Clinical Policy: Fecal Incontinence Treatments

Reference Number: LA.CP.MP.137
Date of Last Revision: 07/~~24~~25

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Fecal incontinence is generally defined as the uncontrolled passage of feces over at least three month's duration in an individual who had previously achieved control.[1] It has substantial social and economic impact and significantly impairs quality of life.[2] The choice of therapy depends upon the etiology of incontinence, the anatomy of the sphincters, and the effect incontinence has on quality of life.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that procedures to treat fecal incontinence are **medically necessary** when meeting both of the following:

A. Severe, chronic fecal incontinence (defined as greater than two incontinent episodes on average per week and duration of incontinence greater than six months), that has not responded adequately to conservative treatments (e.g. pharmacotherapy, dietary management, strengthening exercises) in a member/enrollee ~~that~~who has previously achieved bowel control;

B. Requested procedure meets one of the following:

1. Sacral nerve stimulation (sacral neuromodulation) for a weak but structurally intact anal sphincter when all of the following criteria are met;
   a. A test of percutaneous stimulation was effective, defined as at least 50% sustained (more than one week) improvement in symptoms;
   b. Condition is not related to anorectal malformation (e.g., congenital anorectal malformation, defects of the external anal sphincter over 60 degrees, visible sequelae of pelvic radiation, active anal abscesses and fistulae) and/or chronic inflammatory bowel disease;
   c. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.
   d. Member/enrollee demonstrates the ability to operate the device or has a supportive caregiver who could otherwise provide assistance;
   ~~d.~~e. Has none of the following contraindications:
      i. Mechanical outlet obstruction;
      ii. Diathermy use (shortwave, microwave, ultrasound);
      ~~iii. Inadequate response to test stimulation or inability to operate the device;~~

~~2. Sphincter repair (sphincteroplasty) when there is a defined defect of the external anal sphincter;~~

~~3.~~2. Artificial bowel sphincter (Acticon Neosphincter) when all of the following criteria are met:
   a. Age~~-~~ ≥ 18 years;
   b. Failure of, or not a candidate for, medical interventions or surgical sphincter repair;

c. Incontinence is not complicated by an irreversibly obstructed proximal segment of bowel;

~~d. Absence of any physical or mental illness that would increase surgical risk;~~

~~4.~~3. Colostomy, as last resort, when all other treatments have failed or are contraindicated.

II. It is the policy of Louisiana Healthcare Connections that all the following procedures have not been proven effective for the treatment of fecal incontinence~~, although they continue to be evaluated in clinical studies:~~:

A. Transanal radiofrequency therapy (Secca procedure);
B. Injectable bulking agents [e.g., dextranomer/hyaluronic acid (Solesta)];
C. Anal electrical stimulation;
D. Posterior tibial nerve stimulation;
E. Vaginal bowel control (e.g., Eclipse system);
F. Sacral nerve stimulation for the treatment of chronic constipation or chronic pelvic pain.

Background

Treatment of fecal incontinence is challenging. The goal of treatment is to restore continence and to improve the quality of life. Dietary and medical management are initially recommended for patients with fecal incontinence. If fecal incontinence is a result of or in conjunction with anatomic defects (e.g., rectovaginal fistula, rectal or hemorrhoidal prolapse etc.), the defects should be corrected first as this often improves or eliminates the incontinence.[1] Although most current interventions show modest improvements, there is limited evidence to support any treatments for fecal incontinence past three to six months.[3,4]

Sacral neuromodulation is thought to modulate rectal sensation by activating or deactivating chemical mediating receptors, stimulating the afferent pathway, and changing brain activity relevant to the continence. Sacral neuromodulation has consistently resulted in a reduction in frequency of fecal incontinence episodes and may be considered for incontinent patients with and without sphincter defects. Sphincter repair (sphincteroplasty) can be a treatment option for symptomatic patients with a defined defect of the external anal sphincter. Implantation of an artificial bowel sphincter remains an effective tool for select patients with severe fecal incontinence; however, its use is limited by complications including explantation in up to one-third of patients.[1,2,5]

Injectable bulking agents [e.g., dextranomer/hyaluronic acid (Solesta)] have been investigated for the treatment of fecal incontinence. However, evidence in the peer reviewed literature evaluating this treatment is limited. There is a paucity of randomized, controlled trials, and studies are limited by their small study sizes.[2] A prospective multicenter trial of 136 patients with fecal incontinence who received non-animal stabilized hyaluronic acid/dextranomer (NASHA Dx) bulking agent reported it provided a significant improvement of fecal incontinence symptoms in a majority of patients, and this effect was stable during the course of the follow-up and was maintained for three years.[3] Long-term data is lacking, however, regarding the durability of this treatment.[6]

Transanal radiofrequency therapy (e.g., Secca procedure) is another procedure proposed for the treatment of fecal incontinence). This procedure uses thermo-controlled delivery of

radiofrequency energy to the anal canal. The reported evidence is relatively sparse and has relevant limitations. Most studies have been small single-center series with short to mid-term follow-up.[7,8]

