



CLINICAL UM POLICY FOR COVERAGE DETERMINATION

Policy Title:	Policy – Sacral Nerve Stimulation for Fecal Incontinence	Number & Version:	UM-SacralStimFecal. v.4
Functional Unit:	Utilization Management	Effective Date:	6/7/2024
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 5

I. POLICY STATEMENT and PURPOSE

In its administration of Medicare Advantage plans (Health Plans), the Company shall determine benefits in accordance with the requirements of the Centers for Medicare & Medicaid Services (CMS). Where CMS has established a national coverage policy on an item or service or a local Medicare contractor has done so as authorized by CMS, the Company follows the Medicare coverage policy. In the absence of fully established Medicare coverage criteria, the Company may develop and implement internal criteria based on current evidence in widely used treatment guidelines or clinical literature. Internal criteria are reviewed and approved by the Medical Management Committee and are made publicly accessible.

CMS has not established coverage criteria for Sacral Nerve Stimulation for Fecal Incontinence, therefore the Company has developed and implemented this coverage policy to ensure that patients receive clinically appropriate, medically necessary care at the appropriate level, which allows for the best clinical outcome and prevents harm. The purpose of this policy is to describe the circumstances under which Sacral Nerve Stimulation for Fecal Incontinence would be considered medically necessary.

II. BACKGROUND

Fecal incontinence is a condition that may result from a multitude of different causes. It is defined as the uncontrolled passage of feces or gas over at least 1 month's duration, in a person who had previously had bowel control, who is at least 4 years of age (Bharucha 2015) (Bordeianou, 2023).

Sacral neuromodulation uses an implanted device to send mild electrical impulses to the sacral nerves. The nerves are located near the tailbone and control the pelvic floor and the muscles related to bladder and bowel function. This procedure can help people who have urinary or fecal incontinence (MAYO, 2020).

III. SCOPE

This Policy applies to Sacral Nerve Stimulation for Fecal Incontinence.

IV. DEFINITIONS

Fecal Incontinence - Fecal incontinence, also called accidental bowel leakage, is the accidental passing of solid or liquid stools from the anus (Bharucha 2015) (NIH, 2022).

Medically Necessary - Covered Services rendered by a Health Care Provider that the Plan determines are:



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- 1) Safe and effective
- 2) Not experimental or investigational
- 3) Appropriate for patients,
 - a) including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is—
 - i) furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member,
 - ii) furnished in a setting appropriate to the patient's medical needs and condition,
 - iii) ordered and furnished by qualified personnel,
 - iv) one that meets, but does not exceed, the patient's medical need; and
 - v) is at least as beneficial as existing and available medically appropriate alternatives.

V. OWNERSHIP & TRAINING

The Senior Director of Utilization Management is responsible for administration, oversight, and training regarding performance under this Policy.

VI. PROTOCOLS / COVERAGE POLICY

The protocols / coverage policy that follow pertain only to the following states: AR, KY, IN, MO, IL, OH, MI

The following states are covered by the Local Coverage Determination(s), as described in section VIII: AL, GA, NC, SC, TN, VA, WV

1. Sacral Nerve Stimulation for Fecal Incontinence is considered medical necessary under the following conditions:
 - i. Chronic fecal incontinence with 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
 - ii. Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
 - iii. A successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms*; AND
 - iv. 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; AND



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- v. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

*to approve a trial, the criteria in 1.i., 1.ii., 1.iv., and 1.v. above must be met.

2. When medical necessity criteria described above are met, normal maintenance activity such as battery replacement, revision or replacement of leads/wires, parts, and/or the stimulator may be approved.
3. Sacral Nerve Stimulation for Fecal Incontinence is considered NOT medical necessary for the treatment of chronic constipation or chronic pelvic pain.

(Bordeianou, 2023) (Dinning, 2015) (Hayes, 2020) (Hull, 2013) (Skull, 2012)

VII. SUMMARY of EVIDENCE

Published evidence evaluating the use of Sacral Nerve Stimulation for Fecal Incontinence exhibit positive outcomes for patients requiring these devices for the treatment of chronic fecal incontinence with a documented failure or intolerance to conventional therapy and a positive test stimulation, as long as the condition was not related to anorectal malformation, defects of the anal sphincter, the results of pelvic radiation, or active anal abscesses and fistulae and/or chronic inflammatory bowel disease or neurologic conditions.

