



MASSACHUSETTS

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## Medical Policy

# Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

### Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

### Policy Number: 471

BCBSA Reference Number: 7.01.19

NCD/LCD: National Coverage Determination (NCD) for Incontinence Control Devices (230.10)

### Related Policies

- Biofeedback as a Treatment of Fecal Incontinence or Constipation [#308](#)
- Biofeedback as a Treatment of Urinary Incontinence [#173](#)
- Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence [#470](#)
- Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction, [#583](#)
- Posterior Tibial Nerve Stimulation for Voiding Dysfunction [#583](#)
- Sacral Nerve Neuromodulation/Stimulation [#153](#)
- Transanal Radiofrequency Treatment of Fecal Incontinence [#309](#)

### Policy

#### Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

##### Urinary Incontinence

The use of carbon-coated spheres, calcium hydroxylapatite, or polydimethylsiloxane may be considered [MEDICALLY NECESSARY](#) to treat stress urinary incontinence in men and women who have failed appropriate conservative therapy.

The use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, adipose-derived stem cells), autologous fat, and autologous ear chondrocytes to treat stress urinary incontinence is considered [INVESTIGATIONAL](#).

The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence is considered [INVESTIGATIONAL](#).

The use of periurethral bulking agents to treat urge urinary incontinence is considered [INVESTIGATIONAL](#).

##### Fecal Incontinence

The use of perianal bulking agents to treat fecal incontinence is considered [INVESTIGATIONAL](#).

## Medicare HMO Blue<sup>SM</sup> and Medicare PPO Blue<sup>SM</sup> Members

### Urinary Incontinence

BCBSMA covers collagen implants, and the procedure to inject it for the following indication(s) for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:

- 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.

Medical necessity criteria and coding guidance can be found through the link below.

### [National Coverage Determinations \(NCDs\)](#)

National Coverage Determination (NCD) for Incontinence Control Devices (230.10)

**Note:** To review the specific NCD, please remember to click “accept” on the CMS licensing agreement at the bottom of the CMS webpage.

### Fecal Incontinence

The use of perianal bulking agents to treat fecal incontinence is considered [INVESTIGATIONAL](#).

## Prior Authorization Information

### Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

### Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is <b>not required</b> .
Commercial PPO and Indemnity	Prior authorization is <b>not required</b> .
Medicare HMO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .
Medicare PPO Blue <sup>SM</sup>	Prior authorization is <b>not required</b> .

## CPT Codes / HCPCS Codes / ICD Codes

*Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

*Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.*

The above **medical necessity criteria MUST** be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

### CPT Codes

CPT codes:	Code Description
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

## HCPCS Codes

HCPCS codes:	Code Description
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

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and HCPCS codes above if medical necessity criteria are met:

## ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
N36.43	Combined hypermobility of urethra and intrinsic sphincter deficiency
N39.3	Stress incontinence (female) (male)
N39.42	Incontinence without sensory awareness
N39.43	Post-void dribbling
N39.44	Nocturnal enuresis
N39.45	Continuous leakage
N39.490	Overflow incontinence
N39.498	Other specified urinary incontinence
R32	Unspecified urinary incontinence

The following CPT and HCPCS codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

## HCPCS Codes

HCPCS codes:	Code Description
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

## Description

### Incontinence

Incontinence, especially urinary, is a common condition and can have a substantial impact on quality of life. Estimates from the National Center for Health Statistics have suggested that, among noninstitutionalized persons 65 years of age and older, 44% have reported issues with urinary incontinence and 17% issues with fecal incontinence.<sup>1</sup>

### Treatment

#### Urinary Incontinence

Injectable bulking agents are space-filling substances used to increase tissue bulk. When used to treat stress urinary incontinence, bulking agents are injected periurethrally to increase tissue bulk and thereby increase resistance to the outflow of urine. The bulking agent is injected into the periurethral tissue as a liquid that solidifies into a spongy material to bulk the urethral wall. Bulking agents may be injected over a course of several treatments until the desired effect is achieved. Periurethral bulking agents have been widely used for incontinence in women. Men have also been treated, typically those with postprostatectomy incontinence.

After the success of periurethral bulking agents for treating stress urinary incontinence, bulking agents injected into the anal canal have been proposed to treat fecal incontinence. In particular, bulking agents are a potential treatment for passive fecal incontinence associated with internal anal sphincter dysfunction. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Current treatment options for fecal incontinence include conservative measures (eg, dietary changes, pharmacotherapy, pelvic floor muscle exercises), sacral nerve stimulation, and surgical interventions to correct an underlying problem.