The Eclipse System (Pelvalon Inc) is a nonsurgical vaginal bowel-control system for the treatment of fecal incontinence in women 18 to 75 years old who have had four or more fecal incontinence episodes in a two-week period. The device includes an inflatable balloon, which is placed in the vagina. Upon inflation, the balloon exerts pressure through the vaginal wall onto the rectal area, thereby reducing the number of fecal incontinence episodes. The device is initially fitted and inflated by a clinician with the use of a pump, and after proper fitting, the patient can inflate and deflate the device at home as needed. The device was granted FDA approval through the de novo classification process based on non-clinical testing as well as a clinical trial of 61 women with fecal incontinence treated with the device. The trial showed that after one month almost 80 percent of women in the study experienced a 50 percent decrease in the number of fecal incontinence episodes while using the device, as compared to baseline. Studies to date are limited by size and lack of long term evidence.[9,10]

American Society of Colon and Rectal Surgeons (ASCRS)
In their most recent 2023 guidelines on the treatment of fecal incontinence, the ASCRS assigns conditional recommendations for sacral neuromodulation and sphincteroplasty based upon low quality of evidence. The ASCRS reports that injection of biocompatible bulking agents into the anal canal may help to decrease episodes of passive fecal incontinence. However, the ASCRS notes that "given the limited improvement over placebo, diminishing long-term results, and cost, injectable bulking agents are not considered first-line treatment for fecal incontinence."[1]

The ASCRS guideline states the application of temperature-controlled radiofrequency energy to the sphincter complex is not recommended for the treatment of fecal incontinence. Per the ASCRS, "the evidence supporting this approach is relatively sparse and has relevant limitations, additionally, no new studies evaluating this modality have been published since 2014."[1]

American College of Gastroenterology (ACG)
Regarding minimally invasive procedures for the treatment of fecal incontinence, the ACG concluded that minimally invasive procedures such as injectable anal bulking agents may have a role in patients with fecal incontinence who do not respond to conservative therapy. However, they note this is a weak recommendation based on moderate quality of evidence. The ACG reported that there is insufficient evidence to recommend radiofrequency ablation treatment to the anal sphincter (SECCA) at this time.[7]

National Institute for Health and Clinical Excellence
An interventional procedure guidance on injectable bulking agents for fecal incontinence concluded that current evidence on the safety and efficacy of injectable bulking agents for fecal incontinence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research, which should take place in the context of a clinical trial or formal audit protocol that includes information on well-defined patient groups.[6]

American College of Obstetricians and Gynecologists (ACOG)

A practice bulletin on fecal incontinence concluded that anal sphincter bulking agents may be effective in decreasing fecal incontinence episodes up to six months and can be considered as a short-term treatment option for fecal incontinence in women who have failed more conservative treatments. However, this was based on limited or inconsistent scientific evidence (Level B).[3]

Coding Implications

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NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

CPT codes that support coverage criteria

CPT® Codes	Description
44320	Colostomy or skin level cecostomy
46750	Sphincteroplasty, anal, for incontinence or prolapse; adult
46751	Sphincteroplasty, anal, for incontinence or prolapse; child
46760	Sphincteroplasty, anal, for incontinence, adult; muscle transplant
46761	Sphincteroplasty, anal, for incontinence, adult; levator muscle imbrication (Park posterior anal repair)
46999	Unlisted procedure, anus
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585*	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595*	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care

CPT® Codes	Description
	professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator /transmitter (eg contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator /transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS codes that support coverage criteria

HCPCS Codes	Description
A4290*	Sacral nerve stimulation test lead, each
A4335	Incontinence supply; miscellaneous
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
E0745*	Neuromuscular stimulator, electronic shock unit
L8680*	Implantable neurostimulator electrode, each
L8681*	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682*	Implantable neurostimulator radiofrequency receiver
L8683*	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684*	Radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management, replacement
L8685*	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686*	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687*	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688*	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

HCPCS Codes	Description
L8689*	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only.

CPT codes that do not support coverage criteria

CPT® Codes	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming

HCPCS codes that do not support coverage criteria

HCPCS Codes	Description
L8605*	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies

Reviews, Revisions, and Approvals	Revision Date	Approval Date	Effective Date
Converted corporate to local policy.	8/15/20		
Annual review completed. References reviewed, updated, and reformatted. "Experimental/investigational" verbiage replaced in policy statement with "have not been proven effective for the treatment of fecal incontinence, although they continue to be evaluated in clinical studies". Replaced all instances of "member" with "member/enrollee". "Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Minor verbiage changes to background with no clinical significance.	1/22	1/22	
Annual review completed. In Section I.B. changed "member" to "member/enrollee". Added "sacral neuromodulation" to Section I.C. Background updated with minor verbiage changes with no clinical significance. Updated description for CPT codes 46760, 46761, 64581, 64590 and HCPCS Code L8683. References reviewed and updated. Specialist reviewed.	9/22	11/28/22	
Annual review. Removed "≥ 4 years age" criteria and added "in a member/enrollee that has previously achieved bowel control" to I.A. Also removed "more than twelve months after vaginal childbirth" from definition of severe, chronic fecal incontinence in I.A. Description and background section updated with no clinical significance. References reviewed and updated. External specialist reviewed.	07/23	10/30/23	
Annual review. Minor rewording in Description and in Background with no impact on criteria. References reviewed and updated.	07/24	9/24/24	10/25/24
Annual review. Added criteria I.B.1.d. Member/enrollee demonstrates the ability…and removed I.B.1.e.iii. Inadequate response to test stimulation…and I.B.3.d. Absence of any physical or mental illness… Removed previous criteria I.B.2. for sphincteroplasty. Reworded policy statement II. with no impact on criteria. Added CPT 44320 and HCPCS C1767, C1778 to coding tables. References reviewed and updated. Reviewed by external specialist.	07/25		

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional

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