Subject: Bulking Agents for Treatment of Fecal Incontinence

Background: Fecal incontinence is defined as the involuntary loss of solid or liquid feces. Injectable bulking agents have been developed to treat fecal incontinence in those who have failed conservative therapy (e.g. diet, fiber therapy, anti-motility medications). Although it has been hypothesized that injection of anal bulking agents may enhance resting anal pressures and improve fecal continence, there is limited efficacy and a lack of long-term follow-up data.

Policy and Coverage Criteria:
Harvard Pilgrim Health Care (HPHC) considers injectable bulking agents (e.g. Solesta) for the treatment of fecal incontinence as experimental/investigational, and it is therefore not covered.

Supporting Information:
Bulking agents are injected into the wall of the lower rectum in order to create one or more bulges, narrowing the opening through which stool will pass and thereby helping to retain it within the rectum. The procedure is usually performed under local anesthesia. Several milliliters of bulking agent are injected into the submucosa just above the dentate line. Injections can be done via the anal canal or via a trans-sphincteric route, with or without ultrasound guidance. More than one round of injections may be given.

The Solesta gel is injected into a layer of tissue beneath the lining of the anus. Typically, there are 4 injections of Solesta during each treatment. Solesta is believed to work by building or "bulking" up tissue in the anal area. By narrowing the opening of the anus, the muscles used to prevent waste from escaping may be able to close better until the patient is ready to empty their bowels.

Further evidence is needed to support the clinical utility and long-term efficacy of injectable bulking agents for the treatment of fecal incontinence.

Guerra et al (2015) investigated the long-term outcomes of bulking agents for the treatment of fecal incontinence and the behavior of implanted materials in the anorectum. A total of 19 patients with idiopathic fecal incontinence who had received bulking agent implants were evaluated at a median follow-up of 7 years. The initial clinical improvements were not maintained over time. Only 14% of the originally injected volume was still detectable on ultrasound.

Morris et al. (2013) published a small randomized study comparing two synthetic injectable bulking agents. Primary outcome measure was Wexner incontinence scale and the secondary measures were SF-36 and manometry. 17 patients were treated with PTZ and 18 with Durasphere. Wexner scores were significantly better at baseline in both groups at 6 weeks and 6 months. However, improvements were not significant at 12 months. There was no significant improvement for either injectable from baseline in mean SF-36 scores at any follow-up.
point. Little difference was noted between the two bulking agents. Morris and colleagues found both agents to be safe and effective, but noted long-term improvement is limited.

A 2013 Cochrane review assessed perianal injectable bulking agents for treatment of fecal incontinence. The authors reviewed available trials to determine effectiveness. Five eligible randomized trials with a total of 382 patients were identified. Four of the trials were at an uncertain or high risk of bias. Most trials reported a short-term benefit from injections regardless of the material used, including placebo saline injection. One study demonstrated dextranomer in stabilized hyaluronic acid (NASHA Dx) to be more effective than sham injection but with more adverse effects. Dextranomer in stabilized hyaluronic acid (NASHA Dx) was better than sham injections at six months. Another study comparing silicone material (PTQ™) to saline injections was too small to demonstrate a clinical benefit compared to the control injection of normal saline. A silicone biomaterial (PTQ™) was shown to provide some advantages and was safer in treating fecal incontinence than carbon-coated beads (Durasphere®) in the short term. Similarly, there were short-term benefits from injections delivered under ultrasound guidance compared with digital guidance. No long-term evidence on outcomes was available and further conclusions were not warranted from the available data. None of the studies reported patient evaluation of outcomes and thus it is difficult to gauge whether the improvement in incontinence scores matched practical symptom improvements that mattered to the patients. The reviewers concluded “One large randomized controlled trial has shown that this form of treatment using dextranomer in stabilized hyaluronic acid (NASHA Dx) improves continence for a little over half of patients in the short term. However, the number of identified trials was limited and most had methodological weaknesses.”

