



Easy Choice Health Plan

Harmony Health Plan of Illinois

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Sacral Nerve Stimulation for the Treatment of Constipation and Fecal Incontinence

Policy Number: HS-150

Original Effective Date: 1/21/2010

**Revised Date(s): 8/12/2011; 4/5/2012;
4/11/2013; 4/3/2014; 4/2/2015; 4/7/2016;
4/6/2017; 3/1/2018**

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Fecal incontinence is defined as the involuntary loss of solid or liquid feces. There are 2 types of fecal incontinence. The first type is urge incontinence which is characterized by the desire to defecate, but incontinence occurs despite efforts to retain stool. The second type, passive incontinence, is characterized by the lack of awareness of the need to defecate before the incontinent episode. Fecal incontinence can have a significant social and financial impact on a patient and can significantly impair quality of life and the ability for some adults to live independently.¹

Initial management of fecal incontinence consists of supportive care and medical therapy. Supportive care includes avoiding foods and activities known to worsen symptoms. Patients are encouraged to keep a food and activity diary so they can track and avoid situations that exacerbate incontinence. There are no specific medications proven to help fecal incontinence so the goal of medical management is reducing stool frequency and improving stool consistency. Patients with low volume or loose stool may be prescribed bulking agents or to improve consistency. In patients with diarrhea, it is important to address the underlying etiology. They may also be given an antidiarrheal agent to help reduce fecal incontinence.¹

Sacral nerve stimulation is reserved for patients who are either not candidates for biofeedback, injectable bulking agents, or sphincteroplasty, or in whom they have failed.¹ The Medtronic sacral neuromodulation system (SNS) (Interstim) permits electrical stimulation of the sacral nerves via an implantable neurostimulator device. The electrical stimulation modulates nerves that supply the bladder, bowels, urinary and anal sphincters, and pelvic floor muscles. The intensity and frequency of the pulses can be modified by both the physician and the patient through an external programmer.² Sacral nerve stimulation appears to be particularly effective in patients with neurologic disorders and those with fecal incontinence after lower anterior resection.¹

Sacral Neuromodulation is performed in two stages. First, the patient will go through the evaluation/test phase to allow their doctor to assess whether or not symptoms will be significantly reduced by Sacral Neuromodulation. If the test phase is successful the patient will go to the implant phase. The implant is placed just beneath the skin in the upper buttock with a thin lead implanted in the lower back and connected to the device. The battery typically lasts approximately 5 years.³

A Cochrane Review by Thaha et al reported that SNS can improve continence in a proportion of patients with fecal incontinence. However, the study added that SNS did not improve symptoms in patients with constipation.²

POSITION STATEMENT

Applicable To:

- Medicaid
- Medicare

Exclusions

Sacral nerve stimulation and pelvic floor stimulation* **are considered experimental and investigational** for the treatment of constipation or chronic pelvic pain. * Includes electrical and extracorporeal magnetic innervation methods.

Sacral nerve stimulation is not considered medically necessary and not considered a covered benefit when the following apply:

1. Mechanical outlet obstruction
2. Diathermy use (shortwave, microwave, ultrasound)
3. Inadequate response to test stimulation or inability to operate the device

Coverage⁴

Sacral nerve stimulation is considered medically necessary and considered a covered benefit when the following apply:

1. Member has 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. Member has documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); **AND,**
3. Member has had a successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms; **AND,**

4. Member's 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**,
5. Member's incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

CODING

Note: There is no specific coding designated for Electrical Stimulation for the Treatment of Constipation. This is considered experimental and investigational for the treatment of constipation.

Covered Codes

None

Non-Covered CPT® Codes

- 64561** Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement Including image guidance, if performed)
- 64555** Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
- 64575** Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve)
- 64581** Incision or 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
- 64585** Revision or removal of peripheral neurostimulator electrodes
- 95970** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple brain, spinal cord or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
- 95973** Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)

Non-Covered HCPCS Codes

- A4290** Sacral Nerve Stimulation test lead, each
- E1399** Durable medical equipment, miscellaneous (would include bulk leads, needles, and cables)
- E0745** Neuromuscular stimulator, electronic shock unit
- L8680** Implantable neurostimulator electrode, each
- 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

Non-Covered ICD-10-CM Diagnosis Codes

K59.00 - K59.09 Constipation

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. Robson, K.M., Lembo, A.J. Fecal incontinence in adults: Management. UpToDate Web site. https://www.uptodate.com/contents/fecal-incontinence-in-adults-management?search=fecal%20incontinence%20treatment&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1. Published August 10, 2016. Accessed February 22, 2018.
2. Ellsworth, P.I. Sacral nerve stimulator. Medscape Web site. <https://emedicine.medscape.com/article/2036909-overview#a1>. Published December 9, 2015. Accessed February 23, 2018.
3. Sacral nerve stimulation. Bladder & Bowel Community Web site. <https://www.bladderandbowel.org/surgical-treatment/sacral-nerve-stimulation/>. Accessed February 23, 2018.
4. Sacral nerve stimulation for urinary and fecal incontinence. Noridan Healthcare Solutions Web site. <https://med.noridianmedicare.com/web/jea/policies/ncd/sacral-nerve-stimulation-for-urinary-and-fecal-incontinence>. Effective October 8, 2015 (Updated January 12, 2018). Accessed February 22, 2018.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
3/1/2018	<ul style="list-style-type: none"> • Approved by MPC. Changes made to title and to include coverage for SNS for fecal incontinence.
4/6/2017, 4/7/2016, 4/2/2015, 4/3/2014	<ul style="list-style-type: none"> • Approved by MPC. No changes.
4/5/2013	<ul style="list-style-type: none"> • Approved by MPC. Added 3 new references (Hayes, 2011; ASCRS, 2011). Statement by the ACCRS regarding FDA approval for SNS.
4/11/2012	<ul style="list-style-type: none"> • Approved by MPC. No changes.
12/1/2011	<ul style="list-style-type: none"> • New template design approved by MPC.
8/12/2011	<ul style="list-style-type: none"> • Approved by MPC. No changes.