**Incontinence Control Devices (NCD 230.10)**

**Guideline Number:** MPG153.04  
**Approval Date:** January 09, 2019

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**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.

**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.

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Related Medicare Advantage Coverage Summary

- Incontinence: Urinary and Fecal Incontinence, Diagnosis and Treatments
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.

**APPLICABLE CODES**

The following list(s) of 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.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>L8603</td>
<td>Injectable bulking agent, collagen implant, urinary tract, 2.5 ml syringe, includes shipping and necessary supplies</td>
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<tr>
<td>Q3031</td>
<td>Collagen skin test (Bundled code)</td>
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<tr>
<th>ICD-10 Diagnosis Code</th>
<th>Description</th>
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<tr>
<td>N36.42</td>
<td>Intrinsic sphincter deficiency (ISD)</td>
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**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 LCDs, NCDs, 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.

**REFERENCES**

**CMS National Coverage Determinations (NCDs)**

NCD 230.10 Incontinence Control Devices

**CMS Articles**

<table>
<thead>
<tr>
<th>Article</th>
<th>Medicare Part A</th>
<th>Medicare Part B</th>
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</thead>
<tbody>
<tr>
<td>A52374 (Collagen Implantation for Urinary Incontinence - Medical Policy Article) NGS</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
<td>CT, IL, MA, ME, MN, NH, NY, RI, VT, WI</td>
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**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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>01/09/2019</td>
<td>• Annual review</td>
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</table>
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.