09-A9000-03

Original Effective Date: 02/15/12

Reviewed: 10/26/23

Revised: 11/15/23

Subject: Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

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 post-prostatectomy 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.

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.

POSITION STATEMENT:

The use of carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel, or polydimethylsiloxane (refer to Other section for proprietary product names) **meets the definition of medical necessity** to treat stress urinary incontinence in men and women who have failed at least 3 months of appropriate conservative therapy [e.g., pelvic floor muscle exercises, behavioral changes (such as fluid management, moderation of physical activities that provoke incontinence); intravaginal estrogen therapy, use of a pessary, or treatment of other underlying causes of incontinence in those amenable to these treatments].

The use of any other periurethral bulking agent, including, but not limited to Teflon (polytetrafluoroethylene), to treat stress urinary incontinence is considered **experimental or investigational**.

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 incontinence, including but not limited to stress urinary incontinence, is considered **experimental or investigational**.

The use of periurethral bulking agents to treat urge urinary incontinence is considered **experimental or investigational.**

The use of perianal bulking agents, including, but not limited to dextranomer/hyaluronic acid, to treat fecal incontinence is considered **experimental or investigational**.

There is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on safety and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

HCPCS Coding:

L8603	Injectable bulking agent, collagen implant, urinary tract, 2.5 mL syringe, includes shipping and necessary supplies
L8604	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1 ml, includes shipping and necessary supplies (**Investigational**)
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies (**Investigational**)
L8606	Injectable bulking agent synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

ICD-10 Diagnosis Codes That Support Medical Necessity:

N39.3	Stress incontinence (female) (male)

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: The following National Coverage Determination (NCD) was reviewed on the last guideline review date: National Coverage Determination (NCD) for Incontinence Control Devices (230.10), located at cms.gov.

DEFINITIONS:

Fecal incontinence: loss of bowel control, causing stool to leak involuntarily from the rectum.

Stress urinary incontinence: involuntary loss of urine caused by dysfunction of the muscles and tissues around the bladder (eg, pelvic floor, sphincter). Coughing or sneezing often causes urine leak.

Urge urinary incontinence: unintentional loss of urine following sudden, overwhelming urge to urinate due to involuntary contractions of the muscular wall of the bladder.

RELATED GUIDELINES:

Pelvic Floor Stimulation as a Treatment of Incontinence, 01-97000-06

Percutaneous Tibial Nerve Stimulation, 02-64000-01

Transvaginal Radiofrequency Bladder Neck Suspension and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence, 02-50000-16

OTHER:

Other terms for injectable bulking agents:

Note: The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Bulkamid® (polyacrylamide hydrogel)
Coaptite® (calcium hydroxylapatite)
Contigen (bovine collagen cross-linked with glutaraldehyde)
Dextranomer/hyaluronic acid (Zuidex; Deflux™)
Durasphere® (carbon-coated spheres)
Macroplastique® (polydimethylsiloxane)
NASHA Dx (marketed as Solesta®; bulking agent to treat fecal incontinence)

REFERENCES:

