

Medical Coverage Policy | Injectable Bulking Agent for Fecal Incontinence



EFFECTIVE DATE: 02|05|2013

POLICY LAST UPDATED: 12|06|2016

OVERVIEW

Bulking agents are injectable substances used to increase tissue bulk. They can be injected periurethrally 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

This policy is applicable to Commercial Products only. For Blue CHIP for Medicare, see related policy section. 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 eg, 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 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

Commercial Products

The following codes are not medically necessary:

0377T Anoscopy with directed submucosal injection of bulking agent for fecal incontinence (Effective January 1, 2015)

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

RELATED POLICIES

BlueCHiP for Medicare National and Local Coverage Determinations Policy

PUBLISHED

Provider Update, January 2017

Provider Update Dec 2015

Provider Update, July 2014

Policy Update, April 2013

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