CLINICAL UM POLICY FOR COVERAGE DETERMINATION

Policy Title:	Sacral Nerve Stimulation for Fecal Incontinence	Number & Version:	UM-Sacral Stim.Fecal v5
Functional Unit:	Utilization Management	Effective Date:	04/18/2025
Policy Owner (Title):	Senior Director, Utilization Management	Page Number:	1 of 4

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 Nere 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 (FI) is a condition of recurrent uncontrolled passage of feces, gas or mucus from the bowel. FI may occur with a sense of urgency, may occur passively without the patient's awareness, or occur as a combination of both (Hayes, 2020).

Sacral Nerve Stimulation (SNS) is a potential treatment option for patients with FI who have failed conventional treatments. If appropriate, SNS begins with a trial period where electrical stimulation is applied to the sacral nerves in attempt to improve a patient's ability to control bowel continence. If during this trial the patient experiences at least 50% relief of FI symptoms, the patient becomes a candidate for permanent implantation of a SNS device for long-term benefit (Hayes, 2020).

III. SCOPE

This Policy applies to Sacral Nerve Stimulation for Fecal Incontinence.

IV. DEFINITIONS

Fecal Incontinence – chronic involuntary loss of bowel control.

Sacral Nerve Stimulation – electrical pulses to sacral nerves that influence sphincter and pelvic floor to improve function.

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) are 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

1. Test stimulation of Sacral Nerve Stimulation for Fecal Incontinence is considered medically necessary under the following conditions:
   i. Chronic fecal incontinence with greater than 2 incontinent episodes on average per week and duration of incontinence greater than 6 months or for more than 12 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. 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
   iv. Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.
2. Sacral Nerve Stimulation for Fecal Incontinence is considered medical necessary when all criteria above are met (1. i. - 1. iv.) AND
   i. A successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms*

3. 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.

4. Sacral Nerve Stimulation for Fecal Incontinence is considered NOT medical necessary for the treatment of chronic constipation or chronic pelvic pain.

VII. SUMMARY of EVIDENCE

Published evidence evaluating the use of Sacral Nerve Stimulation for Fecal Incontinence exhibit positive outcomes for patients when there is documented failure of conventional therapy followed by a positive test stimulation.

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

IX. PROFESSIONAL REFERENCES / CITATIONS

1. Hayes. Health Technology Assessment: Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence. Issued 2020. Accessed April 2025. https://evidence.hayesinc.com/report/ar.staged3295

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APPROVALS:

Chief Medical Officer
(MMC Chair): Saria Saccocio, MD ___

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 substantiative 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.
05	04/01/2025	Sheila Gray / Kerrie Stehl	Annual review; no substantive changes to coverage guidelines; reformatting; reference checks. Approved by MMC 04/16/2025.