OKLAHOMA HEALTH CARE AUTHORITY
MEDICAL PROFESSIONAL SERVICES
PRIOR AUTHORIZATION GUIDELINES

Medical Authorization Director Signature / Date

Physician Medical Director Signature / Date

Author Signature / Date

SUBJECT: **Sacral Nerve Stimulator for Urinary Incontinence and Fecal Incontinence**

EFFECTIVE: January 5, 2015

OBJECTIVE: To provide guidelines to assure medical necessity and consistency in the prior authorization process.

DISCLAIMER: This document is not a contract, and these guidelines do not reflect or represent every conceived situation. Although all items contained in these guidelines may be met, this does not reflect, or imply, any responsibility of this agency or department to change the plan provision to include the stated service as an eligible benefit.

DESCRIPTION OF PROCEDURE:
Sacral nerve stimulation (SNS) is a pulse generator device that transmits electrical impulses to the sacral nerve through an implanted wire. SNS is the implantation of a permanent device that stimulates the sacral nerves and helps to control bladder function and fecal incontinence in members who have failed behavioral and/or pharmacologic therapies. SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Currently, the Medtronic InterStim sacral nerve stimulator is the only system that is currently approved by the Food and Drug Administration.

DOCUMENTATION REQUIREMENTS:
Documentation submitted in order to request services or substantiate previously provided services must demonstrate through adequate objective medical records, evidence sufficient to justify the member's needs for the service in accordance with **OAC 317: 30-3-1 (f)(2).**

Prior Authorization is required for <u>BOTH</u> temporary testing stimulation and permanent implantation of the sacral nerve stimulator and electrodes.

GUIDELINES FOR PRIOR AUTHORIZATION:

I. Treatment of Urge Urinary Incontinence and/or Urge-Frequency Incontinence:
   A. Prior to permanent sacral nerve stimulator implantation, a **screening trial** of sacral nerve stimulation is considered medically necessary for the treatment of *urge urinary incontinence or symptoms of urge-frequency* when **all** of the following criteria are met:
      1. The member has experienced urge UI or symptoms of urge-frequency for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); **and**
      2. Pharmacotherapies (i.e., at least 2 different anti-cholinergic drugs or a combination of an anti-cholinergic and a tricyclic anti-depressant) as well as behavioral treatments (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management) have failed; **and**
      3. The member is able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant testing procedure can be properly evaluated.
   B. Permanent sacral nerve stimulator implantation is considered medically necessary for the treatment of *urge urinary incontinence or symptoms of urge-frequency* when **all** of the criteria above (IA1, 2 & 3) are met **and** the test stimulation of the device has provided at least a 50% improvement in symptoms. Improvement is measured through voiding diaries.

II. Treatment of Non-Obstructive Urinary Retention:
   A. Prior to permanent sacral nerve stimulator implantation, a **screening trial** of sacral nerve stimulation is considered medically necessary for the treatment of *non-obstructive urinary retention* when **all** of the following criteria are met:
      1. Member has experienced urinary retention for at least 12 months and the condition has resulted in significant disability (the frequency and/or severity of symptoms are limiting the member's ability to participate in daily activities); **and**
      2. Pharmacotherapies (e.g., alpha blockers, cholinergics, and antibiotics for urinary tract infections) as well as intermittent catheterization have failed or are not well tolerated; **and**
      3. The member is able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant testing procedure can be properly evaluated.
   B. Permanent sacral nerve stimulator implantation is considered medically necessary for the treatment of *non-obstructive urinary retention* when **all** of the criteria above (IIA1,2 &3) are met **and** a test stimulation of the device has provided at least a 50% decrease in residual urine volume as determined by ultrasound.

