Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

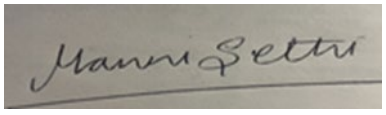
Plan: AmeriHealth Caritas Pennsylvania & Keystone First	Submission Date: 8/1/25
Policy Number: CCP.1168	Effective Date: 10/1/15 Revision Date: 7/1/25
Policy Name: Injectable bulking agents — fecal incontinence	

Type of Submission:

☐ New Policy	☒ Prior Authorization Policy
☒ Revised Policy*	☐ Base Policy
☐ Annual Review- no revisions	☒ Experimental/Investigational Policy
	☐ Statewide PDL
	☐ Other:

*All revisions to the policy must be highlighted using track changes throughout the document.

Please provide any clarifying information for the policy below:

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	Signature of Authorized Individual: 

Keystone First
Family of Health Plans

Injectable bulking agents — fecal incontinence

Clinical Policy ID: CCP.1168

Recent review date: 7/2025

Next review date: 11/2026

Policy contains: Durasphere; fecal incontinence; non-animal stabilized hyaluronic acid/dextranomer; pelvic floor dysfunction; Solesta.

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Injectable bulking agents for fecal incontinence are investigational/not clinically proven and, therefore, not medically necessary.

Limitations

Other uses of injectable bulking agents may be medically necessary for other gastro-urinary indications, such as urinary incontinence.

Alternative covered services

- Biofeedback.
- Bladder or bowel training.
- Dietary management.
- Electrical stimulation.
- Pelvic floor muscle training.
- Pharmacotherapy.
- Surgery (e.g., post-anal repair, sphincteroplasty, artificial anal sphincter implantation, total pelvic floor repair, or bowel diversion).

Background

Fecal incontinence, also called anal incontinence or accidental bowel leakage, is loss of control of the bowels resulting in involuntary loss of liquid or solid feces, or flatus, from the rectum. Fecal incontinence is a symptom of an extensive list of underlying causes. The prevalence of fecal incontinence ranges from 7% to 15% in community-dwelling men and women and may be higher in institutionalized patients (Bharucha, 2015). Fecal incontinence has a negative impact on activities of daily living and quality of life and is associated with a substantial economic burden, particularly in patients who require surgical therapy. For those who fail initial options, the remaining choices are pelvic floor biofeedback, perianal bulking agent injections, and sacral nerve stimulation that have not been compared with each other (Bharucha, 2021).

The strongest independent risk factors for fecal incontinence in community populations are bowel disturbances such as diarrhea, the symptom of rectal urgency, trauma, and chronic illness. The pathophysiological mechanisms responsible for fecal incontinence include diarrhea, anal and pelvic floor weakness, reduced rectal compliance, and reduced or increased rectal sensation. Many patients have multifaceted anorectal dysfunctions. The type (urge, passive, or combined), etiology (anorectal disturbance, bowel symptoms, or both), and severity, classify the symptoms (Bharucha, 2015). Diagnosis encompasses a detailed medical history, physical exam, and a range of tests to assess the structure and function of the rectum, anus, and pelvic floor muscles (National Institute of Diabetes and Digestive and Kidney Diseases, 2017).

Current treatments for fecal incontinence range from conservative medical therapy aimed at reducing symptoms to surgical interventions intended to correct anal sphincter or pelvic floor abnormalities. Injectable perianal bulking agents have emerged as potential minimally invasive treatment alternatives following their reported success in treating urinary incontinence (Wald, 2014). A biocompatible material is injected into the anal submucosa or intersphincteric space to close the anal canal or raise the pressure inside the anal canal to avoid fecal incontinence. Typically, a colorectal surgeon or gastroenterologist performs the procedure under local anesthesia, and the procedure may be done in an outpatient clinic setting. The simplicity, minimal invasiveness, and cost of this procedure make it an attractive treatment alternative for fecal incontinence (Bharucha, 2021).