VIII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs) None
 CMS Local Coverage Determinations (LCDs) L39543

ID	Title	Type	Service Area	Contractor
L39543	Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence	LCD	AL, GA, NC, SC, TN, VA, WV	Palmetto GBA

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IX. PROFESSIONAL REFERENCES / CITATIONS

1. Bharucha, Adil E et al. “Epidemiology, pathophysiology, and classification of fecal incontinence: state of the science summary for the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) workshop.” *The American journal of gastroenterology* vol. 110,1 (2015): 127-36. doi:10.1038/ajg.2014.396. Accessed at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4418464/> on March 27, 2024.
2. Bordeianou, Liliana G. M.D., M.P.H.; et. al. The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management of Fecal Incontinence. *Diseases of the Colon & Rectum* 66(5):p 647-661, May 2023. Accessed at: https://journals.lww.com/dcrjournal/Fulltext/2023/05000/The_American_Society_of_Colon_and_Rectal_Surgeons.6.aspx?WT.mc_id=HPxADx20100319xMP on February 28, 2024.
3. Dinning, Phil G et al. “Treatment efficacy of sacral nerve stimulation in slow transit constipation: a two-phase, double-blind randomized controlled crossover study.” *The American journal of gastroenterology* vol. 110,5 (2015): 733-40. doi:10.1038/ajg.2015.101. Accessed at <https://pubmed.ncbi.nlm.nih.gov/25895520/> on March 27, 2024.
4. Hayes. Knowledge Center. Search Results. Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence. April 29, 2020. Accessed at: <https://evidence.hayesinc.com/report/ar.staged3295> on February 28, 2024.
5. Hull, Tracy et al. “Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence.” *Diseases of the colon and rectum* vol. 56,2 (2013): 234-45. doi:10.1097/DCR.0b013e318276b24c. Accessed at: <https://pubmed.ncbi.nlm.nih.gov/23303153/> on March 27, 2024.
6. Mayo Clinic Health System (MAYO). Patient Stories. December 28, 2020. Embarrassed no more: Nerve stimulation helps overcome fecal incontinence. Accessed at: <https://www.mayoclinichealthsystem.org/hometown-health/patient-stories/nerve-stimulation-helps-overcome-fecal-incontinence#:~:text=Sacral%20neuromodulation%20uses%20an%20implantable,have%20urinary%20or%20fecal%20incontinence> on February 28, 2024.
7. National Institutes of Health (NIH). Health Information. Digestive Diseases. Bowel Control Problems (Fecal Incontinence). Reviewed July 2017. Accessed at: <https://www.niddk.nih.gov/health-information/digestive-diseases/bowel-control-problems-fecal->



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[incontinence#:~:text=Fecal%20incontinence%2C%20also%20called%20accidental,leakage%20and%20not%20know%20it](#) on February 28, 2024.

8. Angela Skull & Tracy L Hull (2012) Sacral nerve stimulation for fecal incontinence, Expert Review of Medical Devices, 9:5, 477-482, DOI: [10.1586/erd.12.37](https://doi.org/10.1586/erd.12.37). Accessed at: <https://www.tandfonline.com/doi/full/10.1586/erd.12.37> on March 27, 2024.
9. Wexner, Steven D et al. “Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study.” *Annals of surgery* vol. 251,3 (2010): 441-9. doi:10.1097/SLA.0b013e3181cf8ed0 Accessed at: <https://pubmed.ncbi.nlm.nih.gov/20160636/> on February 28, 2024.



X. RELATED POLICIES / PROCEDURES

None

XI. ATTACHMENTS

See Section VIII.

APPROVALS:

	Printed Name	Signature
Senior Medical Officer (MMC Chair):	<u>Michael Fusco, MD</u>	
Corporate Chief Medical Officer:	<u>Debbie Zimmerman, MD</u>	

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	03/23/2023	Gina Vehige	Original – Approved by MMC
02	03/27/2024	Gina Vehige	Updated References and added LCD. No substantive changes to policy.
03	04/10/2024	Gina Vehige	Updated section numbering and formatting
04	04/24/2024	Gina Vehige	Corrected date on Hayes reference; Updated signatories' titles. Approved by MMC 6/7/2024.