

## Medical Policy:

### Fecal Incontinence Treatment

POLICY NUMBER	LAST REVIEW
MG.MM.ME.63bC	May 13, 2022

**Medical Guideline Disclaimer Property of EmblemHealth. All rights reserved.**

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## Definitions

EmblemHealth utilizes the definitions in the table below for this guideline.

Anal incontinence	Involuntary loss of solid or liquid feces or flatus
Severe fecal incontinence	Involuntary loss of solid or liquid feces or flatus on a weekly, or more, frequent basis
Conservative medical interventions	Dietary management, pharmacotherapy, strengthening exercises

## Guideline

Any of the following treatments is considered medically necessary for severe fecal incontinence when any conservative intervention has failed:

1. Anal sphincter repair
2. Colostomy — member has failed/is not a candidate for medical interventions or surgical sphincter repair (e.g., post-anal repair, sphincteroplasty or total pelvic floor repair, biofeedback pelvic training [check member benefits])

3. Acticon™ Neosphincter artificial bowel sphincter — member is ≥ 18 years of age and has failed/is not a candidate for medical interventions or surgical sphincter repair (e.g., post-anal repair, sphincteroplasty, or total pelvic floor repair)
4. Sacral nerve stimulation (sacral neuromodulation) for chronic fecal incontinence — member has had an inadequate response to conservative treatments and has a weak but structurally intact anal sphincter

Note: A 2–3-week trial with a temporary percutaneous peripheral nerve electrode must be completed before implantation with a permanent implantable pulse generator (e.g., InterStim®) can be considered. Implantation is considered medically necessary when there is a ≥ 50 % improvement in incontinence symptoms derived from the temporary percutaneous peripheral nerve stimulation.

## Limitations and Exclusions

The Acticon Neosphincter is not considered medically necessary when the above criteria are not met and when its use is contraindicated. (I.e., incontinence complicated by irreversibly obstructed proximal segment of bowel, poor candidacy for surgery or anesthesia, etc.)

The following interventions are not considered medically necessary due to insufficient evidence of therapeutic value:

1. Radiofrequency energy delivery (e.g., Secca Therapy)
2. Perianal electrical stimulation
3. Injectable bulking agents (e.g., Solesta®)
4. Vaginal bowel control (e.g., eclipse system™) (Covered for Medicare members only)
5. Injection of autologous myoblast cells
6. Injection of mesenchymal stem cells
7. Topical estrogen
8. Tibial nerve stimulation
9. Pudendal nerve terminal motor latency
10. Interna® Dermal Regeneration FENIX™ Contenance Restoration System

## Procedure Codes

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable implantable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) 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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator
L8695	External recharging system for battery (external) for use with implantable neurostimulator

## ICD-10 Diagnoses

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, 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 (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable implantable neurostimulator pulse generator
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) 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, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator
L8695	External recharging system for battery (external) for use with implantable neurostimulator

