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 1 for treating fecal incontinence.
This policy is applicable to Commercial Products only. For Blue CHiP for Medicare, see related policy section.

MEDICAL CRITERIA
Not applicable.

PRIOR AUTHORIZATION
Not applicable.

POLICY STATEMENT
Commercial Products

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 (eg, myoblasts, fibroblasts, muscle-derived stem cells, adipose-derived stem cells), autologous fat, autologous ear chondrocytes, or any other periurethral bulking agent not listed above, including, but not limited to Teflon® **to** treat stress urinary incontinence is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

The use of periurethral bulking agents to treat urge urinary incontinence is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Fecal Incontinence
The use of perianal bulking agents to treat fecal incontinence is considered is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the appropriate Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND
Injectable bulking agents are space-filling substances used to increase tissue bulk. When used to treat stress urinary incontinence (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.

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.

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), and ethylene vinyl alcohol copolymer implants (eg, Tegress, formerly Uryx). Tegress was voluntarily removed from the market due to safety concerns.

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 (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 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 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 outcome measures 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 important to determine the durability of any treatment effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

CODING

Commercial Products

The following codes are not medically necessary:

0377T Anoscopy with directed submucosal injection of bulking agent for fecal incontinence

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

The following codes are medically necessary when filed with 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, 1 ml syringe, includes shipping and necessary supplies

There no specific HCPCS for bulking agents that are not medically necessary. Claims should be filed with an unlisted HCPCS code

RELATED POLICIES
BlueCHiP for Medicare National and Local Coverage Determinations Policy

PUBLISHED
Provider Update October 2017
Provider Update, January 2017
Provider Update Dec 2015
Provider Update, July 2014
Policy Update, April 2013

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