

Corporate Medical Policy

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

File Name: injectable_bulking_agents_for_the_treatment_of_urinary_and_fecal_incontinence
Origination: 8/1985
Last Review: 11/2023

Description of Procedure or Service

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. A number of products have been developed, and there are several U.S. Food and Drug Administration (FDA)-approved options for treating urinary incontinence. One product is commercially available to date for treating fecal incontinence.

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 the tissue bulk and thereby increase resistance to the outflow of urine. The bulking agent is injected into the periurethral tissue as a liquid that then 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.

Following the success of periurethral bulking agents for treating SUI, bulking agents injected into the anal canal have been proposed for treating fecal incontinence. In particular, bulking agents are a potential treatment for passive fecal incontinence associated with internal anal sphincter (IAS) 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 (e.g., dietary changes, pharmacotherapy and 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 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 the FDA for urinary incontinence include carbon-coated beads (e.g., 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 (e.g., Tegress®, formerly URYX®). Tegress was later voluntarily removed from the market due to safety concerns.

Several agents identical to or similar to those used for urinary incontinence e.g., Durasphere, silicone biomaterial, etc. have been studied for the treatment of fecal incontinence. To date, only one bulking agent has been approved by the FDA for treating fecal incontinence. This is a formulation of non-animal stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx) and is marketed by Palette Life Sciences as Solesta. A hyaluronic

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

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.

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 has not received 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 will undergo self-renewal and multipotent differentiation, which could result in regeneration of the sphincter and its neural connections.

Regulatory Status

Several periurethral bulking agents have been approved by the FDA through the premarket approval process for the treatment of stress urinary incontinence due to intrinsic sphincter deficiency; other than Contigen®, approval is only for use in adult women. Products include:

- In 1993, Contigen® (Allergan, Inc.), a cross-linked collagen, was approved. A supplemental approval in 2009 limited the device's indication to treatment of urinary incontinence due to intrinsic sphincter deficiency in patients (men or women) who have shown no improvement in incontinence for at least 12 months. The manufacturer of the product ceased production in 2011; no reason for discontinuation was provided to the public.
- In 1999, Durasphere® (Advanced UroScience), pyrolytic carbon-coated zirconium oxide spheres, was approved.
- In 2004, Uryx® (CR Bard), vinyl alcohol copolymer implants, was approved. In 2005, approval was given to market the device under the trade name Tegress. In 2007, Tegress was voluntarily removed from the market due to safety concerns.
- In 2005, Coaptite® (Boston Scientific, previously BioForm Medical, and Merz Aesthetics), spherical particles of calcium hydroxylapatite, suspended in a gel carrier, was approved for soft tissue augmentation in the treatment of stress urinary incontinence due to intrinsic sphincter deficiency in adult females.
- In 2006, Macroplastique® (Laborie, previously Cogentix Medical), polydimethylsiloxane, was approved.
- In 2020, Bulkamid Urethral Bulking System (Axonics Modulation Technologies, Inc.), a soft hydrogel that consists of 97.5% water and 2.5% polyacrylamide, was approved.

One bulking agent was approved by the FDA through the premarket approval process for treating fecal incontinence. In 2011, non-animal stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx) marketed as Solesta® (Q-Med now Palette Life Sciences) is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy.

Related Policies

Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
Percutaneous Tibial Nerve Stimulation for Voiding Dysfunction
Vesicoureteral Reflux, Treatment with Periureteral Bulking Agents
Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

Policy

BCBSNC will provide coverage for periurethral bulking agents for the treatment of urinary incontinence, when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

The use of perianal bulking agents to treat fecal incontinence is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Periurethral Bulking Agents for the Treatment of Urinary Incontinence is covered

Periurethral bulking agents for the treatment of urinary incontinence are covered when one of the following conditions is present:

1. For incontinence due to intrinsic sphincter deficiency where the individual has failed appropriate conservative therapy.

OR

2. For stress urinary incontinence when all of the following are met:
 - a. incontinence has been present for 6 months; and
 - b. no other causes of stress urinary incontinence have been identified (e.g., urinary tract infection); and
 - c. stress urinary incontinence limits activities of daily living;

AND carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel, or polydimethylsiloxane are used as the periurethral bulking agent.

When Periurethral Bulking Agents for the Treatment of Urinary Incontinence is not covered

- For conditions other than noted above.
- The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence is considered investigational.

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

- The use of autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells), autologous fat, and autologous ear chondrocytes as periurethral bulking agents is considered investigational and is not covered.
- The use of periurethral bulking agents to treat urge urinary incontinence is considered investigational.
- The use of perianal bulking agents to treat fecal incontinence is considered investigational.