III. Treatment for Chronic Fecal Incontinence:
   A. Prior to permanent sacral nerve stimulator implantation, a **screening trial** of sacral nerve stimulation over a period of up to 14 days is considered medically necessary for the treatment of *chronic fecal incontinence* when **all** of the following criteria are met:
      1. Member has a structurally intact anal sphincter; **and**
      2. Member has experienced chronic fecal incontinence of greater than 2 incontinent episodes on average per week with duration greater than 6 months; **and**
      3. Documentation of inadequate response to conservative treatment (e.g. biofeedback,

dietary management, pharmacotherapy, strengthening exercises).
4. Member is able to demonstrate adequate ability to record incontinence diary data such that clinical results of the implant testing procedure can be properly evaluated.

B. Permanent sacral nerve stimulator implantation is considered medically necessary for the treatment of *chronic fecal incontinence* when **all** of the criteria above (IIIA1,2,3&4) are met **and** the test stimulation of the device, over a period of up to 14 days, has provided at least a 50% decrease in symptoms. Improvement is measured through incontinence diaries.

C. Sacral nerve stimulation for *fecal incontinence* is contraindicated if **either** of the following apply:
1. The condition is related to anorectal malformation or defects of the anal sphincter over 60 degrees, visible sequelae of pelvic radiation such as active anal abscess(es) or anal fistula(s), or chronic inflammatory disease; **or**
2. Fecal incontinence is related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Sacral nerve stimulation is not covered in the following situations:
- Pregnancy;
- Pediatric use (under age 18);
- Patients with progressive, systemic neurological diseases

Bilateral Sacral Nerve Stimulation Implantation will not be covered. Per literature from Medtronic, the safety and effectiveness for bilateral stimulation has not been established.

Sacral nerve stimulation is considered investigational and not medically necessary for all other indications because the effectiveness for indications other than the ones listed above has not been established.

SOURCES:

1. Oklahoma Health Care Authority; Policies & Rules, **OAC 317:30-3-1; 317:30-5-8.**
2. CMS, National Coverage Determination for Sacral Nerve Stimulation for Urinary
3. Incontinence (230.18), 1/1/2002.
3. Novitas, Local Coverage Determination (LCD): Sacral Nerve Stimulation (L34707), Oklahoma, 10/9/2014.
4. BlueCross BlueShield of North Carolina Medicare C/D Medical Coverage Policy, Sacral Nerve Stimulators for Urinary Incontinence and Fecal Incontinence, February 19, 2014.
5. Aetna Clinical Policy Bulletin: Urinary Incontinence Treatments, Number 0223, 05/16/2014.
6. Aetna Clinical Policy Bulletin: Fecal Incontinence Treatments, Number 0611, 10/22/2014.
7. Medtronic for Healthcare Professionals; Sacral Neuromodulation, Indications, Safety and Warnings; www.professional.medtronic.com/pt/uro/snm.ind/index.htm
8. Medtronic, Sacral Neuromodulation for Urinary Control and Bowel Control, Commonly Billed Codes, January 2014.
9. Hayes; Implantable Sacral Nerve Stimulation for Urinary Voiding Dysfunction, July 12, 2010.

10. Hayes: Implantable Interstim Neurostimulator (Medtronic Inc.) for Sacral Neuromodulation In Treatment of Fecal Incontinence in Adults, September 20, 2011.
11. Surgical Procedures: Sacral Nerve Stimulation, Medtronic InterStim Therapy for Urinary Control, www.urologymatch.com/medtronic_InterStim
12. Mai Banakhar, Tariq Al-Shaiji and Magdy Hassouna (2012). Challenges in Sacral Neuromodulation, Topics in Neuromodulation Treatment, Dr. Jose Carrillo-Ruiz (Ed.), ISBN: 978-953-51-0, InTech, pages 35-62. Available from http://www.intechopen.com/books/topics-in-neuromodulation-treatment/challenges-in-sacral-neuromodulation
13. Maaike P. Terra, M.D., Regina G. H. Beets-Tan, M.D., PhD, et al; Anal Sphincter Defects in Patients with Fecal Incontinence; Endoanal versus External Phased Array MR Imaging; Radiology, September 2005, Volume 235, Issue 3.