Several different materials have been used to treat urinary incontinence, but to date, the U.S. Food and Drug Administration (2011) has approved only one bulking agent for treatment of fecal incontinence: dextranomer in stabilized sodium hyaluronate, also known as non-animal stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid or NASHA Dx, marketed under the trade name Solesta® (Q-Med AB, Sweden for Salix Pharmaceuticals, Inc., Raleigh, North Carolina) as a class III medical device for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy (e.g., diet, fiber therapy, anti-motility medications). It is contraindicated in patients with the following conditions:

- Active inflammatory bowel disease.
- Immunodeficiency disorders or ongoing immunosuppressive therapy.
- Previous radiation treatment to the pelvic area.
- Significant mucosal or full-thickness rectal prolapse.
- Active anorectal conditions, including abscess, fissures, sepsis, bleeding, proctitis, or other infections.
- Anorectal atresia, tumors, stenosis, or malformation.
- Rectocele.
- Rectal varices.
- Pregnancy, breast feeding, or without adequate contraception within the first year, or within one year postpartum.
- Presence of existing implant (other than Solesta) in the anorectal region.
- Allergy to hyaluronic acid-based products.

As a condition of approval, the U.S. Food and Drug Administration (2011) requires the manufacturer to provide data regarding numbers of devices sold and distributed with necessary context to ascertain the frequency and prevalence of adverse events, and mandates two additional studies to assess the long-term safety and durability of Solesta:

- A single-arm, multicenter observational study of safety and durability through 36 months.
- A substudy to show the anatomic stability of Solesta in at least 30 subjects by comparing anatomical positioning via transrectal ultrasonography at time of injection to positioning at six and 36 months.

Findings

Guidelines

The American College of Gastroenterology (Wald, 2021), the American Society of Colon and Rectal Surgeons (Bordeianou, 2023), and European professional medical societies (Assmann, 2022) offer conflicting recommendations for injectable bulking agents for treating fecal incontinence. The American College of Gastroenterology suggests offering injectable bulking agents such as dextranomer sodium in selected patients with fecal incontinence who do not respond to conservative therapy or biofeedback (conditional recommendation; low quality of evidence) (Wald, 2021).

The American Society of Colon and Rectal Surgeons issued a conditional recommendation against routinely recommending injection of biocompatible bulking agents for fecal incontinence, as low quality evidence showing limited improvement over placebo, diminishing long-term results, and high cost suggest injectable bulking agents should not be considered first-line treatment for fecal incontinence (Bordeianou, 2023). European professional medical societies recommend injectable bulking agents as one first-line treatment for fecal incontinence, based on a low level of evidence, for patients with loose stools and personalized based on patient responses (Assmann, 2022). However, these guidelines also emphasize the need for further studies to establish the efficacy and safety of these treatments.

Evidence review

The PIVOTAL study (Graf, 2011; ClinicalTrials.gov identifier NCT00605826) is the primary data set demonstrating the safety and effectiveness of Solesta, along with supporting evidence from one uncontrolled, multisite open-label study (ClinicalTrials.gov identifier NCT01110681), and one single-site, proof-of-concept study (ClinicalTrials.gov identifier NCT01380132). Another small randomized controlled trial (ClinicalTrials.gov identifier NCT00303030) and several small uncontrolled studies using Solesta and other bulking agents add to the evidence base for Solesta. All but one of the Solesta studies were industry sponsored. These studies had methodological limitations, including small sample sizes, lack of blinding, and high numbers of dropouts.

The study populations comprised patients with fecal incontinence unresponsive to conservative treatment (21 to 206 patients per study). All patients received four injections of 1 mL of Solesta in each quadrant of the anal submucosa. After one month, patients without symptom improvement were offered a second treatment. Efficacy endpoints included the change in the number of incontinence episodes, with a significant treatment response defined as a 50% or greater decrease in fecal incontinence episode frequency compared with baseline, the number of incontinence-free days, and changes in incontinence scores using validated instruments. Patients recorded fecal incontinence episodes and patterns in diaries when warranted. The duration of follow-up ranged from three months to three years.

The results for Solesta suggest the procedure was well tolerated, with the majority of treatment-related adverse events considered mild or moderate in intensity, including mild or moderate pain or discomfort in the rectum or anus, minor to moderate bleeding or spotting from the rectum, fever, abdominal pain, diarrhea, and constipation after treatment. Solesta is associated with some modest but statistically significant symptomatic improvements

and may be a cost-effective alternative up to three years of follow-up in persons who have not responded to conservative treatment. However, improvement in many incontinence scores and general health was not statistically significant, and it is unclear if improvement in incontinence scores correlated with practical symptom improvements that mattered to the patients. Results of the sham-controlled study suggest a significant placebo effect, and the other controlled study suggested comparable results between Solesta and anal sphincter training with biofeedback.

