



CLINICAL UM POLICY FOR COVERAGE DETERMINATION

Policy Title:	Policy – Sacral Nerve Stimulation for Fecal Incontinence	Number & Version:	UM- SacralStimFecal. v.1
Functional Unit:	Utilization Management	Effective Date:	03/30/2023
Policy Owner (Title):	Director, Utilization Management	Page Number:	1 of 5

I. **POLICY STATEMENT and PURPOSE**

The purpose of this policy is to describe the circumstances under which Sacral Nerve Stimulation for Fecal Incontinence would or would not be considered medically necessary for members under the guidelines used for clinical review of organizational determinations.

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 (Paquette, 2015).

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 (NIH, 2022).

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

- 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.



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V. OWNERSHIP & TRAINING

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

VI. PROTOCOLS / COVERAGE POLICY

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
 - 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.

(Hayes, 2022), (Paquette, 2015)



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VII. REGULATORY REFERENCES / CITATIONS

CMS National Coverage Determinations (NCDs)	None
CMS Local Coverage Determinations (LCDs)	None
CMS Articles	A53017 (Noridian – AK, ID, OR, WA, AZ, MT, ND, SD, UT, WY) A55835 (CGS – KY, OH) A53359 (Noridian – CA, AS, GU, HI, MP, NV)

NOTE: A table on the last page of the policy lists the states covered by the contractor.

VIII. PROFESSIONAL REFERENCES / CITATIONS

1. 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 September 21, 2022.
2. 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 September 21, 2022.
3. National Institutes of Health (NIH). Health Information. Digestive Diseases. Bowel Control Problems (Fecal Incontinence). Accessed at: <https://www.niddk.nih.gov/health-information/digestive-diseases/bowel-control-problems-fecal-incontinence#:~:text=Fecal%20incontinence%2C%20also%20called%20accidental,leakage%20and%20not%20know%20it> on September 21, 2022.
4. Paquette, Ian, et. al. Diseases of the Colon & Rectum Volume 58: 7 (2015)/ Practice Parameters. The American Society of Colon and Rectal Surgeons' Clinical Practice Guideline for the Treatment of Fecal Incontinence. Accessed at: https://fascrs.org/ascrs/media/files/downloads/Clinical%20Practice%20Guidelines/clinical_practice_guideline_for_the_treatment_of_fecal_incontinence.pdf on September 21, 2022.
5. 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 September 21, 2022.



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IX. RELATED POLICIES / PROCEDURES

None

X. ATTACHMENTS

See Section VII.

APPROVALS:

	Printed Name	Signature
Senior Medical Director, UM:	<u>Michael Fusco, MD</u>	
Corporate Chief Medical Officer (QMMC Chair):	<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



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Medicare Administrative Contractors (MACs) As of June 2021

MAC Jurisdiction	Processes Part A & Part B Claims for the following states/territories:	MAC
DME A	Connecticut, Delaware, District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont	Noridian Healthcare Solutions, LLC
DME B	Illinois, Indiana, Kentucky, Michigan, Minnesota, Ohio, Wisconsin	CGS Administrators, LLC
DME C	Alabama, Arkansas, Colorado, Florida, Georgia, Louisiana, Mississippi, New Mexico, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, Virginia, West Virginia, Puerto Rico, U.S. Virgin Islands	CGS Administrators, LLC
DME D	Alaska, Arizona, California, Hawaii, Idaho, Iowa, Kansas, Missouri, Montana, Nebraska, Nevada, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
5	Iowa, Kansas, Missouri, Nebraska	Wisconsin Physicians Service Government Health Administrators
6	Illinois, Minnesota, Wisconsin **HH + H for the following states: Alaska, American Samoa, Arizona, California, Guam, Hawaii, Idaho, Michigan, Minnesota, Nevada, New Jersey, New York, Northern Mariana Islands, Oregon, Puerto Rico, US Virgin Islands, Wisconsin and Washington	National Government Services, Inc.
8	Indiana, Michigan	Wisconsin Physicians Service Government Health Administrators
15	Kentucky, Ohio **HH + H for the following states: Delaware, District of Columbia, Colorado, Iowa, Kansas, Maryland, Missouri, Montana, Nebraska, North Dakota, Pennsylvania, South Dakota, Utah, Virginia, West Virginia, and Wyoming	CGS Administrators, LLC
E	California, Hawaii, Nevada, American Samoa, Guam, Northern Mariana Islands	Noridian Healthcare Solutions, LLC
F	Alaska, Arizona, Idaho, Montana, North Dakota, Oregon, South Dakota, Utah, Washington, Wyoming	Noridian Healthcare Solutions, LLC
H	Arkansas, Colorado, New Mexico, Oklahoma, Texas, Louisiana, Mississippi	Novitas Solutions, Inc.
J	Alabama, Georgia, Tennessee	Palmetto GBA, LLC
K	Connecticut, New York, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont **HH + H for the following states: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont	National Government Services, Inc.
L	Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania (includes Part B for counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia)	Novitas Solutions, Inc.
M	North Carolina, South Carolina, Virginia, West Virginia (excludes Part B for the counties of Arlington and Fairfax in Virginia and the city of Alexandria in Virginia) **HH + H for the following states: Alabama, Arkansas, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Mississippi, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, and Texas	Palmetto GBA, LLC
N	Florida, Puerto Rico, U.S. Virgin Islands	First Coast Service Options, Inc.

**Also Processes Home Health and Hospice claims