MEDICAL POLICY

POLICY TITLE	INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE
POLICY NUMBER	MP 4.012

CLINICAL BENEFIT	☒ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**7/1/2025**

I. POLICY

The use of carbon-coated spheres (Durasphere®), calcium hydroxylapatite (CaHA) (Coaptite®), polyacrylamide hydrogel (Bulkamid®), or polydimethylsiloxane (Macroplastique®) may be considered **medically necessary** to treat urinary stress incontinence in men and women who have failed appropriate conservative therapy.

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 to treat stress urinary incontinence is considered **investigational**.

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

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.** There is insufficient evidence to support a general conclusion concerning the health outcomes related to their efficacy for the above listed investigational indications.

Policy Guidelines

Individuals should have had an 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.

Cross-References

POLICY TITLE	INJECTABLE BULKING AGENTS FOR THE TREATMENT OF URINARY AND FECAL INCONTINENCE
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MP 1.033 Sacral Nerve Modulation/Stimulation and Pelvic Floor Stimulation Devices
MP 1.134 Percutaneous Tibial Nerve Stimulation
MP 2.064 Biofeedback and Neurofeedback Therapy
MP 4.034 Transvaginal and Transurethral Radiofrequency Tissue Remodeling for Urinary Stress Incontinence

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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.

Treatment

Urinary 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 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.

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 (e.g., 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 (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 voluntarily removed from the market due to safety concerns.

Fecal Incontinence

After 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.

Several agents identical or similar to those used for urinary incontinence (e.g., Durasphere, silicone biomaterial) 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 formulation of 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.

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

In May 2023, the American Society of Colon and Rectal Surgeons published Clinical Practice Guidelines for the Management of Fecal Incontinence. The guideline states that “injection of biocompatible bulking agents into the anal canal is not routinely recommended for the treatment of FI (fecal incontinence)” citing limited improvement over placebo, diminishing long-term results, and cost.

Regulatory Status

Several periurethral bulking agents have been approved by the FDA through the premarket approval process for the treatment of SUI 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. Allergan 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 (Merz Aesthetics, previously BioForm Medical), spherical particles of calcium hydroxylapatite, suspended in a gel carrier, was approved
- In 2006, Macroplastique (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.

In 2011, NASHA Dx, marketed as Solesta® (Q-Med), was approved by FDA through the premarket approval process as a bulking agent to treat fecal incontinence in patients 18 years and older who have failed conservative therapy. FDA product code: LNM.

IV. RATIONALE

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Summary of Evidence

For individuals who have SUI 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 (e.g., 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 Food and Drug Administration (FDA) FDA-approved carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel and, 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

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.

V. DEFINITIONS

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510(K) APPROVAL refers to section 510(k) of the Food, Drug and Cosmetic Act. Under 510(k), before a manufacturer can market a medical device in the United States, they must demonstrate to FDA's satisfaction that it is substantially equivalent (as safe and effective) to a device already on the market.

MIXED INCONTINENCE is a combination of stress and urge incontinence.

OVERFLOW INCONTINENCE is characterized by small frequent voiding due to overfilling of the bladder or to a bladder with pathologically decreased volume.

PESSARY is a device inserted into the vagina to function as a support structure for the uterus.

STRESS INCONTINENCE is an involuntary loss of urine that occurs during physical activity, such as coughing, sneezing, laughing or exercise. This incontinence occurs as a result of weakened pelvic muscles that support the bladder and urethra, or because of malfunction of the urethral sphincter.

URGE INCONTINENCE is a condition characterized by a strong desire to urinate immediately before an involuntary bladder contraction with a loss of a large amount of urine.

VI. DISCLAIMER

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Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as required by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These polices are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.

VII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore, not covered:

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Procedure Codes								
L8605	0963T							

Covered when medically necessary:

Procedure Codes								
L8606	51715							

ICD-10-CM Diagnosis Code	Description
N36.42	Intrinsic sphincter deficiency (ISD)
N36.43	Combined hypermobility of urethra and intrinsic sphincter deficiency
N36.8	Other specified disorders of urethra
N39.3	Stress incontinence (female) (male)
N39.4	Other specified urinary incontinence
N39.46	Mixed incontinence (urge and stress incontinence)

VIII. REFERENCES

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IX. POLICY HISTORY

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MP 4.012	**04/10/2020 Consensus Review.** No change to policy statements. References, rationale and coding updated.
	11/01/2021 Minor Review. Medically necessary policy statement in men and women with stress urinary incontinence who have failed appropriate conservative therapy expanded to include polyacrylamide hydrogel, which is now FDA approved. Updated: Description/Background and Rationale sections, references and FEP language. Removed dx code N36.41, removed L8603.
	11/23/2022 Consensus Review. No change to policy statement. Updated background, references. No coding changes.
	12/18/2023 Consensus Review. No change to policy statement. Updated background, references. No coding changes.
	12/06/2024 Consensus Review. No changes to policy statement. Updated references. No coding changes.
	06/10/2025 Administrative Update. Added new code 0963T Eff 07/01/2025
	06/12/2025 Administrative Update. Removed Benefit Variations Section and updated Disclaimer.

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