Systematic reviews

Several systematic reviews and meta-analyses have been conducted on the use of injectable bulking agents for fecal incontinence and support the above conclusions for Solesta. A Cochrane review (Maeda, 2013) and a systematic review carried out by the Agency for Healthcare Research and Quality (Forte, 2016) examined surgical and nonsurgical treatments for fecal incontinence. Both reviews found low-quality evidence at six months' follow-up suggesting that dextranomer anal bulking injections are more effective than sham injections on outcome measures of quality of life, the number of fecal incontinence-free days, and the percent of adults with at least 50% reduction from baseline episodes. However, they were not more effective than pelvic floor muscle training plus biofeedback with or without electrostimulation on measures of fecal incontinence severity and quality of life, and not more effective than sham injection on fecal incontinence severity or episode frequency.

In studies with a minimum follow-up of one year, Hong (2017) found that administration of injectable bulking agents has demonstrated significant improvement midterm. The adverse events rate was 18.0%, and most adverse events were minor and short-lived. Further research is needed to improve the quality of the evidence.

Lal (2019) found moderate-quality evidence suggesting Durasphere® (Coloplast Corp., Minneapolis, Minnesota), which is approved for stress urinary incontinence and represents an off-label use for fecal incontinence, reduced fecal incontinence severity for up to six months, but gains diminished thereafter.

A separate systematic review that looked at eight studies (n = 166) with a goal of comparing outcomes of self-expanding implantable bulking agents with non-self-expandable injectable bulking agents. No comparison was possible due to lack of controlled studies of injectable agents (Gassner, 2022).

A systematic review encompassing 16 nonrandomized studies (n= 420) patients investigated the efficacy of conventional injectable bulking agents, including carbon, Teflon, silicon, collagen, and autologous fat, for the treatment of passive fecal incontinence. The review revealed limited evidence supporting their effectiveness, with only two studies demonstrating improvement exceeding 50%, while the remaining studies reported improvements ranging from 15% to 50% at long-term follow-up assessments. Complications affected up to 10% of patients, and side effects were observed in up to 12% of cases. A more recent material, non-animal stabilized hyaluronic acid/dextranomer, initially exhibited promising results in a randomized, placebo-controlled trial involving 206 patients (Graf, 2011), but the complete continence rate at six months was only 6%, and concerns regarding the durability, cost, and uncertain patient selection criteria have hindered its widespread adoption (Dexter, 2024).

In 2018, we added no new information to add that would materially change the policy.

In 2019, we updated the references with no material changes to coverage. The policy ID was changed from CP# 08.02.04 to CCP.1168.

In 2020, we identified no newly published, relevant literature to add to the policy.

In 2021, we identified no newly published, relevant literature to add to the policy.

In 2022, we added a current European consortium guideline algorithm (Assmann, 2022), relevant to the policy, with no material changes to coverage.

In 2023, we added a systematic review (Gassner, 2022) that compared outcomes of self-expanding implantable bulking agents with non-self-expandable injectable bulking agents.

In 2024, we reorganized the findings section to more clearly delineate between evidence types (i.e., clinical guidelines, systematic reviews, and other forms of evidence, and we added a new systematic review that examined effectiveness and safety of injectable bulking agents for the treatment of passive fecal incontinence (Dexter, 2024). No policy changes are warranted.

In 2025, we updated the references with no policy changes warranted.

References

On April 25, 2025, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “fecal incontinence (MeSH),” “bulking agent,” “NASHA,” and “dextranomer.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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Policy updates

5/2015: initial review date and clinical policy effective date: 10/2015

7/2016: Policy references updated.

7/2017: Policy references updated.

7/2018: Policy references updated.

7/2019: Policy references updated. Policy ID changed.

7/2020: Policy references updated.

7/2021: Policy references updated.

7/2022: Policy references updated.

7/2023: Policy references updated.

7/2024: Policy references updated.

7/2025: Policy references updated.