Policy Guidelines

Urinary 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. 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 (i.e., it is effective in some patients who 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 produce outcomes and have 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.

There is insufficient published evidence on the efficacy of autologous cellular therapy, autologous fat, autologous ear chondrocytes, and other treatments such as Teflon. Therefore, use of these agents to treat urinary incontinence is considered investigational.

There is insufficient published evidence regarding the effectiveness of periurethral bulking agents to improve health outcomes in individuals with urgency incontinence.

Individuals should have had inadequate response to conservative therapy or therapies; in general, these treatments should have been used for at least 3 months. Conservative therapy for stress incontinence 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 patients amenable to these treatments.

Individuals whose incontinence does not improve with five injection procedures are considered treatment failures and should not receive further injections.

Fecal Incontinence

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 two RCTs with the FDA-approved product

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

NASHA Dx (Solesta) and two 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 that the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbssc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 51715, L8603, L8604, L8605, L8606, Q3031

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Policy entitled: Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence

BCBSA Medical Policy Reference Manual - 12/95

BCBSA Medical Policy Reference Manual - 7/97

Kumon H, Tsugawa M. Endoscopic correction of vesicoureteral reflux by subureteric Teflon (polytetrafluoroethylene) injection: review of 6-year experience. *Int J Urol.* 1997;4(6):541-5.

Belman Ab. Vesicoureteral reflux. *Pediatr Clin North Am.* 1997;44(5):1171-90.
Medical Policy Advisory Group 3/99

New policy entitled: Treatment of Urinary Incontinence

BCBSA TEC Evaluation, June 2000; Volume 15, No. 2

BCBSA TEC Evaluation, August 2000; Volume 15, No. 8

BCBSA Medical Policy Reference Manual, 12/15/00; 1.01.17

Specialty Matched Consultant Advisory Panel - 5/2001

Specialty Matched Consultant Advisory Panel - 9/2001

BCBSA Medical Policy Reference Manual, 2/15/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 7.01.69

BCBSA Medical Policy Reference Manual, 12/18/02; 1.01.17

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

BCBSA Medical Policy Reference Manual, 4/29/03; 7.01.19

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.69, 7/15/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.17, 4/15/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.60, 11/9/04

Specialty Matched Consultant Advisory Panel - 5/2005

New policy entitled: Periurethral Bulking Agents for the Treatment of Urinary Incontinence

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 4/1/05

Specialty Matched Consultant Advisory Panel - 5/8/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 4/17/07

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 5/8/08

Specialty Matched Consultant Advisory Panel - 9/2009

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 10/8/10

Specialty Matched Consultant Advisory Panel review 12/2010

Abrams P, Andersson KE, Birder L, et al. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and Treatment of Urinary Incontinence, Pelvic Organ Prolapse, and Fecal Incontinence. *Neurourology and Urodynamics* 29:213-240 (2010).

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* 2010

Davila GW. Nonsurgical outpatient therapies for the management of female stress urinary incontinence: long-term effectiveness and durability. *Adv Urol* 2011. Retrieved on November 1, 2011 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124122/?tool=pubmed>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 10/4/11

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 10/11/12

Specialty Matched Consultant Advisory Panel review 11/2012

Policy re-titled: Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

National Institute for Health and Clinical Excellence (NICE). Injectable bulking agents for faecal incontinence: February 2007. Retrieved from <http://www.nice.org.uk/guidance/IPG210> .

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Siproudhis L, Morcet J, Laine F. Elastomer implants in faecal incontinence: a blind, placebo-controlled study. *Aliment Pharmacol Ther* 2007; 25(9):1125-32. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1111/j.1365-2036.2007.03293.x/pdf>

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* 2011; 1(4):202-06. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3350896/>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 2/14/13

Medical Director review 3/2013

Specialty Matched Consultant Advisory Panel review 11/2013

Medical Director review 11/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 3/13/14

Specialty Matched Consultant Advisory Panel - 11/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 3/12/15

Specialty Matched Consultant Advisory Panel - 11/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 9/8/16

Specialty Matched Consultant Advisory Panel - 11/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 8/10/2017

Specialty Matched Consultant Advisory Panel - 11/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 8/9/2018

Specialty Matched Consultant Advisory Panel - 11/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 8/8/2019

Specialty Matched Consultant Advisory Panel - 11/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 8/13/2020

Specialty Matched Consultant Advisory Panel - 11/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.19, 10/24/2021

