Preauthorization is not required.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: • With urinary or fecal incontinence who have failed conservative treatment</td>
<td>Interventions of interest are: • Sacral nerve neuromodulation</td>
<td>Comparators of interest are: • Continued conservative therapy (e.g., dietary modification, addition of bulking and pharmacologic treatment)</td>
<td>Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With constipation who have failed conservative treatment</td>
<td>Interventions of interest are: • Sacral nerve neuromodulation</td>
<td>Comparators of interest are: • Continued conservative therapy (e.g., dietary modification, addition of pharmacologic treatment)</td>
<td>Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals: • With chronic pelvic pain</td>
<td>Interventions of interest are: • Sacral nerve neuromodulation</td>
<td>Comparators of interest are: • Continued conservative therapy (e.g., cognitive-behavioral therapy, pharmacologic treatment)</td>
<td>Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity</td>
</tr>
</tbody>
</table>

Description

Sacral nerve neuromodulation (SNM), also known as sacral nerve stimulation (SNS), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. This Protocol addresses use of SNM in the treatment of urinary or fecal incontinence, urinary or fecal nonobstructive retention, and chronic pelvic pain in patients with intact neural innervation of the bladder and/or rectum.

Summary of Evidence

There is sufficient evidence from randomized controlled trials to conclude that SNM improves the net health outcome in selected patients with urge incontinence, urgency-frequency, and nonobstructive urinary retention. In addition, the evidence is considered sufficient for SNM to be an option for the treatment for chronic fecal incontinence in well-selected patients who have failed conservative therapy. Not all patients will benefit, and the adverse event rate for this procedure is high. Patients should therefore be provided with adequate information to make an informed choice regarding the potential risks and benefits of this procedure.
Limited evidence reports that more patients have a positive stimulation trial when stage-1 surgery is used compared with percutaneous nerve evaluation and that most patients with a positive stage-1 test experience a reduction in symptoms after permanent implantation. This evidence does not determine with certainty that health outcomes are improved with the stage-1 trial stimulation. However, there is some supportive evidence and strong clinical support for surgical lead placement as an alternative to percutaneous test stimulation. The literature on SNS for constipation and SNS for chronic pelvic pain remains insufficient to evaluate the effect of this technology on health outcomes.

Policy

**Urinary Incontinence and Non-obstructive Retention**

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in patients who meet all of the following criteria:

1. There is a diagnosis of at least one of the following:
   a. Urge incontinence
   b. Urgency-frequency syndrome
   c. Non-obstructive urinary retention
   d. Overactive bladder.

2. There is documented failure or intolerance to at least two conventional therapies (e.g., behavioral training such as bladder training, prompted voiding, or pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, and/or surgical corrective therapy).

3. The patient is an appropriate surgical candidate.

4. Incontinence is not related to a neurologic condition.

B. Permanent implantation of a sacral nerve neuromodulation device may be considered **medically necessary** in patients who meet all of the following criteria:

1. All of the criteria in A. 1-4 above are met.

2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Other urinary/voiding applications of sacral nerve neuromodulation are considered **investigational**, including but not limited to treatment of stress incontinence or urge incontinence due to a neurologic condition, e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury, or other types of chronic voiding dysfunction.

**Fecal Incontinence**

A. A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead may be considered **medically necessary** in patients who meet all of the following criteria:

1. There is a diagnosis of chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than six months or for more than 12 months after vaginal childbirth.

2. There is documented failure or intolerance to conventional conservative therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment) for at least a sufficient duration to fully assess its efficacy.

3. The patient is an appropriate surgical candidate.
4. The condition 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 and fistulae) or chronic inflammatory bowel disease.

5. Incontinence is not related to a neurologic condition.

6. The patient has not had rectal surgery in the previous 12 months, or in the case of cancer, the patient has not had rectal surgery in the past 24 months.