1. Abe T, Kunimoto M, Hachiro Y, Ohara K, Inagaki M. Injection of Aluminum Potassium Sulfate and Tannic Acid in the Treatment of Fecal Incontinence: A Single-Center Observational Study. Ann Coloproctol. 2021 Jul 21. doi: 10.3393/ac.2021.00248.0035. Epub ahead of print.
2. Akinjise-Ferdinand O, Hubbard R, Osman NI, Chapple CR. A diagnostic conundrum: Is it a periurethral diverticulum/cyst or a bulking agent (Bulkamid)? Neurourol Urodyn. 2023 Feb;42(2):547-554. doi: 10.1002/nau.25068. Epub 2022 Oct 26. PMID: 36285552.
3. American College of Gastroenterology. Diagnosis and Management of Fecal Incontinence (Am J Gastroenterol 1999;99:1585-1604. Received February 27, 2004; accepted March 5, 2004.).
4. American Society of Colon and Rectal Surgeons. Practice Parameters for the Treatment of Fecal Incontinence (Dis Colon Rectum 2007; 50: 1497–1507).
5. Bawazir O. The treatment of vesicoureteral reflux in children by endoscopic sub-mucosal intra-ureteral injection of dextranomer/hyaluronic acid: A case-series, multi-centre study. Electron Physician. 2017 Apr 25;9(4):4145-4149. doi: 10.19082/4145. eCollection 2017 Apr.
6. Blue Cross Blue Shield Association Evidence Positioning System®. 7.01.19 - Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence, 11/22.
7. Brosche T, Kuhn A, Lobodasch K, Sokol ER. Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence. Neurourol Urodyn. 2021 Jan;40(1):502-508. doi: 10.1002/nau.24589. Epub 2021 Jan 7.
8. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for Incontinence Control Devices (230.10) (10/07/96).
9. 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. 2017;72(3):424-431. doi:10.1016/j.eururo.2017.03.048. PMID: 28413126.
10. Chapple C, Dmochowski R. Particulate Versus Non-Particulate Bulking Agents In The Treatment Of Stress Urinary Incontinence. Res Rep Urol. 2019;11:299-310. Published 2019 Nov 12. doi:10.2147/RRU.S220216.
11. ClinicalTrials.gov:
    a. NCT01110681- Study to Evaluate Solesta for Treatment of Fecal Incontinence Condition: Fecal Incontinence.
    b. NCT00971269 - Pilot Study of NASHA/Dx Gel for Fecal Incontinence Condition: Fecal Incontinence.
    c. NCT00303030 - A Randomized, Controlled, Clinical Trial of Biofeedback and Anal Injections as First Treatment of Fecal Incontinence Condition: Fecal Incontinence.
    d. NCT01380132 - Safety and Efficacy of Anorectal Application of Dx-gel for Treatment of Anal Incontinence Condition: Fecal Incontinence.
    e. NCT00605826 - ClinicalTrials.gov – A Randomized, Blinded, Multicenter Study to Evaluate NASHA/Dx for the Treatment of Fecal Incontinence.
    f. NCT01647906 - Long Term Safety and Efficacy of Solesta® Injectable Bulking Agent for the Treatment of Fecal Incontinence (SoFI).
12. Danielson J, Karlbom U, Wester T, Graf W. Injectable bulking treatment of persistent fecal incontinence in adult patients after anorectal malformations. J Pediatr Surg. 2020;55(3):397-402. doi:10.1016/j.jpedsurg.2019.06.026. PMID: 31493885.