Specialty Matched Consultant Advisory Panel - 11/2021

Specialty Matched Consultant Advisory Panel - 11/2022

Specialty Matched Consultant Advisory Panel - 11/2023

Medical Director Review -11/2023

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

Policy Implementation/Update Information

Policy entitled: Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence

- 8/85 Original Policy: Experimental/investigative for Teflon implant
8/88 Reviewed: Investigational for Teflon implant
- 4/94 Evaluated: Use of GAX collagen implantation for the treatment of urinary stress incontinence due to intrinsic sphincter deficiency in patients who have urinary incontinence of greater than 12 months duration is eligible for coverage.
- 7/96 Reviewed: National Association reviewed 12/95. No changes.
- 5/99 Reaffirmed based on the MPAG review. No changes.
- 6/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 8/00 Coding system changes.
- 12/00 2001 HCPCS code added; L8606. System coding changes.

New policy entitled: Treatment of Urinary Incontinence

- 5/01 Policies combined and renamed. Added criteria for Pelvic Floor Stimulation as a Treatment of Urinary Incontinence. Specialty Matched Consultant Advisory Panel. No changes to policy.
- 9/01 Specialty Matched Consultant Advisory Panel review. Added description and coverage criteria for carbon-coated spheres or beads for Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence.
- 10/01 Coding format changes.
- 3/02 Added codes 64561 and 64581 to the Billing/Coding Section in Section II Sacral Nerve Stimulation for Urinary Incontinence and System Application Guidelines.
- 4/02 Format changes.
- 11/03 Specialty Matched Consultant Advisory Panel review 5/23/03. Benefits Application section revised. For Section I, Periurethral Injection of Implant Material, revised description for clarity; revised Policy Guidelines to indicate that "Patients whose incontinence does not improve with five injection procedures....". For Section II, Sacral Nerve Stimulation, removed codes 64555, 64575, E0751, E0753, E1399 and added codes 95971, E0752 and E0759. For Section III, Pelvic Floor Stimulation, revised description for clarity; added Innova Feminine Incontinence Treatment System to this section; added code 0029T to Billing/Coding section and removed codes 97014 and 97032. Deleted Section IV, Innova Feminine Incontinence Treatment System.

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

- 2/04 Added HCPCS codes L8603 and Q3031 to Billing/Coding section of Section I re: Periurethral Injection of Implant Material.
- 6/16/05 Specialty Matched Consultant Advisory Panel review 5/24/05. **Section I** - Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence; description revised, included biocompatible copolymer implant (e.g., URYX) in description; For “When Covered”- 2.d. “Cross-linked collagen or carbon-coated beads are used as the implantable material.” pulled out as a separate sentence so need 1 or 2 and use of listed materials; also added biocompatible copolymers as one of the approved materials; For “When not Covered” added “The use of autologous fat and autologous ear chondrocytes as periurethral bulking agents are considered investigational and are not covered.”; For “Policy Guidelines” removed sentence re: “15 ml of paste are injected...” since the procedure is included in the description. **Section II** - Sacral Nerve Modulation/Stimulation...description of procedure revised to provide additional information; For “When Covered” - changed #2 to indicate that the urinary incontinence conditions listed in #1 should not be related to a neurologic condition; #3 now reads: “Medical records document that the patient has failed at least a 3 month trial of conservative treatment such as behavioral therapy (i.e., diet modification, bladder training, biofeedback, Kegel exercises) and/or pharmacotherapy (i.e., 2 or more anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant); #4 is now re: the percutaneous test stimulation. For “When not Covered” #1 - added several examples of conditions “Any conditions other than those listed above including but not limited to the following: stress incontinence, urge incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis or spinal cord injury), other types of chronic voiding dysfunction, patients with mechanical urethral obstruction such as benign prostatic hypertrophy, cancer or urethral stricture.” **Section III** - Pelvic Floor Stimulation...added policy guidelines re: investigational status: “Available data are insufficient to determine whether this treatment is as effective as alternatives. Additionally, the treatments lack standardization of delivery. There are minimal data for magnetic stimulation and no randomized trials. There is insufficient medical and scientific evidence to permit the Plan to evaluate the therapeutic value of pelvic floor stimulation as a treatment of urinary incontinence. For further information, please refer to separate policy number MED1263, Investigational (Experimental) Services.” Added - **Section IV** re: Transvaginal Radiofrequency Bladder Neck Suspension for Urinary Stress Incontinence as investigational. Notice given 6/16/05. Effective date 8/18/05.
- 1/5/06 Removed deleted codes E0752, E0756, E0757, E0758 & E0759 from appropriate Billing/Coding sections.
- 2/26/07 Added HCPCS codes L8680, L8681, L8682, L8683, L8685, L8686, L8687, L8688, L8689 to Section II - Sacral Nerve Modulation/Stimulation for Urinary Incontinence. (pmo)

