

## Clinical Policy: Fecal Incontinence Treatments

Reference Number: CP.MP.137

Effective Date: 12/16

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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.<sup>1</sup> 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 CP.MP.168 Biofeedback.*

### Policy/Criteria

- I. It is the policy of health plans affiliated with Centene Corporation® 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 health plans affiliated with Centene Corporation 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;
  - E. Vaginal bowel control (e.g, Eclipse system).

### **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 explanation in up to one-third of patients.<sup>2</sup>

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.<sup>3</sup> 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.

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 FI 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 FI 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 FI 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 FI episodes while using the device, as compared to baseline. Studies to date are limited by size and lack of long term evidence.

*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.”<sup>1</sup>

*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.<sup>4</sup>

*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.<sup>5</sup>

**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.

<b>CPT® Codes</b>	<b>Description</b>
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

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<b>CPT® Codes</b>	<b>Description</b>
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 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

<b>HCPCS Codes</b>	<b>Description</b>
A4290	Sacral nerve stimulation test lead, each
A4335	Incontinence supply; miscellaneous
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

HCPCS Codes	Description
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
Policy adopted from Health Net NMP325 Fecal Incontinence Treatments	11/16	12/16
Removed criteria and related background for biofeedback treatment, as this was incorporated into CP.MP.168 Biofeedback.	06/17	
Added II.E. Vaginal bowel control (e.g, Eclipse system) as investigational. References and codes reviewed and updated.	11/17	12/17

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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 organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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