

## Injectable Bulking Agents for Fecal Incontinence

Policy Number: PG0260  
Last Review: 02/01/2023

HMO AND PPO  
ELITE (MEDICARE ADVANTAGE)  
MARKETPLACE

### GUIDELINES:

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions, and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

### SCOPE:

☒ Professional  
☒ Facility

### DESCRIPTION:

Fecal incontinence (FI) is the loss of control of the bowels resulting in the involuntary loss of liquid or solid feces. The overall prevalence of FI ranges from 1% to 7% in otherwise healthy individuals. It affects nearly 18 million community-dwelling adults in the United States. FI has a negative impact on the activities of daily living and quality of life. Current treatments for FI range from conservative measures aimed at reducing symptoms (e.g., biofeedback, dietary modification, pelvic floor muscle training, and/or pharmacotherapy) to surgical interventions aimed at correcting anal sphincter or pelvic floor abnormalities.

Solesta® (Oceana Therapeutics, Inc., Edison, NJ, USA) received FDA-approval (P100014) in May 2011. This injectable bulking agent 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." Transanal submucosal injection of Solesta is a minimally invasive treatment for FI, which is intended to augment anal sphincter function. Following evacuation enema, and using an anoscope, the surgeon injects 4 x 1 milliliters (mL) of Solesta into each quadrant of the submucosa, slightly above the dentate line. The procedure can be repeated 4 weeks after the first treatment, if necessary. Administration of Solesta is an outpatient procedure with or without local anesthesia.

### POLICY:

#### **Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans**

#### **Paramount Commercial Insurance Plans and Paramount Advantage Medicaid**

- Injectable bulking agents (e.g. Solesta) for the treatment of fecal incontinence is non-covered.

#### **Elite (Medicare Advantage) Plans**

- Injectable bulking agents (e.g. Solesta) for the treatment of fecal incontinence requires prior authorization.

#### **Additional medical policies addressing fecal incontinence are the following (may not be an all-inclusive listing):**

- PG0057 Transanal Radiofrequency Therapy

- PG0306 Sacral Nerve Stimulation for Urinary and Fecal Incontinence
- PG0413 Peristeen Anal Irrigation System
- PG0462 Rectal Control System for Fecal Incontinence (Eclipse)

## COVERAGE CRITERIA:

### Paramount Commercial Insurance Plans and Elite (Medicare Advantage) Plans

#### **Paramount Commercial Insurance Plans and Paramount Advantage Medicaid**

Paramount has determined that injectable bulking agents (e.g. Solesta) for the treatment of fecal incontinence is experimental and investigational and therefore non-covered because there is insufficient evidence in the peer-reviewed medical literature of the effectiveness of this procedure.

#### **Elite (Medicare Advantage) Plans**

While there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long-term outcomes of injectable bulking agents (e.g. Solesta) for the treatment of fecal incontinence, CMS guidelines requires this procedure be reviewed for medical necessity therefore it may be covered with a prior authorization for Elite/ProMedica Medicare Plan members

CMS LCD considers Solesta™ as **medically appropriate for the FDA-approved indication of fecal incontinence** when all of the following criteria are met:

- Patient is 18 years or older
- Has a documented history of fecal incontinence for at least 12 months
- Documentation supports the patient has tried and failed conservative therapy (e.g., diet, fiber, anti-motility medications)
- Documentation supports ≥ 4 fecal incontinence episodes over a 14-day period; and
- The beneficiary does NOT have any of the following conditions:
  - Active inflammatory bowel disease
  - Immunodeficiency disorders or ongoing immunosuppressive therapy
  - Previous radiation treatment to the pelvic area
  - Significant mucosal or full thickness rectal prolapse
  - Active anorectal conditions including: abscess, fissures, sepsis, bleeding, proctitis, or other infections
  - Anorectal atresia, tumors, stenosis or malformation
  - Rectocele
  - Rectal varices
  - Presence of existing implant (other than Solesta) in anorectal region
  - Allergy to hyaluronic acid based products (e.g., Synvisc, Synvisc-One, Hyalgan, Supartz, Euflexxa, Orthovisc)

Other uses of Solesta™ will be considered investigational and will be denied accordingly

## CODING/BILLING INFORMATION:

The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

### HCPCS CODES

<b>L8605</b>	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal
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## REVISION HISTORY EXPLANATION: ORIGINAL EFFECTIVE DATE: 07/18/2014

Date	Explanation & Changes
07/18/14	<ul style="list-style-type: none"> <li>• Injectable bulking agents (e.g. Solesta) for the treatment of fecal incontinence is now covered with prior authorization for Elite per CMS guidelines.</li> <li>• Policy created to reflect most current clinical evidence per TAWG</li> </ul>

12/03/14	<ul style="list-style-type: none"> <li>Added new 2015 CPT code 0377T</li> </ul>
08/20/15	<ul style="list-style-type: none"> <li>Policy reviewed and updated to reflect most current clinical evidence per TAWG</li> </ul>
07/22/16	<ul style="list-style-type: none"> <li>Policy reviewed and updated to reflect most current clinical evidence per TAWG</li> </ul>
12/18/2020	<ul style="list-style-type: none"> <li>Medical policy placed on the new Paramount Medical Policy Format</li> </ul>
02/01/2023	<ul style="list-style-type: none"> <li>Policy reviewed and updated to reflect most current clinical evidence</li> <li>Paramount added the coverage criteria for the Medicare Advantage Plans</li> <li>Paramount removed deleted code 0377T</li> </ul>
03/29/2023	<ul style="list-style-type: none"> <li>Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.</li> </ul>
03/06/2024	<ul style="list-style-type: none"> <li>Medical policy placed on the new Paramount Medical Policy Format</li> </ul>

**Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to**

<https://www.paramounthealthcare.com/providers/medical-policies/policy-library>

## REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals> <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs>

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services <https://www.ama-assn.org/amaone/cpt-current-procedural-terminology>

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

U.S. Preventive Services Task Force, <https://www.uspreventiveservicestaskforce.org/uspstf/>  
Industry Standard Review

Hayes, Inc., <https://www.hayesinc.com/>

Industry Standard Review