

Medical Coverage Policy | Injectable Bulking Agent for Fecal Incontinence



EFFECTIVE DATE: 02|05|2013

POLICY LAST UPDATED: 10|06|2015

OVERVIEW

Bulking agents are injectable substances used to increase tissue bulk. They can be injected periurethrally and perianally to treat fecal incontinence. A number of products have been developed; the U.S. Food and Drug Administration (FDA) has approved 1 for treating fecal incontinence.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Injectable bulking agents in the treatment of fecal incontinence are considered not medically necessary as there is insufficient evidence in published peer reviewed medical literature to support their use.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for limitations of benefits/coverage when services are not medically necessary.

BACKGROUND

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 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 have been studied for the treatment of fecal incontinence. To date, only 1 bulking agent has been approved by the FDA for treating fecal incontinence. This is a formulation of nonanimal stabilized hyaluronic acid/dextranomer in stabilized hyaluronic acid (NASHA Dx) and is marketed by Q-Med as Solesta.

Overall, the evidence is not sufficient to conclude whether bulking agents are an effective treatment for fecal incontinence. Therefore, injectable bulking agents in the treatment of fecal incontinence are not medically necessary due to insufficient evidence in published peer reviewed medical literature to support its use.

CODING

BlueCHiP for Medicare and Commercial Products

The following codes are not medically necessary:

0377T

L8605 Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update December 2015

Provider Update, July 2014

Policy Update, April 2013

REFERENCES

1. Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. *Cochrane Database Syst Rev* 2013; 2:CD007959.
2. Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. *Cochrane Database Syst Rev* 2010; (5):CD007959.
3. Hussain ZI, Lim M, Stojkovic SG. Systematic review of perianal implants in the treatment of faecal incontinence. *Br J Surg* 2011; 98(11):1526-36.
4. Leung FW. Treatment of fecal incontinence - review of observational studies (OS) and randomized controlled trials (RCT) related to injection of bulking agent into peri-anal tissue. *J Interv Gastroenterol* 2011; 1(4):202-06.
5. Graf W, Mellgren A, Matzel KE et al. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. *Lancet* 2011; 377(9770):997-1003.
6. Dehli T, Stordahl A, Vatten LJ et al. Sphincter training or anal injections of dextranomer for treatment of anal incontinence: a randomized trial. *Scand J Gastroenterol* 2013.
7. La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of faecal incontinence. *Colorectal Dis* 2013; 15(5):569-74.
8. Morris OJ, Smith S, Draganic B. Comparison of bulking agents in the treatment of fecal incontinence: a prospective randomized clinical trial. *Tech Coloproctol* 2013; 17(5):517-23.
9. National Institute for Health and Clinical Excellence (NICE). Injectable bulking agents for faecal incontinence: February 2007. Available online at: <http://www.nice.org.uk/nicemedia/live/11288/31713/31713.pdf>. Last accessed January, 2014.
10. Tjandra JJ, Dykes SL, Kumar RR et al. Practice parameters for the treatment of fecal incontinence. *Dis Colon Rectum* [Practice Guideline]. 2007; 2007/08/04:1497-507. Available online at: <http://www.ncbi.nlm.nih.gov/pubmed/17674106>. Last accessed January, 2014. URYX.
11. FDA Summary of Safety and Effectiveness. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030030b.pdf. Last accessed January, 2014.

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