B. Permanent implantation of a sacral nerve neuromodulation device may be considered medically necessary in patients who meet all of the following criteria:

1. All of the criteria in A. 1-6 above are met.
2. A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.

Sacral nerve neuromodulation is investigational in the treatment of chronic constipation or chronic pelvic pain.

Policy Guidelines

The International Continence Society states that overactive bladder syndrome (OAB) “is defined as urinary urgency, usually with urinary frequency and nocturia, with or without urgency urinary incontinence.” Available at: [http://wiki.ics.org/Overactive+Bladder](http://wiki.ics.org/Overactive+Bladder).

Medicare Advantage

The preceding policy statements apply with the following exceptions:

*Urinary Incontinence and Non-obstructive Retention*

- A.2 Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy).
- B.2 Before a patient is eligible for permanent implantation; he/she must demonstrate a 50% or greater improvement through test stimulation.

Background

Treatment using SNM, also known as indirect SNS, is one of several alternative modalities for patients with fecal or urinary incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies. Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes and is a prominent symptom of interstitial cystitis (also called bladder pain syndrome). Urinary retention is the inability to completely empty the bladder of urine. Fecal incontinence can arise from a variety of mechanisms, including rectal wall compliance, efferent and afferent neural pathways, central and peripheral nervous systems, and voluntary and involuntary muscles. Fecal incontinence is more common in women, due mainly to muscular and neural damage that may occur during vaginal delivery.

The SNM device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet is kept by the
patient and can be used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for four to seven days. This lead is connected to an external stimulator, which is carried by patients in their pocket or on their belt. The results of this test phase are used to determine whether patients are appropriate candidates for the permanent device. If patients show a 50% or greater reduction in symptom frequency, they are deemed eligible for the permanent device.

The second type of testing is a 2-stage surgical procedure. In the first stage, a quadripolar-tined lead is implanted (stage 1). The testing phase can last as long as several weeks, and if patients show a 50% or greater reduction in symptom frequency, they can proceed to stage 2 of the surgery, which is permanent implantation of the neuromodulation device. The 2-stage surgical procedure has been used in various ways. These include its use instead of PNE, for patients who failed PNE, for patients with an inconclusive PNE, or for patients who had a successful PNE to further refine patient selection.

The permanent device is implanted with the patient under general anesthesia. An incision is made over the lower back, and the electrical leads are placed in contact with the sacral nerve root(s). The wire leads are extended through a second incision underneath the skin, across the flank to the lower abdomen. Finally, a third incision is made in the lower abdomen where the pulse generator is inserted and connected to the wire leads. Following implantation, the physician programs the pulse generator to the optimal settings for that patient. The patient can switch the pulse generator between on and off by placing the control magnet over the area of the pulse generator for one to two seconds.

Regulatory Status
In 1997, the Medtronic InterStim® Sacral Nerve Stimulation system received U.S. Food and Drug Administration (FDA) approval for marketing for the indication of urinary urge incontinence in patients who have failed or could not tolerate more conservative treatments. In 1999, the device received FDA approval for the additional indications of urgency-frequency and urinary retention in patients without mechanical obstruction. In 2006, the Medtronic InterStim II System received FDA approval for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original system and is reported to be suited for those with lower energy requirements or small stature. The device also includes updated software and programming options. In 2011, the Medtronic InterStim System received FDA approval for the indication of chronic fecal incontinence in patients who have failed or could not tolerate more conservative treatments. The InterStim device has not been specifically approved by FDA for treatment of chronic pelvic pain. FDA product code: EZW.

Note: This Protocol does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed separately in the Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence Protocol. In addition, this Protocol does not address devices that provide direct SNS in patients with spinal cord injuries.

Related Protocols
Biofeedback as a Treatment of Fecal Incontinence or Constipation
Biofeedback as a Treatment of Urinary Incontinence in Adults
Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence
Percutaneous Tibial Nerve Stimulation
Transanal Radiofrequency Treatment of Fecal Incontinence

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References
We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


