

Clinical Policy: Fecal Incontinence Treatments

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Description

Fecal incontinence defined as the uncontrolled passage of feces or gas over at least 1 month's duration, in an individual of at least four years of age, who had previously achieved control. It has a negative impact on self-esteem and quality of life.¹ The choice of therapy depends upon the etiology of incontinence, the anatomy of the sphincters, and also on the effect of incontinence on the quality of life.

Note: For biofeedback treatment for fecal incontinence, please refer to PA.CP.MP.168 Biofeedback.

Policy/Criteria

- I. It is the policy of Pennsylvania Health and Wellness[®] (PHW) that any of the following procedures are **medically necessary** for treatment of severe, chronic fecal incontinence when there has been an inadequate response to conservative treatments (e.g. pharmacotherapy, dietary management, strengthening exercises) and the treatment-specific criteria have been met:
 - A. Sacral nerve stimulation for a weak but structurally intact anal sphincter;
 - B. Sphincter repair (sphincteroplasty) when there is a defined defect of the external anal sphincter;
 - C. Artificial bowel sphincter (Acticon Neosphincter) when all of the following criteria is met:
 1. Age 18 or older;
 2. Failure of or not a candidate for medical or surgical interventions;
 3. Incontinence is not complicated by an irreversibly or obstructed proximal segment of bowel;
 4. Absence of any physical or mental illness that would increase surgical risk;
 - D. Colostomy, as last resort, when all other treatments have failed.

- II. It is the policy of PHW that any the following procedures are considered **investigational** for the treatment of fecal incontinence. Although they continue to be evaluated in clinical studies, current medical literature does not support their efficacy:
 - 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.

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 recommended as first-line therapy 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.

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 shown to result in a reduction in frequency of fecal incontinence episodes and may be considered for incontinent patients with and without sphincter defects. Sphincter repair (sphincteroplasty) may be offered to 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.²

Injectable bulking agents [e.g., dextranomer/hyaluronic acid (Solesta)] have been investigated for the treatment of fecal incontinence. However, evidence in the peer review literature evaluating this treatment is limited. There is a paucity of randomized, controlled trials and studies are limited by their small study sizes. 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 maintained for 3 years.³ Long-term data is lacking, however, regarding the durability of this treatment.

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.

American Society of Colon and Rectal Surgeons (ASCRS)

In their most recent guidelines on the treatment of fecal incontinence, the ASCRS assigns strong recommendations in favor of sacral neuromodulation, and sphincteroplasty based upon moderate 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, based upon moderate-quality evidence, this is a weak recommendation. The ASCRS notes that although modest improvements have been reported in short-term outcomes, long-term follow-up with regard to safety and efficacy awaits further experience.

The ASCRS guideline states the application of temperature-controlled radiofrequency energy to the sphincter complex may be used to treat fecal incontinence. However, this is also a weak recommendation based on moderate-quality of evidence. The ASCRS reports that most studies have been small single-center series with short-term follow-up. Per the ASCRS, “Because of the limitations in the available data, alternative treatments should be pursued before considering radiofrequency energy delivery.”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

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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.⁴

National Institute for Health and Clinical Excellence

An interventional procedure guidance on injectable bulking agents for fecal incontinence concluded the 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.⁵

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2017, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| CPT® Codes | Description |
|------------|---|
| 46750 | Sphincteroplasty, anal, for incontinence or prolapse; adult |
| 46751 | Sphincteroplasty, anal, for incontinence or prolapse; child |
| 46760 | Sphincteroplasty, anal, for incontinence or prolapse, adult; muscle transplant |
| 46761 | Sphincteroplasty, anal, for incontinence or prolapse, adult; levator muscle imbrication (Park posterior anal repair) |
| 46762 | Sphincteroplasty, anal, for incontinence or prolapse, adult; implantation artificial sphincter |
| 46999 | Unlisted procedure, anus |
| 64561 | Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) including image guidance, if performed |
| 64581 | Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) |
| 64585 | Revision or removal of peripheral neurostimulator electrodes |
| 64590 | Insertion and replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling |
| 64595 | Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver |
| 95970 | Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or |

| CPT® Codes | Description |
|-------------------|--|
| | peripheral (i.e. cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming |
| 95971 | Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude. Pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming |
| 95972 | Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude. pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord or peripheral (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse/generator/transmitter, with intraoperative or subsequent programming |
| 97110 | Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility |
| 97530 | Therapeutic procedure, one or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility |

| HCPCS Codes | Description |
|--------------------|---|
| A4290 | Sacral nerve stimulation test lead, each |
| 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 (internal) 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 |
| L8689 | External recharging system for battery (internal) for use with implantable neurostimulator, replacement only. |

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

| ICD-10-CM Code | Description |
|----------------|--------------------|
| R15-R15.9 | Fecal incontinence |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|-----------------------------------|------|---------------|
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