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

EFFECTIVE DATE: 02|5|2013
POLICY LAST UPDATED: 09|03|2020

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 BlueCHiP 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 necessa
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 November 2020
Provider Update December 2019
Provider Update February 2019
Provider Update October 2017
Provider Update January 2017

REFERENCES:

1. Gorina Y, Schappert S, Bercovitz A, et al. Prevalence of incontinence among older Americans. Vital Health Stat 3. Jun 2014(36):1-33. PMID 24964267.
2. Kirchin V, Page T, Keegan PE, et al. Urethral injection therapy for urinary incontinence in women. Cochrane Database Syst Rev. Feb 15 2012;2(2):CD003881. PMID 22336797.
3. Davila GW. Nonsurgical outpatient therapies for the management of female stress urinary incontinence: long- term effectiveness and durability. Adv Urol. 2011;2011:176498. PMID 21738529.
4. Agency for Health Care Policy and Research. Clinical Practice Guideline. Urinary Incontinence in Adults. Rockville, MD: Department of Health and Human Services; 1996.
5. Corcos J, Collet JP, Shapiro S, et al. Multicenter randomized clinical trial comparing surgery and collagen injections for treatment of female stress urinary incontinence. Urology. May 2005;65(5):898-904. PMID 15882720.
6. Lightner D, Calvosa C, Andersen R, et al. A new injectable bulking agent for treatment of stress urinary incontinence: results of a multicenter, randomized, controlled, double-blind study of Durasphere. Urology. Jul 2001;58(1):12-15. PMID 11445471.
7. Hurtado E, McCrery R, Appell R. The safety and efficacy of ethylene vinyl alcohol copolymer as an intra-urethral bulking agent in women with intrinsic urethral deficiency. Int Urogynecol J Pelvic Floor Dysfunct. Aug 2007;18(8):869-873. PMID 17103121.
8. Food and Drug Administration. Summary of Safety and Effectiveness: URYX Urethral Bulking Agent. 2004; https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030030b.pdf. Accessed August 29, 2019.
9. Mayer RD, Dmochowski RR, Appell RA, et al. Multicenter prospective randomized 52-week trial of calcium hydroxylapatite versus bovine dermal collagen for treatment of stress urinary incontinence. Urology. May 2007;69(5):876-880. PMID 17482925.
10. Ghoniem G, Corcos J, Comiter C, et al. Cross-linked polydimethylsiloxane injection for female stress urinary incontinence: results of a multicenter, randomized, controlled, single-blind study. J Urol. Jan 2009;181(1):204- 210. PMID 19013613.
11. Ghoniem G, Corcos J, Comiter C, et al. Durability of urethral bulking agent injection for female stress urinary incontinence: 2-year multicenter study results. J Urol. Apr 2010;183(4):1444-1449. PMID 20171691.
12. Lightner D, Rovner E, Corcos J, et al. Randomized controlled multisite trial of injected bulking agents for women with intrinsic sphincter deficiency: mid-urethral injection of Zuidex via the Implacer versus proximal urethral injection of Contigen cystoscopically. Urology. Oct 2009;74(4):771-775. PMID 19660800.
13. Chapple CR, Haab F, Cervigni M, et al. An open, multicentre study of NASHA/Dx Gel (Zuidex) for the treatment of stress urinary incontinence. Eur Urol. Sep 2005;48(3):488-494. PMID 15967568.