New policy entitled: Periurethral Bulking Agents for the Treatment of Urinary Incontinence

- 6/4/07 Section I (Periurethral Injection of Implant Material for the Treatment of Urinary Incontinence) of the policy entitled “Urinary Incontinence, Treatment“ issued as a separate policy entitled “Periurethral Bulking Agents for the Treatment of Urinary Incontinence”. Newly FDA approved bulking agents added to “Description” and “When Covered” sections. Reference Sources added. (pmo)
- 7/2/07 Reference source added. (pmo)

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

- 9/28/09 Under When Not Covered, third bullet - added autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, or adipose-derived stem cells) to the list of investigational periurethral bulking agents. Reference sources added. (pmo)
- 6/22/10 Policy Number(s) removed (amw)
- 1/18/11 Specialty Matched Consultant Advisory Panel review 12/2010. Added code L8604 to policy. Added statement to “When not covered” section: “The use of periurethral bulking agents to treat urge urinary incontinence is considered investigational.” Updated Description section. Updated Policy Guidelines section. Updated references. (mco)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. Revised the following statement in the “When not Covered” section: “Periurethral Teflon® injection for the treatment of urinary incontinence is considered investigational and is not covered.” to “The use of any other periurethral bulking agent, including, but not limited to Teflon®, to treat stress urinary incontinence is considered investigational.” References updated. (mco)
- 1/15/13 Specialty Matched Consultant Advisory Panel review 11/2012. Description section updated. References updated. No changes to Policy Statements. (mco)

Policy re-titled: Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

- 4/1/13 Policy re-titled from “Periurethral Bulking Agents for Treatment of Urinary Incontinence” to “Injectable Bulking for the Treatment of Urinary and Fecal Incontinence.” Description section extensively revised. New Policy Statement as follows: “The use of perianal bulking agents to treat fecal incontinence is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.” Added new code C9735 to Billing/Coding section. References updated. Policy Guidelines updated. Medical Director review 3/2013. (mco)
- 12/10/13 Specialty Matched Consultant Advisory Panel review 11/2013. Revised “When Covered” statement #1 as follows: “Periurethral bulking agents for the treatment of urinary incontinence are covered when one of the following conditions is present: For incontinence due to intrinsic sphincter deficiency where the patient has failed appropriate conservative therapy.” Added L8605 to Billing/Coding section. Medical Director review 11/2013. (mco)
- 12/9/14 Specialty Matched Consultant Advisory Panel review 11/24/2014. Added information that the production of Contigen® was discontinued in 2011. Added related policies “Transanal Radiofrequency Treatment of Fecal Incontinence” and “Sacral Nerve Neuromodulation/Stimulation for Pelvic Floor Dysfunction”. Added new code 0377T to Billing/Coding section. No change to Policy statements. (sk)
- 12/30/14 Code C9735 deleted effective 12/31/2014. (sk)
- 4/28/15 Reference added. Removed cross-linked collagen and ethylene vinyl alcohol copolymers from the When Covered section as these products are no longer available. (sk)

Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

- 12/30/15 Specialty Matched Consultant Advisory Panel review 11/18/2015. (sk)
- 1/27/17 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 11/30/2016. (sk)
- 9/15/17 Reference added. (sk)
- 12/15/17 Specialty Matched Consultant Advisory Panel review 11/29/2017. (sk)
- 10/12/18 Reference added. (sk)
- 12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. Related policy titled “Biofeedback” removed. (sk)
- 10/15/19 Reference added. (sk)
- 12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. (sk)
- 5/4/21 Reference added. Specialty Matched Consultant Advisory Panel review 11/18/2020. (sk)
- 12/14/21 Reference added. Description, Regulatory Status, and Policy Guidelines updated. Polyacrylamide hydrogel added to list of covered periurethral bulking agents. Specialty Matched Consultant Advisory Panel review 11/17/2021. (sk)
- 6/30/23 Policy review. Expired code 0377T removed from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 11/16/2022. (sk)
- 12/29/23 References added. Updated Regulatory Status. Specialty Matched Consultant Advisory Panel review 11/2023. Medical Director review 11/2023. (rp)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.