Medical Coverage Policy | Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

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OVERVIEW
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.

This policy is applicable to Commercial Products only. For Medicare Advantage Plans, see Related Policies section.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Commercial Products

Urinary Incontinence
The use of carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel, 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 (eg, myoblasts, fibroblasts, muscle-derived stem cells, adipose-derived stem cells), autologous fat, and autologous ear chondrocytes, to treat stress urinary incontinence is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of any other periurethral bulking agent, including, but not limited to Teflon, to treat stress urinary incontinence is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

The use of periurethral bulking agents to treat urge urinary incontinence is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Fecal Incontinence
The use of perianal bulking agents to treat fecal incontinence is considered not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND

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.

Definition of Failed Appropriate Conservative Therapy for Stress Urinary Incontinence (SUI)

- Treatments used for at least 3 months.
- Includes pelvic floor muscle exercises and behavioral changes, such as fluid management and moderation of physical activities that provoke incontinence.
- Additional options include intravaginal estrogen therapy, use of a pessary, and treatment of other underlying causes of incontinence in individuals amenable to these treatments.

Treatment of Urinary Incontinence

Injectable bulking agents are space-filling substances used to increase tissue bulk. When used to treat SUI, 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.

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 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®), cross-linked polyacrylamide hydrogel (Bulkamid®), and ethylene vinyl alcohol copolymer implants (eg, Tegress®, formerly Uryx). Tegress was voluntarily removed from the market due to safety concerns.

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 is hypothesized that transplanted stem cells would undergo self-renewal and multipotent differentiation, which could result in regeneration of the sphincter and its neural connections.

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. The trials vary by bulking agents used and comparator interventions (eg, placebo, conservative therapy, surgical procedure, another bulking agent). Due to this heterogeneity across studies, and the small number of studies in each category, Cochrane reviewers were unable to draw specific conclusions about the efficacy of specific bulking agents compared with alternative treatments. Additionally, authors of another recent systematic review concluded that bulking agents were less effective than surgical procedures regarding subjective improvement after treatment, with no difference between the interventions with regard to complications. 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 FDA-approved carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel, 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 an improvement in the net health outcome.

Fecal Incontinence
After the success of periurethral bulking agents for treating SUI, 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.

Several agents identical to 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) and is 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

For individuals who have fecal 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. 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 that the technology results in an improvement in the net health outcome.

CODING

Commercial Products

Urinary Incontinence
The following HCPCS codes are medically necessary when filed with ICD-10 code:
N39.3 Stress incontinence (female) (male)

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, 1ml syringe, includes shipping and necessary supplies

There are no specific HCPCS codes for bulking agents or therapies that are identified in the Policy Statement as not medically necessary. Claims for these services should be filed with an unlisted HCPCS code.

Fecal Incontinence
The following HCPCS code is not medically necessary:
L8605 Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

RELATED POLICIES
Medicare Advantage Plans National and Local Coverage Determinations

PUBLISHED
Provider Update, February 2023
Provider Update, March 2022
Provider Update, November 2020
Provider Update, December 2019
Provider Update, February 2019

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