Protocol

Sacral Nerve Neuromodulation/Stimulation

(70169)

Medical Benefit		**Effective Date**: 01/01/16	**Next Review Date**: 09/19
Preauthorization	No	**Review Dates**: 01/08, 11/08, 09/09, 09/10, 09/11, 09/12, 09/13, 09/14, 09/15, 09/16, 09/17, 09/18	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With urinary incontinence who have failed conservative	Interventions of interest are: • Sacral nerve neuromodulation	Comparators of interest are: • Pharmacologic treatment	Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity
Individuals: • With fecal incontinence who have failed conservative treatment	Interventions of interest are: • Sacral nerve neuromodulation	Comparators of interest are: • Continued conservative therapy (e.g., dietary modification, bulking, pharmacologic treatment)	Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity
Individuals: • With constipation who have failed conservative treatment	Interventions of interest are: • Sacral nerve neuromodulation	Comparators of interest are: • Continued conservative therapy (e.g., dietary modification, pharmacologic treatment)	Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity
Individuals: • With chronic pelvic pain	Interventions of interest are: • Sacral nerve neuromodulation	Comparators of interest are: • Continued conservative therapy (e.g., cognitive-behavioral therapy, pharmacologic treatment)	Relevant outcomes include: • Symptoms • Morbid events • Treatment-related morbidity

DESCRIPTION

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

SUMMARY OF EVIDENCE

For individuals with urinary incontinence who have failed conservative treatment who receive SNM, the evidence includes randomized controlled trials (RCTs), systematic reviews, and case series. Relevant outcomes

are symptoms, morbid events, and treatment-related morbidity. Results from the RCTs and case series with long-term follow-up have suggested that SNM reduces symptoms of urge incontinence, urgency-frequency syndrome, nonobstructive urinary retention, and overactive bladder in selected patients. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with fecal incontinence who have failed conservative treatment who receive SNM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. Although relatively small, the available trials had a low risk of bias and demonstrated improvements in incontinence relative to alternatives. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with constipation who have failed conservative treatment who receive SNM, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The available trials have not consistently reported improvements in outcomes with SNM. Additional studies are needed to demonstrate the health benefits of this technology. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with chronic pelvic pain who receive SNM, the evidence is limited to case series. Relevant outcomes are symptoms, morbid events, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

POLICY

URINARY INCONTINENCE AND NON-OBSTRUCTIVE RETENTION

Criteria 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 conservative 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.

Criteria 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

Criteria 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 more than two incontinent episodes on average per week for more 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°; 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.

Criteria 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 has defined overactive bladder syndrome (OAB) as “urinary urgency, usually with urinary frequency and nocturia, with or without urgency urinary incontinence.” (Available at https://www.ics.org/committees/standardisation/terminologydiscussions/overactivebladder).

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

URINARY AND FECAL INCONTINENCE

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 empty the bladder of urine completely. 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.

Treatment

Treatment using sacral nerve neuromodulation, also known as indirect sacral nerve stimulation, is one of several alternative modalities for patients with urinary or fecal incontinence (urge incontinence, significant symptoms of urgency-frequency, nonobstructive urinary retention) who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

The sacral nerve neuromodulation 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, kept by the patient, is 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 two 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. They 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 refine patient selection further.

The permanent device is implanted with the patient under general anesthesia. The electrical leads are placed in contact with the sacral nerve root(s) via an incision in the lower back, and 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 on and off by placing the control magnet over the area of the pulse generator for one to two seconds.

This protocol does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed separately (see the Pelvic Floor Stimulation as a Treatment of Urinary and Fecal Incontinence Protocol). Also, this protocol does not address devices that provide direct sacral nerve stimulation in patients with spinal cord injuries.

REGULATORY STATUS

In 1997, the InterStim® Sacral Nerve Stimulation system (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process 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 InterStim II® System (Medtronic) was approved by FDA through the premarket approval process for treatment of intractable cases of overactive bladder and urinary retention. The new device is smaller and lighter than the original 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 InterStim® System was approved by FDA through the premarket approval process 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.

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.

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