National Coverage Determination (NCD)

Incontinence Control Devices

230.10

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Tracking Information

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230.10

Manual Section Title
Incontinence Control Devices

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1

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10/07/1996

Description Information

Benefit Category
Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Indications and Limitations of Coverage
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 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 have urology training in the use of a cystoscope and must complete a collagen implant training program.

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 H2O 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 sessions may be allowed but must be supported by medical justification.

Cross Reference

See the Medicare Benefit Policy Manual, Chapter 15

Transmittal Information

Transmittal Number

89

Revision History

09/1996 - Revised coverage guidelines. Effective date 10/07/1996. (TN 89)

06/1994 - Specified patient selection criteria that must be met before implant product or procedure can be covered. Effective date 07/11/1994. (TN 70)

Additional Information

Other Versions

Title	Version	Effective Between	
Incontinence Control Devices	1	10/07/1996 - N/A	You are here