Key factors in determining the optimal product are biocompatibility, durability, and absence of migration. A number of periurethral bulking agents to treat urinary incontinence have been cleared for marketing by the U.S. Food and Drug Administration (FDA); however, products developed to date have not necessarily met all criteria of the ideal bulking agents. The first FDA approved product was cross-linked collagen (eg, Contigen). The agent was found to be absorbed over time and symptoms could recur, requiring additional injections. Contigen production was discontinued in 2011. Other periurethral bulking agents cleared by FDA for urinary incontinence include carbon-coated beads (eg, Durasphere), spherical particles of calcium hydroxylapatite (CaHA) in a gel carrier (Coaptite), polydimethylsiloxane (silicone, Macroplastique), and ethylene vinyl alcohol copolymer implants (eg, Tegress, formerly Uryx). Tegress was voluntarily removed from the market due to safety concerns.

### **Fecal Incontinence**

Several agents identical or similar to those used for urinary incontinence (eg, Durasphere, silicone biomaterial) have been studied for the treatment of fecal incontinence. To date, only 1 bulking agent has been approved by FDA for fecal incontinence. This formulation is a non-animal-stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx), marketed by Q-Med as Solesta. A hyaluronic acid/dextranomer formulation (Deflux™) from the same company has been commercially available for a number of years for the treatment of vesicoureteral reflux in children (see evidence review 7.01.102 on the treatment of vesicoureteral reflux with bulking agents).

Autologous fat and autologous ear chondrocytes have also been used as periurethral bulking agents; autologous substances do not require FDA approval. Polytetrafluoroethylene (Teflon) has been investigated as an implant material but does not have FDA approval. A more recently explored alternative is cellular therapy with myoblasts, fibroblasts, or stem cells (muscle-derived or adipose-derived). In addition to their use as periurethral bulking agents, it has been hypothesized that transplanted stem cells would undergo self-renewal and multipotent differentiation, which could result in regeneration of the sphincter and its neural connections.

### **Summary**

Bulking agents are injectable substances used to increase tissue bulk. They can be injected periurethrally to treat urinary incontinence and perianally to treat fecal incontinence. The U.S. Food and Drug Administration (FDA) has approved several bulking agent products for treating urinary incontinence and one for treating fecal incontinence.

For individuals who have stress urinary incontinence who receive injectable bulking agents, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Studies have shown that cross-linked collagen improves the net health outcome (ie, it is effective in some patients who have failed conservative treatment with fewer adverse events than surgery), although products that cross-link in such a way are no longer commercially available. There is evidence that the FDA approved carbon-coated spheres, calcium hydroxylapatite, and polydimethylsiloxane have efficacy for treating incontinence, and further that they produce outcomes with a safety profile similar to cross-linked collagen. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have fecal incontinence who receive injectable bulking agents, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. A comparative effectiveness review from the Agency for Healthcare Research and Quality evaluated 2 RCTs with the FDA approved product NASHA Dx (Solesta) and 2

RCTs with Durasphere (off-label in the United States). One RCT comparing NASHA Dx with sham found that NASHA Dx improved some outcomes but not others. The other RCT did not find a significant difference in efficacy between NASHA Dx and biofeedback. Two additional RCTs evaluating Durasphere found only short-term improvements in fecal incontinence severity. Controlled trials with longer follow-up are needed to determine the durability of any treatment effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Policy History

Date	Action
10/2020	BCBSA National medical policy review. Description, summary, and references updated. Policy statements unchanged.
1/2020	Clarified coding information.
10/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
11/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified. 11/2018
10/2018	BCBSA National medical policy review. No changes to policy statements. New references added. Background and summary clarified.
9/2017	New references added from BCBSA National medical policy.
10/2016	New references added from BCBSA National medical policy.
8/2015	BCBSA National medical policy review. Contigen removed from medically necessary statement as it is no longer available. Clarified coding information. Effective 8/1/2015.
1/2015	Clarified coding information.
7/2014	Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.
5/2014	New references from BCBSA National medical policy.
11/2013	Removed HCPCS codes L8604, Q3031 and diagnosis code 788.33 as they do not meet the intent of the policy.
9/2013	BCBSA National medical policy review. New investigational indications described. Effective 9/1/2013.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
1/2010	BCBSA National medical policy review. No changes to policy statements.
6/2009	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
6/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
5/2008	BCBSA National medical policy review. No changes to policy statements.
8/2007	BCBSA National medical policy review. Changes to policy statements.

## Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

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