

Clinical Policy: Fecal Incontinence Treatments

Reference Number: NC.CP.MP.137

Date of Last Revision: 07/21

[Coding Implications](#)

[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 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 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)

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) ²⁵A 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 2018, 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

CPT® Codes	Description
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
Annual review of CP.MP.137 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.	07/21	07/21

References

1. Paquette IM, Varma MG, Kaiser AM, Steele SR, Rafferty JF. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence. *Dis Colon Rectum*. 2015;58(7):623-636. doi:10.1097/DCR.0000000000000397.
2. Robson K.M, Lembo A.J. Fecal incontinence in adults: management. UpToDate. www.uptodate.com. Updated September 28, 2020. Accessed June 25, 2021.
3. Mellgren A, Matzel KE, Pollack J, et al. Long-term efficacy of NASHA Dx injection therapy for treatment of fecal incontinence. *Neurogastroenterol Motil*. 2014;26(8):1087-1094. doi:10.1111/nmo.12360.
4. Wald A, Bharucha AE, Cosman BC, Whitehead WE. ACG clinical guideline: management of benign anorectal disorders. *Am J Gastroenterol*. 2014 Aug;109(8):1141-57; (Quiz) 1058. doi: 10.1038/ajg.2014.190. Epub 2014 Jul 15. PMID: 25022811.

5. National Institute for Health and Clinical Excellence. Injectable bulking agents for fecal incontinence. <https://www.nice.org.uk/guidance/ipg210/resources/injectable-bulking-agents-for-faecal-incontinence-pdf-1899865208328901> Published February 28, 2007. Updated March 2010. Accessed June 25, 2021.
6. Hayes Health Technology Brief. Solesta (NASHA Dx; Q-Med AB) for Treatment of Fecal Incontinence. Published October 16, 2014. (archived November 16, 2017). Accessed June 25, 2021.
7. Sanchez JE, Brenner DM, Franklin H, Yu J, Barrett AC, Paterson C. Validity of the $\geq 50\%$ Response Threshold in Treatment With NASHA/Dx Injection Therapy for Fecal Incontinence. *Clin Transl Gastroenterol*. 2015;6(1):e70. Published 2015 Jan 15. doi:10.1038/ctg.2014.20.
8. Lefebure B, Tuech JJ, Bridoux V, Gallas S, Leroi AM, Denis P, Michot F. Temperature-controlled radio frequency energy delivery (Secca procedure) for the treatment of fecal incontinence: results of a prospective study. *Int J Colorectal Dis*. 2008 Oct;23(10):993-7. doi: 10.1007/s00384-008-0514-0. Epub 2008 Jul 2. PMID: 18594840.
9. Ruiz D, Pinto RA, Hull TL, Efron JE, Wexner SD. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? *Dis Colon Rectum*. 2010 Jul;53(7):1041-6. doi: 10.1007/DCR.0b013e3181deff8. PMID: 20551757.
10. Felt-Bersma RJ. Temperature-controlled radiofrequency energy in patients with anal incontinence: an interim analysis of worldwide data. *Gastroenterol Rep (Oxf)*. 2014 May;2(2):121-5. doi: 10.1093/gastro/gou016. Epub 2014 Apr 12. PMID: 24759350; PMCID: PMC4020122.
11. Lam TJ, Visscher AP, Meurs-Szojda MM, Felt-Bersma RJ. Clinical response and sustainability of treatment with temperature-controlled radiofrequency energy (Secca) in patients with fecal incontinence: 3 years follow-up. *Int J Colorectal Dis*. 2014 Jun;29(6):755-61. doi: 10.1007/s00384-014-1882-2. Epub 2014 May 8. PMID: 24805249.
12. Takahashi-Monroy T, Morales M, Garcia-Osogobio S, Valdovinos MA, Belmonte C, Barreto C, Zarate X, Bada O, Velasco L. SECCA procedure for the treatment of fecal incontinence: results of five-year follow-up. *Dis Colon Rectum*. 2008 Mar;51(3):355-9. doi: 10.1007/s10350-007-9169-0. Epub 2008 Jan 19. PMID: 18204954.
13. Efron JE, Corman ML, Fleshman J, Barnett J, Nagle D, Birnbaum E, Weiss EG, Noguera JJ, Sligh S, Rabine J, Wexner SD. Safety and effectiveness of temperature-controlled radiofrequency energy delivery to the anal canal (Secca procedure) for the treatment of fecal incontinence. *Dis Colon Rectum*. 2003 Dec;46(12):1606-16; discussion 1616-8. doi: 10.1007/BF02660763. PMID: 14668584.
14. Sanchez JE, Brenner DM, Franklin H, Yu J, Barrett AC, Paterson C. Validity of the $\geq 50\%$ Response Threshold in Treatment With NASHA/Dx Injection Therapy for Fecal Incontinence. *Clin Transl Gastroenterol*. 2015 Jan 15;6(1):e70. doi: 10.1038/ctg.2014.20. PMID: 25588523; PMCID: PMC4418408.
15. La Torre F, de la Portilla F. Long-term efficacy of dextranomer in stabilized hyaluronic acid (NASHA/Dx) for treatment of fecal incontinence. *Colorectal Dis*. 2013 May;15(5):569-74. doi: 10.1111/codi.12155. PMID: 23374680.
16. Franklin H, Barrett AC, Wolf R. Identifying factors associated with clinical success in patients treated with NASHA(®)/Dx injection for fecal incontinence. *Clin Exp Gastroenterol*. 2016 Mar 2;9:41-7. doi: 10.2147/CEG.S95238. PMID: 27042136; PMCID: PMC4780737.

