Sacral Nerve Stimulation for Fecal Incontinence

[For the list of services and procedures that need preauthorization, please refer to www.mcs.com.pr. Go to "Comunicados a Proveedores", and click "Cartas Circulares".]

Medical Policy:	**MP-DME-01-17**
Original Effective Date:	**September 01, 2017**
Revised:	**July 29, 2024**
Next Revision:	**August 2025**

This policy applies to products subscribed by the following corporations, MCS Life Insurance Company (Commercial), and MCS Advantage, Inc. (Classicare) and Medical Card System, Inc., provider's contract; unless specific contract limitations, exclusions or exceptions apply. Please refer to the member's benefit certification language for benefit availability. Managed care guidelines related to referral authorization, and precertification of inpatient hospitalization, home health, home infusion and hospice services apply subject to the aforementioned exceptions.

All medical policies are developed taking into consideration the Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

DESCRIPTION

Fecal incontinence is a frequent and debilitating 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 an individual of at least 4 years of age, who had previously achieved control.

Dietary modifications, adjustment of medications, and a trial of biofeedback should be the first line of therapy in most patients. Patients with severe fecal incontinence and those in whom conservative management fails can be referred for further evaluation by a colorectal surgeon and/or urogynecologist. Patients with gastrointestinal disorders contributing to incontinence should be evaluated first by a gastroenterologist.

The mechanism of function of the Sacral Nerve Stimulation is thought to modulate rectal sensation by activating or deactivating chemical mediating receptors, stimulating the afferent pathway, and changing the brain activity relevant to the continence mechanism.

Several surgical options are currently available to treat fecal incontinence and should be individualized on the basis of degree and type of symptoms, the cause of the incontinence, and patient-related factors. These options vary from local anal sphincter repair, injectables, and radiofrequency energy treatment to implantable devices such as the sacral nerve stimulator and artificial bowel sphincter.

A sacral nerve stimulator (Medtronic, Minneapolis, MN, USA) was approved by the Food and Drug Administration for the treatment of fecal incontinence in the U.S. Originally; sacral nerve stimulation was initially used to treat patients with urinary incontinence.

The treatment entails 2 procedures: an initial implantation of a percutaneous lead in the third sacral foramen with a brief trial (typically 1 to 2 weeks), followed by the implantation of the permanent device. During the test period, the patient maintains a diary recording the frequency of episodes of

incontinence. An improvement of 50% or more in the patient's symptoms leads to the implantation of the device, which typically has a battery life of 3 to 5 years depending on the degree of stimulation.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate member certificate and subscriber agreement contract for applicable diagnostic imaging, DME, laboratory, machine tests, benefits and coverage.

INDICATIONS

The evaluation of medical necessity for the placement of a Sacral Nerve NeuroStimulator for Fecal Incontinence is treated as a two (2)-step process.

I. <u>For the Sacral Nerve NeuroStimulator Trial</u>:

Medical Card System, Inc., (MCS) will cover and considers **medically necessary,** for <u>Both</u> the Commercial and Classicare (Advantage) Lines of Business (LOB), the Trial for the Sacral Neurostimulator for Fecal Incontinence in patients of 18 years of age or older, when **<u>ALL</u>** of the following criteria are met:

1. The patient suffers from 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

2. Have documented failure or intolerance to conventional therapy (e.g., biofeedback, dietary management, pharmacotherapy, strengthening therapy); AND

3. The 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), a weak but structurally intact sphincter and/or chronic inflammatory bowel disease; AND

4. The incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

II. <u>Permanent Sacral Nerve NeuroStimulator:</u>

Medical Card System, Inc., (MCS) will cover and considers **medically necessary,** for <u>Both</u> the Commercial and Classicare (Advantage) Lines of Business (LOB), the Permanent implantation of Sacral Nerve Stimulation for the treatment of Fecal Incontinence in patients of 18 years of age or older, when **<u>ALL</u>** of the following criteria are met:

1. The use of sacral nerve stimulation for the treatment of fecal incontinence requires the patient have a test stimulation trial.

2. A successful percutaneous stimulation trial in order to support medical necessity must be met for the subsequent implantation, defined as at least of 50% sustained improvement in symptoms.

3. Improvement must be measured through diaries of episodes of fecal incontinence per week.

4. The patient must be able to demonstrate adequate ability to record fecal incontinence diary data such that clinical results of the implant procedure can be properly evaluated.

CONTRAINDICATIONS

1. The administration of shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) is contraindicated on any patients implanted with an InterStim neurostimulation system.

2. Implantation of an InterStim neurostimulation system is contraindicated in patients who have not demonstrated an appropriate response to test stimulation.

