

Injectable Bulking Agents for Fecal Incontinence

Policy Number: PG0260

Last Reviewed Date: 03/01/2025

Last Revised: 03/01/2025

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) is a biocompatible bulking agent administered by submucosal trans-anal injection. Solesta® may enhance perianal tissue bulking, resulting in narrowing of the anal opening and improved muscle control, thereby reducing involuntary loss of feces. Solesta® is intended for individuals 18 years and older who have failed conventional therapy for fecal incontinence.

POLICY:

Paramount Commercial Insurance Plans

- 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 does not require a prior authorization.

COVERAGE CRITERIA:

Paramount Commercial Insurance Plans

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

Injectable bulking agents (e.g., Solesta) for the treatment of fecal incontinence does not require a prior

authorization.

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

L8605	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">• Injectable bulking agents (e.g., Solesta) for the treatment of fecal incontinence is now covered with prior authorization for Elite per CMS guidelines.• Policy created to reflect most current clinical evidence per TAWG
12/03/14	<ul style="list-style-type: none">• Added new 2015 CPT code 0377T
08/20/15	<ul style="list-style-type: none">• Policy reviewed and updated to reflect most current clinical evidence per TAWG
07/22/16	<ul style="list-style-type: none">• Policy reviewed and updated to reflect most current clinical evidence per TAWG
12/18/2020	<ul style="list-style-type: none">• Medical policy placed on the new Paramount Medical Policy Format
02/01/2023	<ul style="list-style-type: none">• Policy reviewed and updated to reflect most current clinical evidence• Paramount added the coverage criteria for the Medicare Advantage Plans• Paramount removed deleted code 0377T
03/29/2023	<ul style="list-style-type: none">• Medical Policy updated to reflect DME limits calculated by CMS criteria/guidelines.
03/06/2024	<ul style="list-style-type: none">• Medical policy placed on the new Paramount Medical Policy Format
10/01/2024	<ul style="list-style-type: none">• Medical Policy reviewed and updated to reflect the most current clinical evidence.• Removed references to additional medical policies addressing fecal incontinence
03/01/2025	<ul style="list-style-type: none">• Medical Policy reviewed and updated to reflect the most current clinical evidence• Removed prior authorization requirement for Elite (Medicare Advantage) Product lines for code L8605, effective 3/1/2025 to align with Medical Mutual.

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>

National Physician Fee Schedule Relative Value File Calendar Year XXXX, Centers for Medicare & Medicaid Services (CMS) <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>

NCCI Policy Manual for Medicare Services, current version, Chapter 1, General Correct Coding Policies

<https://www.cms.gov/files/document/medicare-ncci-policy-manual-2023-chapter-1.pdf>

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>

Centers for Medicare & Medicaid Services (CMS), ICD-10-CM Official Guidelines for Coding and Reporting

<https://www.cms.gov/medicare/coding/icd10>

Centers of Medicare & Medicaid Services (CMS), Medicare Claims Processing Manual, Chapter 23-Fee

Schedule administration and coding Requirements <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c23.pdf>

Centers for Medicare & Medicaid Services (CMS), National Correct Coding Initiative (NCCI) Policy Manual for

Medicare Services <https://www.cms.gov/medicare-medicare-coordination/national-correct-coding-initiative-ncci/ncci-medicare>

Center for Medicare and Medicaid Services, Medicare NCCI Medically Unlikely Edits (MUEs)

<https://www.cms.gov/medicare/coding-billing/national-correct-coding-initiative-ncci-edits/medically-unlikely-edits>

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

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

Industry Standard Review