

Solesta® for Fecal Incontinence

Solesta is an injectable bulking agent used in the treatment of fecal incontinence for individuals who have failed more conservative treatments. It is a biocompatible tissue bulking agent, injected in the submucosal layer of the anal canal, consisting of a viscous combination of stabilized hyaluronic acid and dextranomer-linked beads. While the exact mechanism of action has not been identified, it is hypothesized that the Solesta injections may narrow the anal canal, allowing for better sphincter control.

The New York State Department of Health will make a determination whether or not to add this treatment to the Medicaid benefit package.

Dossier sources of evidence already submitted:

The following evidence was recently submitted to the Department:

1. Bernstein MA, Purdy CH, Becker A et al. Three-Year Cost-effectiveness Model for Non-Animal Stabilized Hyaluronic Acid and Dextranomer Copolymer Compared With Sacral Nerve Stimulation After Conservative Therapy for the Management of Fecal Incontinence. *Clin Ther* 2014 May 8.
2. Danielson J, Karlbom U, Sonesson AC, Wester T, Graf W. Submucosal injection of stabilized nonanimal hyaluronic acid with dextranomer: a new treatment option for fecal incontinence. *Dis Colon Rectum*. 2009;52:1101-1106.
3. Danielson, J., Karlbom, U., Wester, T., Graf., W. Efficacy and quality of life 2 years after treatment for faecal incontinence with injectable bulking agents. *Tech Coloproctol*. 2013 Aug;17(4):389-95.
4. Dodi G, Jongen J, de la Portilla F, et al. An open-label, noncomparative, multicenter study to evaluate efficacy and safety of NASHA/Dx gel as a bulking agent for the treatment of fecal incontinence. *Gastroenterol Res Pract*. 2010;2010:467136.
5. Graf W, Mellgren A, Matzel KE, et al. Efficacy of dextranomer in stabilized hyaluronic acid for treatment of faecal incontinence: a randomized, sham-controlled trial. *Lancet*. 2011;377:997-1003.
6. 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):569-574.
7. Mellgren A, Matzel KE, Pollack J, et al. Long-term efficacy of NASHA Dx injection therapy for treatment of fecal incontinence. *Neurogastroenterol Motil*. 2014 May 19.

8. Mevik K, Norderval S, Kileng H, Johansen M, Vonen B. Long-term results after anterior sphincteroplasty for anal incontinence. *Scan J Surg.* 2009;234-238.
9. Schwandner O, Brunner M, Dietl O. Quality of life and functional results of submucosal injection therapy using dextranomer hyaluronic acid for fecal incontinence. *Surgical Innovation.* 2011;18(2):130-135.