Clinical Policy: Fecal Incontinence Treatments

Reference Number: CP.MP.137 Coding Implications
Date of Last Revision: 07/21 Revision Log

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

Description

Fecal incontinence is 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 health plans affiliated with Centene Corporation® that procedures to treat fecal incontinence are **medically necessary** when meeting 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 **or** for more than twelve months after vaginal childbirth), and has not responded adequately to conservative treatments (e.g. pharmacotherapy, dietary management, strengthening exercises);

B. Age ≥ 4 years and the member has previously achieved bowel control;

C. Requested procedure meets one of the following:

1. Sacral nerve stimulation for a weak but structurally intact anal sphincter when all of the following criteria is 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. 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. Artificial bowel sphincter (Acticon Neosphincter) when all of the following criteria is 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. Colostomy, as last resort, when all other treatments have failed or are contraindicated.

II. It is the policy of health plans affiliated with Centene Corporation that 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 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.

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]

American College of Obstetricians and Gynecologists (ACOG) [25] A practice bulletin on fecal incontinence concluded that anal sphincter bulking agents may be effective in decreasing fecal incontinence episodes up to 6 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)

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 2020, 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 that support coverage criteria

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)
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/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 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 system [e.g. 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

CPT® Codes	Description
	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
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 codes that support coverage criteria

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

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
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
Added that all other treatments are contraindicated in I.C.4. Added age at least 4 years and previously achieved bowel control. References reviewed and updated.	10/18	11/18
Added definition of severe FI to I.A for clarity. Revised I.C.3.b. To state, "Failure of, or not a candidate for, medical interventions or surgical sphincter repair." Added recommendation from ACOG to background. References reviewed and updated. CPT code 46762 deleted. Added CPT code 64566 and HPCPS code L8605 as codes that do not support medical necessity. Revised description of CPT codes 95970, 95971 and 95972. Reviewed by specialist.	11/19	11/19
Additional criteria added for sacral nerve stimulators from local coverage article (A53017). Clarified definition of chronic fecal incontinence as greater than two incontinent episodes on average per week and duration of incontinence greater than six months or for more than twelve months after vaginal childbirth. Added additional criteria requiring a successful percutaneous test stimulation, condition not be related to anorectal malformation and/or chronic inflammatory bowel disease, incontinence not be related to another neurologic condition and contraindications for device. Added sacral nerve stimulation for the treatment of chronic constipation or chronic pelvic pain to the not medically necessary section II.	07/20	07/20
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	07/21	07/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		

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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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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible

for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members/enrollees, 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/enrollees, 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.