



## FEP Medical Policy Manual

### FEP 7.01.19 Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

**Annual Effective Policy Date: January 1, 2024**

**Original Policy Date: December 2012**

**Related Policies:**

1.01.17 - Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence

7.01.102 - Periureteral Bulking Agents as a Treatment of Vesicoureteral Reflux

7.01.106 - Percutaneous and Subcutaneous Tibial Nerve Stimulation

## Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence

### Description

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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 one for treating fecal incontinence.

### OBJECTIVE

The objective of this evidence review is to determine whether injectable bulking agents improve the net health outcome for individuals with stress urinary incontinence or fecal incontinence.

## POLICY STATEMENT

The use of carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel, 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, 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 **not medically necessary**.

## 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 individuals amenable to these treatments.

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Periurethral bulking agents may benefit both men and women with stress urinary incontinence. However, only Contigen, which is no longer commercially available, has FDA approval for use in men and women.

## FDA REGULATORY STATUS

Several periurethral bulking agents have been approved by 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), a cross-linked collagen, was approved. A supplemental approval in 2009 limited the device's indication to the 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 publicly.
- In 1999, Durasphere (Advanced UroScience), a pyrolytic carbon-coated zirconium oxide sphere, was approved.
- In 2004, Uryx (CR Bard), a vinyl alcohol copolymer implant, was approved. In 2005, approval was given to market the device under the 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.
- 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.

In 2011, NASHA Dx, marketed as Solesta (Q-Med now Palette Life Sciences), 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.

## RATIONALE

### Summary of Evidence

For individuals who have stress urinary incontinence (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 (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 (ie, it is effective in some patients who have 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 the U.S. Food and Drug Administration (FDA) approved carbon-coated spheres, calcium hydroxylapatite, polyacrylamide hydrogel and polydimethylsiloxane have efficacy for treating incontinence, and further that they produce outcomes with 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.

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 non-animal-stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (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 outcomes 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 needed 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.

## SUPPLEMENTAL INFORMATION

### Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

#### Urinary Incontinence

##### American College of Obstetricians and Gynecologists

In 2015 (reaffirmed in 2022), the American College of Obstetricians and Gynecologists updated its practice bulletin on urinary incontinence in women.<sup>35</sup> The practice bulletin stated that "urethral bulking injections are a relatively noninvasive treatment for stress urinary incontinence that may be appropriate if surgery has failed to achieve adequate symptom reduction, if symptoms recur after surgery, in women with symptoms who do not have urethral mobility, or in older women with comorbidities who cannot tolerate anesthesia or more invasive surgery. However, urethral bulking agents are less effective than surgical procedures such as sling placement and are rarely used as primary treatment for stress urinary incontinence." There was insufficient evidence to recommend any specific bulking agent.

##### American Urological Association and Society of Urodynamics

The 2017 joint guidelines on the surgical treatment of female stress urinary incontinence (SUI) from the American Urological Association and Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction stated that bulking agents are an option for patients considering surgery for SUI.<sup>36</sup> The guidelines also stated that there are few long-term data on the efficacy of bulking agents and that retreatment is common. These recommendations are consistent in the 2023 update to the guidelines.<sup>37</sup>

## National Institute for Health and Care Excellence

In 2019, the National Institute for Health and Care Excellence updated its guidance on urinary incontinence in women.<sup>38</sup> The updated guidance recommends "intramural bulking agents to manage stress urinary incontinence if alternative surgical procedures are not suitable for or acceptable to the woman." The patient should be educated that these are permanent injectable materials, repeat injections may be needed, and there is limited evidence on long-term effectiveness and adverse events.

## Fecal Incontinence

### American College of Obstetricians and Gynecologists

In 2019 (reaffirmed 2023), the American College of Obstetricians and Gynecologists published a practice bulletin on the clinical management of fecal incontinence in women.<sup>39</sup> The College stated that "anal sphincter bulking agents may be effective in decreasing fecal incontinence episodes up to 6 months and can be considered as a short-term treatment option for fecal incontinence in women who have failed more conservative treatments." This recommendation is based on limited or inconsistent scientific evidence.

### American Gastroenterological Association

In 2017, the American Gastroenterological Association (AGA) published guidance on surgical interventions and the use of device-aided therapy for the treatment of fecal incontinence and defecatory disorders.<sup>40</sup> The AGA recommends, "Perianal bulking agents such as intra-anal injection of dextranomer may be considered when conservative measures and biofeedback therapy fail."

### American Society of Colon and Rectal Surgeons

In 2023, the American Society of Colon and Rectal Surgeons updated its practice parameters for the treatment of fecal incontinence.<sup>41</sup> The Society states, "Injection of biocompatible bulking agents into the anal canal is not routinely recommended for the treatment of FI [fecal incontinence]" based on low quality evidence showing limited improvement over placebo, diminishing long-term results, and cost.

## National Institute for Health and Care Excellence

In 2007, the National Institute for Health and Care Excellence published guidance on injectable bulking agents for treating fecal incontinence.<sup>42</sup> The guidance stated that there is insufficient evidence to support the safety and efficacy of injectable bulking agents for fecal incontinence.

## U.S. Preventive Services Task Force Recommendations

Not applicable.

## Medicare National Coverage

The 1996 Medicare National Coverage Determination for Incontinence Control Devices (230.10) addressed collagen implants but not other types of bulking agents.<sup>43</sup> Specific coverage information on collagen implants is as follows:

"Coverage of a collagen implant, and the procedure to inject it, is limited to the following types of patients with stress urinary incontinence due to ISD [intrinsic sphincteric deficiency]:

- Male or female patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;
- Male or female patients with acquired sphincter weakness secondary to spinal cord lesions;
- Male patients following trauma, including prostatectomy and/or radiation; and
- Female patients without urethral hypermobility and with abdominal leak point pressures of 100 cm H<sub>2</sub>O or less.

Patients whose incontinence does not improve with 5 injection procedures (5 separate treatment sessions) are considered treatment failures, and no further treatment of urinary incontinence by collagen implant is covered. Patients who have a recurrence of incontinence following successful treatment with collagen implants in the past (eg, 6 to 12 months previously) may benefit from additional treatment sessions. Coverage of additional sessions may be allowed but must be supported by medical justification."

No national coverage determination was identified on injectable bulking agents for treating fecal incontinence.

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2012	New policy	
June 2013	Replace policy	Policy expanded to include fecal incontinence. Statement added that perianal bulking agents to treat fecal incontinence is not medically necessary. Title changed to Injectable Bulking Agents for the Treatment of Urinary and Fecal Incontinence. References 19-24, 26 and 27 added; other references renumbered.
June 2014	Replace policy	Policy updated with literature review, adding references 15, 20, 26 and 27. No changes to the policy statement.
September 2015	Replace policy	Policy updated with literature review; references 14, 17, and 22 added; Contigen removed from medically necessary statement as it is no longer available.
March 2017	Replace policy	Policy updated with literature review; references 15 and 24 added; 35-36 updated. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; references 32-33 added. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through June 7, 2018; reference 1 added. Policy statements unchanged.
December 2019	Replace policy	Policy updated with literature review through July 11, 2019. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through May 22, 2020; no references added. Policy history for June 2013 corrected to read: Statement added that perianal bulking agents to treat fecal incontinence is NOT medically necessary. Policy statements remain unchanged.
December 2021	Replace policy	Policy updated with literature review through August 29, 2021; references added. 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.
December 2022	Replace policy	Policy updated with literature review through August 24, 2022; reference added. Policy statements unchanged.
December 2023	Replace policy	Policy updated with literature review through August 30, 2023; references added. Policy statements unchanged.

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