using HCPCS code A4335 (Incontinence Supply; Miscellaneous) ▪ Code A4335 is billed as 1 unit of service (UOS) at initial issue, and is all inclusive (catheter, activator) ▪ Code A4335 must also be used on separate claim lines for replacement of any of the individual components of the inFlow Intraurethral Valve-Pump system (catheter, activator) ○ For claims with DOS on or after Oct. 1, 2020, the inFlow system must be billed using HCPCS code(s): ▪ K1010 (Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each) ▪ K1011 (Activation device for intraurethral drainage device with valve, replacement only, each) and/or ▪ K1012 (Charger and base station for intraurethral activation device, replacement only) ○ The initial sizing and insertion of the inFlow device is typically performed by the treating practitioner in their office, as a service incident to the practitioner's office visit ▪ Claims for these services, billed to the DME MAC, will be denied as wrong jurisdiction ▪ Replacement of the K1010 device is typically done by a trained caregiver at home and may be billed on a monthly basis ▪ Since K1011 and K1012 are provided at the time of initial issue to the beneficiary, these may only be billed to the DME MAC as a replacement **Applicable Codes** • Added HCPCS codes K1010, K1011, and K1012 **Supporting Information** • Updated *References* section to reflect the most current information • Archived previous policy version MPG153.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support

coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.