14. Lone F, Sultan AH, Thakar R. Long-term outcome of transurethral injection of hyaluronic acid/dextranomer (NASHA/Dx gel) for the treatment of stress urinary incontinence (SUI). Int Urogynecol J. Nov 2010;21(11):1359- 1364. PMID 20571764.
15. Sokol ER, Karram MM, Dmochowski R. Efficacy and safety of polyacrylamide hydrogel for the treatment of female stress incontinence: a randomized, prospective, multicenter North American study. J Urol. Sep 2014;192(3):843-849. PMID 24704117.
16. Pai A, Al-Singary W. Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid((R))) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Cent European J Urol. Feb 2015;68(4):428-433. PMID 26855795.
17. Lose G, Sorensen HC, Axelsen SM, et al. An open multicenter study of polyacrylamide hydrogel (Bulkamid(R)) for female stress and mixed urinary incontinence. Int Urogynecol J. Dec 2010;21(12):1471-1477. PMID 20645077.
18. Leone Roberti Maggiore U, Alessandri F, Medica M, et al. Outpatient periurethral injections of polyacrylamide hydrogel for the treatment of female stress urinary incontinence: effectiveness and safety. Arch Gynecol Obstet. Jul 2013;288(1):131-137. PMID 23371485.
19. Mouritsen L, Lose G, Moller-Bek K. Long-term follow-up after urethral injection with polyacrylamide hydrogel for female stress incontinence. Acta Obstet Gynecol Scand. Feb 2014;93(2):209-212. PMID 24372312.
20. Lee PE, Kung RC, Drutz HP. Periurethral autologous fat injection as treatment for female stress urinary incontinence: a randomized double-blind controlled trial. J Urol. Jan 2001;165(1):153-158. PMID 11125386.
21. Bent AE, Tutrone RT, McLennan MT, et al. Treatment of intrinsic sphincter deficiency using autologous ear chondrocytes as a bulking agent. Neurourol Urodyn. 2001;20(2):157-165. PMID 11170190.
22. Strasser H, Marksteiner R, Margreiter E, et al. Autologous myoblasts and fibroblasts versus collagen for treatment of stress urinary incontinence in women: a randomised controlled trial. Lancet. Jun 30 2007;369(9580):2179-2186. PMID 17604800.
23. Kleinert S, Horton R. Retraction--autologous myoblasts and fibroblasts versus collagen [corrected] for treatment of stress urinary incontinence in women: a [corrected] randomised controlled trial. Lancet. Sep 6 2008;372(9641):789-790. PMID 18774408.
24. Peters KM, Dmochowski RR, Carr LK, et al. Autologous muscle derived cells for treatment of stress urinary incontinence in women. J Urol. Aug 2014;192(2):469-476. PMID 24582537.
25. Forte ML, Andrade KE, Butler M, et al. Treatments for Fecal Incontinence (Comparative Effectiveness Review No. 165). Rockville, MD: Agency for Healthcare Research and Quality; 2016.
26. Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. Cochrane Database Syst Rev. Feb 28 2013;2(2):CD007959. PMID 23450581.
27. Hussain ZI, Lim M, Stojkovic SG. Systematic review of perianal implants in the treatment of faecal incontinence. Br J Surg. Nov 2011;98(11):1526-1536. PMID 21964680.
28. Leung FW. Treatment of fecal incontinence - review of observational studies (OS) and randomized controlled trials (RCT) related to injection of bulking agent into peri-anal tissue. J Interv Gastroenterol. Oct 2011;1(4):202- 206. PMID 22586538.
29. Graf W, Mellgren A, Matzel KE, et al. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. Lancet. Mar 19 2011;377(9770):997-1003. PMID 21420555.
30. Dehli T, Stordahl A, Vatten LJ, et al. Sphincter training or anal injections of dextranomer for treatment of anal incontinence: a randomized trial. Scand J Gastroenterol. Mar 2013;48(3):302-310. PMID 23298304.
31. Morris OJ, Smith S, Draganic B. Comparison of bulking agents in the treatment of fecal incontinence: a prospective randomized clinical trial. Tech Coloproctol. Oct 2013;17(5):517-523. PMID 23525964.
32. La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of faecal incontinence. Colorectal Dis. May 2013;15(5):569-574. PMID 23374680.
33. Kobashi KC, Albo ME, Dmochowski RR, et al. Surgical treatment of female stress urinary incontinence: AUA/SUFU Guideline. J Urol. Oct 2017;198(4):875-883. PMID 28625508.

34. Chapple CR, Cruz F, Deffieux X, et al. Consensus Statement of the European Urology Association and the European Urogynaecological Association on the Use of Implanted Materials for Treating Pelvic Organ Prolapse and Stress Urinary Incontinence. Eur Urol. Sep 2017;72(3):424-431. PMID 28413126.
35. Lovatsis D, Easton W, Wilkie D, et al. Guidelines for the evaluation and treatment of recurrent urinary incontinence following pelvic floor surgery. J Obstet Gynaecol Can. Sep 2010;32(9):893-904. PMID 21050525.
36. National Institute for Health and Care Excellence (NICE). Urinary incontinence and pelvic organ prolapse in women: management [NG123]. 2019; https://www.nice.org.uk/guidance/ng123. Accessed August 29, 2019.
37. American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. May 2016;127(5):e66-81. PMID 27548423.
38. Paquette IM, Varma MG, Kaiser AM, et al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. Dis Colon Rectum. Jul 2015;58(7):623-636. PMID 26200676.
39. National Institute for Health and Care Excellence (NICE). Injectable bulking agents for faecal incontinence [IPG210]. 2007; https://www.nice.org.uk/guidance/ipg210/chapter/1-guidance. Accessed August 29, 2019.
40. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Incontinence Control Devices (230.10). 1996; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=241&ncdver=1&DocID=230.10&bc=gAAAAAgAAAAAAA%3D%3D&. Accessed August 29, 2019.