La Torre and de la Portilla (2013) reported long-term 24-month results of 83 patients treated with NASHA/Dx for fecal incontinence. 62.7% of patients responded and experienced a greater than or equal to 50% reduction in the total number of incontinence episodes. Episodes of both solid and liquid stool incontinence decreased. The mean number on incontinence-free days increased from 14.6 at baseline to 21.7 at 24 months. Graf et al. (2011) published results of a randomized, double-blind, sham-controlled trial comparing injections of dextranomer in stabilized hyaluronic acid vs. sham injection for the treatment of fecal incontinence. Patients and investigators were masked to assignment for 6 months when the effect on severity of fecal incontinence and quality of life was assessed with a 2-week diary and clinical assessments. Primary end point was response to treatment based on number of incontinence episodes. The most common adverse events (AEs) were proctalgia (13.3%) and pyrexia (9.6%). The majority of AEs were mild to moderate, self-limited and resolved within 1 month of the injection. The authors found the injectable to be effective and durable of a 24-month period, Danielson et al. (2012) discussed the efficacy and quality of life of 34 patients who underwent injection with NASHA/Dx and were followed for 24 months. 18 of the 34 patients had additional injections following the initial treatment. Results found the injections had a significant and sustained effect on both the number of fecal incontinence episodes and self-assessment of bowel function for at least up to 24 months. The authors felt the injection could be a useful adjunct for patients experiencing fecal incontinence.

Watson et al. (2012) performed a systematic review to assess and evaluate reports of studies on the efficacy of anal bulking agents for FI. Their evaluation found the use of anal bulking agents is unlikely to significantly benefit patients with severe symptoms but a marked improvement can be achieved in most patients with mild to moderate degrees of soilage.

A 2010 Cochrane review evaluated perianal injectable bulking agents as treatment for fecal incontinence. The review noted, "A definitive conclusion cannot be drawn regarding the effectiveness of perianal injection of bulking agents for fecal incontinence due to the limited number of identified trials together with methodological weaknesses. Within the available data, however, we found no reliable evidence for effectiveness of one treatment

**HPHC Clinical Medical Policy**

**Bulking Agents for Treatment of Fecal Incontinence**

*HPHC policies are based on medical science, and written for the majority of people with a given condition.*

**Coverage described in this policy is standard under most HPHC plans. Specific benefits may vary by product and/or employer group. Please reference appropriate member materials (e.g., Benefit Handbook, Certificate of Coverage) for member-specific benefit information.***
over another in improving fecal incontinence. Larger well-designed trials with adequate numbers of subjects using reliable validated outcome measures are needed to allow definitive assessment of the treatment for both effectiveness and safety.”

The American Society of Colon and Rectal Surgeons published 2015 clinical practice guidelines for the treatment of fecal incontinence and concluded weak recommendation based on moderate-quality evidence for dextranomer gel injections. Although modest improvements in short-term outcomes were seen, long-term follow-up is still necessary with regards to safety and efficacy.

Solesta® (Oceana Therapeutics, Inc., Edison, NJ, USA) received FDA-approval (P100014) in May 2011. It is approved 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). This product was developed under the name “NASHA/Dx Fecal.” Solesta is a sterile, viscous gel contained in a disposable 1 mL assembled glass syringe with a standard luerlock fitting. Solesta consists of dextranomer microspheres, 50 mg/mL, and stabilized sodium hyaluronate, 15 mg/mL, in phosphate buffered 0.9 % sodium chloride solution.

**Coding:**
Codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible.

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<th>HCPCS Codes</th>
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<tr>
<td>L8605</td>
<td>Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies</td>
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**Billing Guidelines:**
Member’s medical records must document that services are medically necessary for the care provided. Harvard Pilgrim Health Care maintains the right to audit the services provided to our members, regardless of the participation status of the provider. All documentation must be available to HPHC upon request. Failure to produce the requested information may result in denial or retraction of payment.

**References:**

Summary of Changes:

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<td>10/17</td>
<td>Reviewed; supporting information and references updated; policy coverage criteria remain the same</td>
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Approved by Medical Review Committee: 12/19/17
Reviewed/Revised: 12/13; 10/15; 10/17
Initiated: 12/13