## References

- Alavi K, Chan S, Wise P, et al. Fecal Incontinence: Etiology, Diagnosis, and Management. *J Gastrointest Surg*. 2015 Oct;19(10):1910-21.
- Barnett JL, Hasler WL, Camilleri M. American Gastroenterological Association medical position statement on anorectal testing techniques. *Gastroenterology*. 1999;116(3):732-760.
- Bharucha AE, Fletcher JG, Melton LJ, 3rd, Zinsmeister AR. Obstetric trauma, pelvic floor injury and fecal incontinence: a population-based case-control study. *Am J Gastroenterol*. 2012;107:902–911.
- Cochrane Database Syst Rev. 2012 Jul 11;(7):CD002111. doi: 10.1002/14651858.CD002111.pub3. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. Norton C1, Cody JD.
- Dehli T, Stordahl A, Vatten LJ et al. Sphincter training or anal injections of dextranomer for treatment of anal incontinence: a randomized trial. *Scand J Gastroenterol* 2013
- Dis Colon Rectum. 2011 Jul;54(7):846-56. doi: 10.1007/DCR.0b013e3182148fef. Biofeedback for fecal incontinence: a randomized study comparing exercise regimens. Bartlett L1, Sloots K, Nowak M, Ho YH.
- Frudinger A, Kölle D, Schwaiger W, et al. Muscle-derived cell injection to treat anal incontinence due to obstetric trauma: Pilot study with 1 year follow-up. *Gut*. 2010;59(1):55-61.
- Hosker G, Norton C, Brazzelli M. Electrical stimulation for faecal incontinence in adults. *Cochrane Database Syst Rev*. 2000;(2). *Int J Colorectal Dis*. 2013 Nov;28(11):1567-77. doi: 10.1007/s00384-013-1739-0. Epub 2013 Jul 31. Electrical stimulation and biofeedback for the treatment of fecal incontinence: a systematic review. Vonthein R1, Heimerl T, Schwandner T, Ziegler A.
- 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 faecal incontinence: 3 years follow-up. *Int J Colorectal Dis*. 2014;29(6):755-761.
- Leung FW. Treatment of fecal incontinence - review of observational studies (OS) and randomized controlled trials (RCT) related to injection of bulking agent into peri-anal tissue. *J Interv Gastroenterol* 2011; 1(4):202-06
- Maeda Y, Laurberg S, Norton C. Perianal injectable bulking agents as treatment for faecal incontinence in adults. *Cochrane Database Syst Rev*. 2013 Feb 28;2:CD007959
- Maslekar S, et al. Injectable collagen for the treatment of fecal incontinence: long-term results. *Dis Colon Rectum* 2013 Mar;56(3):354-9.
- Nandivada P, Nagle D. Surgical therapies for fecal incontinence. *Curr Opin Gastroenterol*. 2014;30(1):69-74.
- National Institute for Clinical Excellence (NICE). Endoscopic radiofrequency therapy of the anal sphincter for faecal incontinence. 2011. <https://www.nice.org.uk/guidance/ipg393>. Accessed May 25, 2022.
- National Institute for Health and Clinical Excellence (NICE). Injectable bulking agents for faecal incontinence. 2007. <https://www.nice.org.uk/guidance/ipg210> . Accessed May 25, 2022.
- National Institute for Health and Clinical Excellence (NICE). Percutaneous tibial nerve stimulation for faecal incontinence. 2011. <https://www.nice.org.uk/guidance/ipg395>. Accessed May 25, 2022.
- Park EJ, Kang 1, Baik SH. Treatment of faecal incontinence using allogeneic-adipose-derived mesenchymal stem cells: A study protocol for a pilot randomised controlled trial. *BMJ Open*. 2016;6(2):e010450.
- Paquette IM, Varma MG, Kaiser AM, et al. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence. July 2015. [https://www.fascrs.org/sites/default/files/downloads/publication/clinical\\_practice\\_guideline\\_for\\_the\\_treatment\\_of\\_fecal\\_incontinence.pdf](https://www.fascrs.org/sites/default/files/downloads/publication/clinical_practice_guideline_for_the_treatment_of_fecal_incontinence.pdf). Accessed May 25, 2022.
- Robson K, Lembo AJ. Fecal incontinence in adults: Etiology and evaluation. UpToDate Inc., Waltham, MA. Last reviewed April 2015.
- Ruiz D, Pinto RA, Hull TL et al. Does the radiofrequency procedure for fecal incontinence improve quality of life and incontinence at 1-year follow-up? *Dis Colon Rectum* 2010; 53(7):1041-6.
- Satish S, Rao M. Diagnosis and management of fecal incontinence. Practice Guidelines. *American Journal of Gastroenterology* 2004;

doi:10.1111/j.1572-0241.2004.40105.x

Treatments for Fecal Incontinence [Internet]. Editors Forte ML, Andrade KE, Butler M, Lowry AC, Bliss DZ, Slavin JL, Kane RL. Source Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 Mar. Report No.: 15(16)-EHC037-EF. AHRQ Comparative Effectiveness Reviews.

Up to Date. Fecal incontinence in adults: Etiology and evaluation. Authors: Kristen M Robson, MD, MBA, FACGAnthony J Lembo, MDSection Editor:Nicholas J Talley, MD, PhDDeputy Editor:Shilpa Grover, MD, MPH. August 10, 2016.

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.

Findlay JM, Maxwell-Armstrong C. Posterior tibial nerve stimulation and faecal incontinence: A review. Int J Colorectal Dis. 2011;26(3):265-273.

National Institute for Health and Care Excellence (NICE) Website. Percutaneous tibial nerve stimulation for faecal incontinence. May 25, 2011.

Thomas GP, Dudding TC, Rahbour G, et al. A review of posterior tibial nerve stimulation for faecal incontinence. Colorectal Dis. 2013;15(5):519-526.

Horrocks EJ, Thin N, Thaha MA, et al. Systematic review of tibial nerve stimulation to treat faecal incontinence. Br J Surg. 2014;101(5):457-468.

Edenfield AL, Amundsen CL, Wu JM, et al. Posterior tibial nerve stimulation for the treatment of fecal incontinence: A systematic evidence review. Obstet Gynecol Surv. 2015;70(5):329-341.

Horrocks EJ, Bremner SA, Stevens N, et al. Double-blind randomised controlled trial of percutaneous tibial nerve stimulation versus sham electrical stimulation in the treatment of faecal incontinence: CONTROL of Faecal Incontinence using Distal Neuromodulation (the CONFIDeNT trial). Health Technol Assess. 2015;19(77):1-164.

Specialty matched clinical peer review.

## Revision History

May 13, 2022	Connecticare adopts clinical criteria of its parent corporation EmblemHealth
Jul. 14, 2017	Added Interna® Dermal Regeneration FENIX™ Continence Restoration System as investigational