3. Implantation of an InterStim neurostimulation system is contraindicated in patients who are unable to operate the neurostimulator.

RATIONALE

Medical devices used by surgeons can provide improved efficacy, longevity, visibility, agility, communication, and monitoring. When evaluating patient-centric medical devices, MCS looks if the device aims to improve patient care, safety, treatment consistency, vials monitoring, or treatment efficacy. The implantation of a permanent Sacral Nerve Neurostimulator for Fecal Incontinence will be considered medically necessary after demonstration of response during the trial period for Sacral Nerve Neurostimulator is favorable, when the specific group of criteria mentioned in the following policy have been met.

CODING INFORMATION

CPT® Codes (List may not be all inclusive)

CPT® Codes	DESCRIPTION
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)

64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without reprogramming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter, programming by physician or other qualified health care professional
95972	Electronic analysis of implanted neurostimulator pulse generator system (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

Current Procedural Terminology (CPT®) 2024 American Medical Association: Chicago, IL.

HCPCS® CODES (List may not be all inclusive)

HCPCS® CODES	DESCRIPTION
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer, neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1883	Adapter/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)
L8679	Implantable neurostimulator, pulse generator, any type

L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

2024 HCPCS LEVEL II Professional Edition® (American Medical Association).

HCPCS MODIFIERS (List may not be all inclusive)

MODIFIERS	DESCRIPTION
N/A	N/A

2024 HCPCS LEVEL II Professional Edition® (American Medical Association).

ICD-10 CM® Diagnosis Codes (List may not be all inclusive)

ICD-10 Codes	DESCRIPTION
R15.9	Full incontinence of feces

2024 ICD-10-CM® The Complete Official Codebook, Professional Edition (American Medical Association).

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POLICY HISTORY

DATE	ACTION	COMMENT
August 8, 2017	Origination of Policy	
September 1, 2017	Approval	MAC Approval
July 17, 2018	Revised	To the Coding Section: • To the CPT Section: The following were added to the Policy: 64590, 95970, 95971, and 95972. To the References Section: • New Reference #8 was added to the Policy.
June 27, 2019	Revised	References Updated. Deleted #4. Added new references #4 & #5. To the Indications Section: • To Indications Set II, #1: Deleted "2-3 week". To the Documentation Requirements Section: • Changed info for link regarding LCD (L36296) Sacral Neuromodulation and replaced with LCA (A56508) billing and Coding: Sacral Neuromodulation with its corresponding link. To the Coding Information Section: • Added new CPT Codes 64585 and 64595. • Added new HCPCS Codes C1767, C1778, C1787, C1897, C1883, C1894 and C1897. • Added new ICD-10 Codes T85.111A, T85.113A, T85.121A, T85.123A, T85.191A, T85.193A, T85.732A, T85.734A, T85.830A, T85.840A, T85.890A and Z45.42.
May 11, 2020	Revised	References updated. To the Indications Section: • To indications Section I, bullet 1: corrected term "continence" to "incontinence"
May 13, 2021	Revised	References updated. To the Documentation Requirements Section: • Section was deleted from policy.

April 11, 2022	**Revised**	**References were updated.** **<u>To the Coding Section:</u>** • **<u>To the HCPCS Code Section</u>:** HCPCS code C1894 was deleted from this Policy
June 29 2023	**Revised**	**References updated. Deleted former #9. Added new #3 & 13.** **To the Coding Information Section:** • **Updated description for CPT Codes 64581 and 95971 .** • **To the HCPCS Code Table: Added C1820** • **To the ICD-10 Codes Table: Updated descriptors for the following existing codes: T85.111A, T85.113A, T85.121A, T85.123A, T85.191A, T85.193A, T85.732A, T85.734A, T85.830A, T85.840A, T85.890A, Z45.42**
April 11, 2024	**UMC Approval**	
July 31, 2024	**Revised**	**<u>To the Title Section:</u>** **<u>New statement was added from Sra. Jessica Figueroa Suggestion:</u>** All medical policies are developed taking into consideration the Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F) **New Rationale Section was added to the Policy in 2024.** **<u>To the Coding Section</u>:** • **<u>To the HCPCS Code Section</u>:** <u>The following HCPCS codes were deleted from this Policy</u>: L8687, and L8688. **<u>To the ICD-10 Codes Section</u>:** **<u>The following ICD-10 Codes were deleted from this Policy:</u>** T85.111A, T85.113A, T85.121A, T85.123A, T85.191A, T85.193A, T85.732A, T85.734A, T85.830A, T85.840A, T85.890A, and Z45.42. <u>To the References Section</u>: • New References #5, 9, and 11 were added to the Policy. • References #7 was deleted from this Policy.