TITLE: SACRAL NERVE STIMULATION (SNS)

EFFECTIVE DATE: January 1, 2017

This policy was developed with input from specialists in neurology, urology, and gastroenterology and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determine the medical necessity of sacral nerve stimulation. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. Conservative therapies are designated as first-line treatments and consist of many components that can be tailored to address the individual patient’s needs and capacities. In addition, they are relatively non-invasive and, in contrast to medication and/or surgery, are associated with virtually no adverse events. Components of conservative therapies may include the following modalities:

1. Urinary incontinence
   a. Pelvic floor muscle therapy, including kegel exercises with biofeedback and vaginal weight training
   b. Bladder training programs, such as challenged voiding, timed/promoted interval voiding, intermittent catheterization and urge suppression techniques
   c. Fluid and dietary modification, such as scheduled fluid intake, eliminating or limiting caffeine and alcohol intake, no use of smoking or tobacco products and increasing high fiber foods.

2. Fecal incontinence
   a. Bowel habit training including scheduled enemas, physical therapy and biofeedback training
   b. Medications as needed to slow down the bowels (anti-diarrheal medications), bind bile acids, or to reduce the reflexory sphincter relaxation
   c. Fluid and dietary modification, such as reducing caffeine and fiber intake.

B. Fecal Incontinence is the involuntary loss of flatus, liquid, or stool.

C. Sacral Nerve Stimulation, also referred to as sacral nerve neuromodulation (SNM), is the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The sacral nerves typically stimulated are S2, S3, or S4.

D. There are two pathways to permanent implantation of an SNS device. According to the manufacturer and the Food and Drug Administration (FDA), either pathway may be utilized for both urinary incontinence and fecal incontinence. Both involve trial stimulation of the sacral nerve for several days (three to seven days for urinary incontinence, up to two weeks for fecal incontinence) while the patient records incontinence/continence activity in bladder/bowel diaries.

1. Percutaneous nerve evaluation (PNE) involves the placement of a temporary lead into the sacral foramina of the patient alongside a sacral nerve. The temporary lead is connected to an external
generator. After completion of a positive trial, the temporary lead is removed and replaced by a surgically implanted stimulator and permanent lead. In the case of a negative trial, the temporary lead is removed.

2. The staged pathway involves initial placement of the permanent lead, which is connected to an external stimulator. After completion of the trial, the lead is either left in place and connected to the permanent stimulator or removed.

E. Urinary incontinence is the inability to control voiding of urine from the bladder.
F. Urinary retention is the inability to completely empty the bladder of urine.
G. Urge Incontinence is the involuntary leakage of urine, associated with a sudden compelling desire to void. Incontinence episodes can be measured reliably with a diary, and the quantity of urine leakage can be measured with pad tests.
H. Urge/Frequency is the need to urinate eight or more times in a 24 hour period. Urinary frequency can be reliably measured with a voiding diary. Traditionally, up to seven voiding episodes during waking hours has been considered normal, but this number is highly variable based upon hours of sleep, fluid intake, comorbid medical conditions and other factors.

II. Comments
A. Urinary dysfunction, including urge incontinence, urgency/frequency, and non-obstructive urinary retention may result from loss of synchrony between stimulator and inhibitory neural impulses controlling the pelvic floor muscles. Symptoms of urgency and leakage are often due to uncontrolled contractions of the bladder musculature. These contractions may be the result of overstimulation or loss of inhibition. Urinary retention can result from underactivity of the bladder muscles or overactivity of the muscles responsible for continence.
B. The SNS device may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, magnetic resonance imaging, theft detectors, or screening devices.

MEDICAL NECESSITY CRITERIA

I. Indications for implantation of a permanent lead for SNS for urinary incontinence
SNS for urinary incontinence is medically necessary when documentation in the medical records indicates that all of the following criteria are met
A. The individual has experienced one of the following diagnoses for at least 12 months:
   1. Chronic urinary urge incontinence
   2. Non-obstructive urinary retention
   3. Urge or frequency syndrome.
B. The individual has failed or is intolerant to at least 2 of the following conservative treatments:
   1. Pelvic floor exercises,
   2. Intermittent catheterization
   3. Biofeedback
   4. Timed voids
   5. Fluid management
   6. Pharmacotherapies.
C. Symptoms have resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the individual’s ability to work or participate in activities outside the home).
D. The incontinence is not related to a neurologic condition.

II. Indications for implantation of a permanent lead for SNS for fecal incontinence
SNS for fecal incontinence is medically necessary when documentation in the medical records indicates that all of the following criteria are met
1. The individual has chronic fecal incontinence, defined as 2 incontinent episodes or more on average per week and duration of incontinence greater than 6 months or for more than 12 months after vaginal childbirth.
2. The individual has failed or is intolerant to at least 2 of the following conservative treatments
   1. Dietary management
   2. Strengthening exercises
   3. Biofeedback therapy
   4. Pharmacotherapies.
3. The individual has failed surgical treatment or is not an appropriate candidate for surgical treatment.
4. Symptoms have resulted in significant disability (e.g., the frequency and/or severity of leakages are limiting the individual’s ability to work or participate in activities outside the home).
5. The incontinence is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses.
6. The incontinence is not related to chronic inflammatory bowel disease.
7. The incontinence is not related to another neurological condition such as peripheral neuropathy or complete spinal cord injury.

III. Indications for revision/replacement

A. Revision/replacement of SNS for urinary incontinence is medically necessary when the documentation in the medical records indicates that all of the following criteria are met:
   1. The initial placement met criteria I. A-D above
   2. The individual has one of the following:
      a. Electrode misalignment or migration
      b. Infection necessitating removal of the stimulation system
      c. Stimulator or battery is no longer operational.

B. Revision/replacement of SNS for fecal incontinence is medically necessary when the documentation in the medical records indicates that all of the following criteria are met:
   1. The initial placement met criteria II. A-G above
   2. The individual has one of the following:
      a. Electrode misalignment or migration
      b. Infection necessitating removal of the stimulation system
      c. Stimulator or battery is no longer operational.

COVERAGE ISSUES
1. Prior authorization is required for implantation of a permanent lead for SNS including revision and replacement.
2. Reprogramming of SNS devices does not require prior authorization.
3. Coverage may vary according to the terms of the member’s plan document.
4. Sacral nerve stimulation is investigative and therefore not covered for all other indications, including but not limited to the following:
   a. Stress urinary incontinence
   b. Neurogenic bladder
   c. Interstitial cystitis/bladder pain syndrome
   d. Chronic constipation
   e. Chronic pelvic pain
   f. SNS for fecal incontinence in children.
5. For Medicare members, refer to the following, as applicable:
6. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.
7. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual’s case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

DOCUMENT HISTORY

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<tr>
<th>Original Effective Date</th>
<th>February 1, 2014</th>
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<tbody>
<tr>
<td>MPC Endorsement Date(s)</td>
<td>11/2013, 11/2014, 06/2015, 06/2016, 09/2016</td>
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<tr>
<td>Administrative Update(s)</td>
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References

Pre-3/2015 Medical Technology Assessment Committee (MTAC) and Medical Policy Committee (MPC):


03/2015 MTAC:


06/2015 MPC:

09/2016 MPC:
No new references added.