13. Davila GW. Nonsurgical outpatient therapies for the management of female stress urinary incontinence: long-term effectiveness and durability. Adv Urol. 2011;2011:176498. doi: 10.1155/2011/176498. Epub 2011 Jun 23.
14. ECRI Product Brief. Solesta Injectable Gel (Salix Pharmaceuticals, Inc.) for Treating Fecal Incontinence (12/2012).
15. Franklin H, Barrett AC, Wolf R. Identifying factors associated with clinical success in patients treated with NASHA(®)/Dx injection for fecal incontinence. Clin Exp Gastroenterol. 2016 Mar 2;9:41-7. doi: 10.2147/CEG.S95238. eCollection 2016.
16. Giuseppe Dodi, Johannes Jongen, Fernando de la Portilla, Manoj Raval, Donato F. Altomare, and Paul-Antoine Lehur. An Open-Label, Noncomparative, Multicenter Study to Evaluate Efficacy and Safety of NASHA/Dx Gel as a Bulking Agent for the Treatment of Fecal Incontinence. Gastroenterology Research and Practice; Volume 2010, Article ID 467136.
17. Graf W, Mellgren A, Matzel KE, et al; NASHA Dx Study Group. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: A randomised, sham-controlled trial. Lancet. 2011;377(9770):997-1003.
18. Kasyan G, Pushkar D. Bulking agents for urinary incontinence: what, when and where? Cent European J Urol. 2015; 68(3): 339.
19. Kobashi KC, Albo ME, Dmochowski RR, et al. Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. J Urol. 2017;198(4):875-883. doi:10.1016/j.juro.2017.06.061. PMID: 28625508.
20. Mamut A, Carlson KV. Periurethral bulking agents for female stress urinary incontinence in Canada (Can Urol Assoc J. 2017 Jun; 11(6Suppl2): S152–S154).
21. Mayo Clinical Health Information - Fecal incontinence treatments (website). Accessed 11/06/12.National Association for Continence. Fecal Incontinence. Charleston, SC: NAFC (website); March 7, 2012.
22. Mellgren, J. Pollack, K. Matzel, T. Hull, M. Bernstein, W. Graf. Long-term Efficacy of NASHA/DX Injection Therapy (Solesta) for Treatment of Fecal Incontinence. Diseases of the Colon & Rectum Volume 55: 5 (2012).
23. National Institute for Health and Clinical Excellence (NICE). Injectable bulking agents for faecal incontinence. Interventional Procedure Guidance 210. London, UK: NICE; 2007.
24. Norton C. Treating faecal incontinence with bulking-agent injections. Lancet. 2011;377(9770):971-972.
25. Rao SC. Practice Guidelines; Diagnosis and Management of Fecal Incontinence. American Journal of Gastroenterology 2004.
26. Ratto C, Parello A, Donisi L, Litta F, De Simone V, Spazzafumo L, Giordano P. Novel bulking agent for faecal incontinence. Br J Surg. 2011 Nov;98(11):1644-52.
27. Sanchez JE, et al. Validity of the ≥50% Response Threshold in Treatment With NASHA/Dx Injection Therapy for Fecal Incontinence. Clin Transl Gastroenterol. 2015 Jan 15;6:e70. doi: 10.1038/ctg.2014.20.
28. Tjandra JJ, Dykes SL, Kumar RR, Ellis CN, Gregorcyk SG, Hyman NH, Buie WD, Standards Practice Task Force of The American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of fecal incontinence. Dis Colon Rectum 2007 Oct; 50(10):1497-507.
29. UpToDate. Fecal incontinence in adults: Management. 2021. Accessed at uptodate.com.
30. UpToDate. Female stress urinary incontinence: Choosing a primary surgical procedure. 2023. Accessed at uptodate.com.
31. UpToDate. Female urinary incontinence: Treatment. 2023. Accessed at uptodate.com.

32. UpToDate. Stress urinary incontinence in women: Persistent/recurrent symptoms after surgical treatment. 2020. Accessed at uptodate.com.
33. U.S. Food and Drug Administration premarket approval for Solesta (P100014) 05/27/11.
34. Zheng Y, Rovner E. Update on Urethral Bulking for Stress Urinary Incontinence in Women. Curr Urol Rep. 2022 Oct;23(10):203-209. doi: 10.1007/s11934-022-01099-5. Epub 2022 Jul 4. PMID: 35781870.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 10/26/23.

GUIDELINE UPDATE INFORMATION:

02/15/12	New Medical Coverage Guideline.
01/01/13	Annual HCPCS coding update: added L8605.
02/15/13	Scheduled review; position statement unchanged, references updated.
02/15/14	Annual review; position statement unchanged; Program Exceptions section updated; references updated.
01/01/15	Annual coding update; added 0377T.
02/15/15	Annual review; position statement unchanged, references updated.
11/01/15	Revision: ICD-9 Codes deleted.
12/15/18	Scheduled review. Revised MCG title, CPT, HCPCS, and ICD10 coding sections; Program Exceptions section, definitions section, related guidelines, and index terms. Added coverage for carbon-coated spheres, calcium hydroxylapatite, or polydimethylsiloxane (urinary stress incontinence). Added (E/I) coverage statements for autologous cellular therapy, autologous fat, autologous ear chondrocytes, and treatment of urge urinary incontinence. Updated references.
01/01/20	Annual CPT/HCPCS coding update. Deleted 0377T.
10/15/20	Scheduled review. Maintained position statement and updated references.
12/15/21	Scheduled review. Added coverage statement for Bulkamid® (polyacrylamide hydrogel). Revised OTHER section and updated references.
11/15/23	Scheduled review. Revised description, maintained position statement, and updated references.