17. Graf W, Mellgren A, Matzel KE, Hull T, Johansson C, Bernstein M; NASHA Dx Study Group. Efficacy of dextranomer in stabilised hyaluronic acid for treatment of faecal incontinence: a randomised, sham-controlled trial. *Lancet*. 2011 Mar 19;377(9770):997-1003. doi: 10.1016/S0140-6736(10)62297-0. PMID: 21420555.
18. Frascio M, Stabilini C, Casaccia M, Testa T, Fornaro R, Parodi MC, Marrone C, Gianetta E, Mandolino F. Radiofrequency Procedure (SECCA®) for Fecal Incontinence: One-Year Experience. *Surg Technol Int*. 2017 Jul 25;30:97-101. PMID: 28277597.
19. Visscher AP, Lam TJ, Meurs-Szojda MM, Felt-Bersma RJF. Temperature-Controlled Delivery of Radiofrequency Energy in Fecal Incontinence: A Randomized Sham-Controlled Clinical Trial. *Dis Colon Rectum*. 2017 Aug;60(8):860-865. doi: 10.1097/DCR.0000000000000861. PMID: 28682972.
20. Al-Bayati I, Saadi M, Elhanafi S, McCallum RW. Effectiveness of Bulking Agent (Solesta) Therapy in Fecal Incontinence in Patients Refractory to Conventional Therapies. *Am J Med Sci*. 2017 Nov;354(5):476-479. doi: 10.1016/j.amjms.2017.09.001. Epub 2017 Sep 5. PMID: 29173359.
21. van der Wilt AA, Giuliani G, Kubis C, van Wunnik BPW, Ferreira I, Breukink SO, Lehur PA, La Torre F, Baeten CGMI. Randomized clinical trial of percutaneous tibial nerve stimulation versus sham electrical stimulation in patients with faecal incontinence. *Br J Surg*. 2017 Aug;104(9):1167-1176. doi: 10.1002/bjs.10590. PMID: 28703936.
22. Richter HE, Matthews CA, Muir T, Takase-Sanchez MM, Hale DS, Van Drie D, Varma MG. A vaginal bowel-control system for the treatment of fecal incontinence. *Obstet Gynecol*. 2015 Mar;125(3):540-547. doi: 10.1097/AOG.0000000000000639. PMID: 25730213.
23. Varma MG, Matthews CA, Muir T, Takase-Sanchez MM, Hale DS, Van Drie D, Richter HE. Impact of a Novel Vaginal Bowel Control System on Bowel Function. *Dis Colon Rectum*. 2016 Feb;59(2):127-31. doi: 10.1097/DCR.0000000000000517. PMID: 26734971.
24. Hayes Health Technology Brief. Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence. Published December 29, 2015. (archived January 29, 2021) Accessed June 25, 2021.
25. ACOG Practice Bulletin No. 210: Fecal Incontinence. *Obstet Gynecol*. 2019 Apr;133(4):e260-e273. doi: 10.1097/AOG.00000000000003187. Erratum in: *Obstet Gynecol*. 2019 Nov;134(5):1121. PMID: 30913197.
26. Local coverage article: billing and coding: sacral nerve stimulation for urinary and fecal incontinence (A53017). Centers for Medicare and Medicaid Services website. <http://www.cms.hhs.gov/mcd/search.asp>. Published October 1, 2015 (revised January 1, 2020). Accessed June 25, 2021.
27. Ellsworth, P.I. Sacral nerve stimulation. Medscape website. <https://emedicine.medscape.com/article/2036909-overview#a1>. Published December 9, 2015 (updated June 7, 2018). Accessed June 25, 2021.

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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

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.

©2016 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene® and Centene Corporation® are registered trademarks exclusively owned by Centene Corporation.