



Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Injectable Bulking Agents for Fecal Incontinence

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Injectable Bulking Agents for the Treatment of Fecal Incontinence (A52923) Noridian retired Local Coverage Article (LCA A52923). These services still need to meet medical necessity as outlined in the LCA and will require review. LCAs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCAs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on Kaiser Permanente commercial criteria or literature search.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Fecal incontinence occurs when a person loses the ability to control his/her bowel movements and is unable to retain feces in the rectum. It can be caused by a wide variety of conditions that affect either the anatomy or function of the anal sphincter. Perineal injury during childbirth is a common cause of fecal incontinence in women. It can also be caused by neurological disorders such as spinal injury and multiple sclerosis, or it can result from anorectal surgery. In any case, fecal incontinence is common and, due to its association with considerable physical and social disability, is often under-reported (Tjandra, Chan et al. 2009).

First line treatment for fecal incontinence is usually conservative and includes antidiarrheal medication and pelvic floor muscle training. In patients for whom conservative treatment fails, alternative treatments include surgery to tighten the anal sphincter, sacral nerve stimulation, creation of a new sphincter from other suitable muscles,

implantation of an artificial sphincter or a permanent colostomy. Injectable bulking agents offer an additional, less invasive, second line treatment for fecal incontinence. The concept is to inject a biocompatible material to close the anal canal to avoid fecal incontinence (Siproudhis, Morcet et al. 2007; Maeda, Vaizey et al. 2008; Graf, Mellgren et al. 2011).

At least ten different materials have been used as bulking agents for fecal incontinence including autologous fat, Teflon, bovine glutaraldehyde, cross-linked collagen, carbon coated zirconium beads, polydimethylsiloxane elastomer, dextranomer in nonanimal stabilized hyaluronic acid, hydrogel cross-linked with polyacrylamide, porcine dermal collagen, synthetic calcium hydroxylapatite ceramic microspheres and polyacrylonitrile in cylinder form (Maeda, Laurberg et al. 2013). The material can be injected either via the perianal skin or via the anal mucosa. The procedure may be performed under local, regional or general anesthesia and the injection may be guided by the surgeon's finger in the anal canal or by ultrasound. This treatment is potentially attractive in its simplicity and minimal invasiveness and can be performed in an outpatient setting.

Several injectable bulking agents have been approved by the U.S. Food and Drug Administration (FDA) in recent years for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy.

The Medical Technology Assessment Committee (MTAC) previously reviewed and failed bulking agents for the treatment of GERD in 2003. Currently, the committee has been asked to review the literature on the safety and efficacy of injectable bulking agents for the treatment of fecal incontinence compared to standard treatment for fecal incontinence. This is the first time that bulking agents have been reviewed for this indication. The topic is being reviewed for decision making guidance.

Medical Technology Assessment Committee (MTAC)

