

## Incontinence Control Devices (NCD 230.10)

<b>Policy Number</b>	230.10	<b>Approved By</b>	UnitedHealthcare Medicare Reimbursement Policy Committee	<b>Current Approval Date</b>	01/08/2014
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### IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies 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.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy. This information is intended to serve only as a general resource regarding UnitedHealthcare’s reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee’s benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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### Table of Contents

<b>Application</b> .....	<b>1</b>
<b>Summary</b> .....	<b>2</b>
Overview .....	2
Reimbursement Guidelines .....	2
<b>CPT/HCPCS Codes</b> .....	<b>3</b>
<b>References Included (but not limited to):</b> .....	<b>3</b>
CMS NCD .....	3
CMS Article(s) .....	3
UnitedHealthcare Medicare Advantage Coverage Summaries .....	3
<b>History</b> .....	<b>3</b>

### Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the

## Incontinence Control Devices (NCD 230.10)

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### Summary

#### Overview

##### A. 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 anatomic and neurologic dysfunctions of the bladder. This class of devices achieves control of urination by compression of the urethra. The materials used and the success rate may vary somewhat from device to device. Such a device is covered when its use is reasonable and necessary for the individual patient.

##### B. Collagen Implant

A collagen implant, which is injected into the submucosal tissues of the urethra and/or the bladder neck and into tissues adjacent to the urethra, is a prosthetic device used in the treatment of stress urinary incontinence resulting from intrinsic sphincter deficiency (ISD). 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 bladder compliance and abnormalities of urethral support. Following that determination, an abdominal leak point pressure (ALLP) test is performed. Leak point pressure, stated in cm H<sub>2</sub>O, 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 H<sub>2</sub>O, the diagnosis of ISD is established.

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

#### Reimbursement 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:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H<sub>2</sub>O or less.

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

## Incontinence Control Devices (NCD 230.10)

sessions may be allowed but must be supported by medical justification.

### CPT/HCPCS Codes

Code	Description
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck
52327 *New	Cystourethroscopy (including ureteral catheterization); with subureteric injection of implant material
53445	Insertion of inflatable urethral/bladder neck sphincter, including placement of pump, reservoir, and cuff
L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies
Q3031	Collagen skin test (Bundled code)

### References Included (but not limited to):

#### CMS NCD

NCD 230.10 Incontinence Control Devices

#### CMS Article(s)

Numerous Articles

#### UnitedHealthcare Medicare Advantage Coverage Summaries

Incontinence - Urinary and Fecal Incontinence, Diagnosis and Treatments

### History

Date	Revisions
01/08/2014	Administrative updates
03/13/2013	No change
03/28/2012	Administrative updates
10/12/2011	Administrative updates
09/08/2010	Administrative updates