

Clinical Policy: Fecal Incontinence Treatments

Reference Number: NC.CP.MP.137

Last Review Date: 03/21

[Coding Implications](#)

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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 CP.MP.168 Biofeedback.

Policy/Criteria

- I. It is the policy of Carolina Complete Health[®] that procedures to treat fecal incontinence are **medically necessary** when meeting the following:
 - A. Severe, chronic fecal incontinence has not responded adequately to conservative treatments (e.g. pharmacotherapy, dietary management, strengthening exercises);
 - B. Age \geq 4 years and the member has previously achieved bowel control;
 - C. Requested procedure meets one of the following:
 1. Sphincter repair (sphincteroplasty) when there is a defined defect of the external anal sphincter;
 2. Artificial bowel sphincter (Acticon Neosphincter) when all of the following criteria is met:
 - a. Age \geq 18 years;
 - b. Failure of, or not a candidate for, medical or surgical interventions;
 - 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;
 3. Colostomy, as last resort, when all other treatments have failed or are contraindicated.
- II. It is the policy of Carolina Complete Health that all 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.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.

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.”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.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

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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

HCPCS Codes	Description
A4335	Incontinence supply; miscellaneous

ICD-10-CM Diagnosis Codes that Support Coverage Criteria

ICD-10-CM Code	Description
R15.0-R15.9	Fecal incontinence

Reviews, Revisions, and Approvals	Date	Approval Date
Policy adapted from CP.MP.137. Removed criteria, codes, and references associated with sacral neurostimulation as it is not on the NC Medicaid fee schedule.	08/19	08/19
Annual review completed. No changes to policy content.	03/21	03/21

References

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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

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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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