Injectable Bulking Agents for Fecal Incontinence

10/21/2013: MTAC REVIEW

Evidence Conclusion: **EFFICACY** *THE* Cochrane Collaboration identified five randomized trials for inclusion in their review to determine if the injection of bulking agents is better than currently available treatments or no treatments for fecal incontinence in adults. Only two of the trials compared a bulking agent to sham treatment and none of the studies made a comparison of bulking agents versus other therapies. On the whole, the studies were of poor quality with only two providing adequate information to reliably assess bias. In addition, most of the studies were small and limited to short-term follow up. Two of the trials reported on the short-term benefit from injections as outcome measures improved with time but neither trial had follow up beyond 12 months (Siproudhis, Morcet et al. 2007; Graf, Mellgren et al. 2011). In addition, there appeared to be some short-term benefits from injections given with ultrasound guidance compared with digital guidance (Tjandra, Han et al. 2004). Two of the studies compared different types of bulking agents with the larger trial reporting that silicone material was better than the carbon coated beads in terms of fecal incontinence at six and 12 months (Tjandra, Chan et al. 2009). The smaller trial, which was not included in this critical appraisal, compared the injection of Bulkamid™ with Permacol™ and showed some improvement in outcomes in both groups but ultimately was too small to detect differences between groups (Maeda, Vaizey et al. 2008). Currently the literature addressing the efficacy of injectable bulking agents is limited for a variety of reasons. First and foremost, outcome measures and the definition of response to treatment are varied, and as a result, problematic for this indication. Furthermore, it is unclear how severity of incontinence at baseline affects outcomes data. Finally, there is a lack of information regarding the volume, the precise location where the agent should be placed, and the choice of guidance of the needle track. Several different techniques were employed with various bulking agents used across all studies making comparisons complicated. **SAFETY** Four of the five studies reported on adverse effects (Tjandra, Han et al. 2004; Siproudhis, Morcet et al. 2007; Tjandra, Chan et al. 2009; Graf, Mellgren et al. 2011). Overall, the observed adverse events were similar across all the studies with few complications reported and the most commonly reported complication being pain at injection site. Safety data collected from these trials is limited as it is not clear if complications were recorded systematically. The severity and duration were not always mentioned, and in many cases, adverse events were recorded with no information on the number of patients reporting these events. (For example, Graf and colleagues reported 128 adverse events in patients treated with NASHA Dx and 29 events in the sham treatment group but do not detail the number of patients reporting these adverse events.) Furthermore, the safety of injectable bulking agents has not been studied past 12 months. Other studies not included in this review also reported experiencing pain or minor ulceration at the injection site or in the anal canal for up to 10 weeks after the procedure (Malouf, Vaizey et al. 2001). Further complications included leakage of the bulking agent in 1 of 10 patients and, in a different study, passing of the bulking agent in 2 of 18 patients (Davis, Kumar et al. 2003). Conclusion: There is evidence from one large randomized trial to suggest that injectable bulking agents are effective up to 12 months. There is evidence to suggest that injectable bulking agents are reasonably safe in the short term. There is no evidence to permit conclusions about long term safety or efficacy of injectable bulking agents for fecal incontinence.

Articles: A literature search was conducted revealing a variety of publications including multiple case-series reports as well as case-control and cohort studies. One recent Cochrane review was also revealed which included five randomized trials measuring the effects of bulking agents versus placebo, bulking agents versus other types of bulking agents and bulking agents versus other minimally invasive interventions. No studies that compared the injection of bulking agent versus conservative treatment were revealed. Four of the studies included reporting of adverse events up to 12 months post treatment. The Cochrane review did not pool the results of the trials due to their heterogeneity. Four of the five trials included in the Cochrane Review were selected for appraisal: Graf W, Mellgren A, Matzel KE, Hull T et al. Efficacy of dextranomer in stabilized hyaluronic acid for treatment of faecal incontinence: a randomized, sham-controlled trial. *Lancet* 2011; **377**(9770):997-1003. [See Evidence Table 1](#). Siproudhis, L., J. Morcet, et al. Elastomer implants in faecal incontinence: a blind, randomized placebo-controlled study. *Alimentary Pharmacology & Therapeutics* 2007;**25**(9):1125-1132. [See Evidence Table 2](#). Tjandra, J., W. Han, et al. (2004). "Injectable silicone biomaterial for faecal incontinence due to internal sphincter dysfunction is effective." *Diseases of the Colon & Rectum* **47**(12): 2138-2146. [See Evidence Table 3](#). Tjandra, J, Chan M, et al. Injectable silicone biomaterial (PTQTM) is more effective than carbon-coated beads (Durasphere®) in treating passive faecal incontinence – a randomized trial." *Colorectal Disease* 2009;**11**(4):382-389. [See Evidence Table 4](#).

The use of Injectable Bulking Agents for Fecal Incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
L8605	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Creation Date	Review Dates	Date Last Revised
12/03/2013	01/07/2014 ^{MPC} , 11/04/2014 ^{MPC} , 09/01/2015 ^{MPC} , 07/05/2016 ^{MPC} , 05/02/2017 ^{MPC} , 03/06/2018 ^{MPC} , 02/05/2019 ^{MPC} , 02/04/2020 ^{MPC} , 02/02/2021 ^{MPC} , 02/01/2022 ^{MPC} , 02/07/2023 ^{MPC}	12/09/2015

^{MPC} Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L35008
12/9/2015	Added LCA A52922