Sacral Nerve Neuromodulation/Stimulation

Introduction

The brain communicates with the body by sending electrical signals along nerves. When it comes time to go to the bathroom, the brain sends signals to specific nerves that travel through the lower back to the muscles that control the opening and closing of the bladder and bowel. Weak electrical signals may be used to address certain kinds of bowel and bladder problems that have not responded to other treatments. This procedure is known as sacral nerve neuromodulation. Another name for it is sacral nerve stimulation. This procedure involves implanting a small device under the skin in the lower back area. Small wires are also implanted so that the electric current activates the nerve important to either bladder or bowel function. This treatment usually is done in two steps. The first is a temporary placement to find out if sacral nerve stimulation works. The second is surgery to place the permanent implant. This policy describes when sacral nerve stimulation may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Note: This policy addresses the InterStim® System (see Regulatory Status section).

<table>
<thead>
<tr>
<th>Service</th>
<th>Medical Necessity</th>
</tr>
</thead>
</table>
| **Urinary Incontinence and Non-obstructive Retention** | **Sacral nerve neuromodulation** 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:**  
  - There is a diagnosis of at least one of the following:  
    - Urge incontinence  
    - Urgency-frequency syndrome  
    - Nonobstructive urinary retention  
    - Overactive bladder  
  **AND**  
  - There is documented failure or intolerance to at least 2 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)  
  **AND**  
  - The patient is an appropriate surgical candidate (see Definition of Terms)  
  **AND**  
  - Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy)   |
| **Permanent implantation, sacral nerve neuromodulation device** | **Permanent implantation of a sacral nerve neuromodulation device** may be considered medically necessary in patients who meet **ALL of the following criteria:**  
  - All of the criteria above are met  
  **AND**  
  - A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours   |
| **Fecal Incontinence**                             | **Sacral nerve neuromodulation** 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:**  
  - There is a diagnosis of at least one of the following:  
    - Urged incontinence  
    - Urgency-frequency syndrome  
    - Nonobstructive urinary retention  
    - Overactive bladder  
  **AND**  
  - There is documented failure or intolerance to at least 2 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)  
  **AND**  
  - The patient is an appropriate surgical candidate (see Definition of Terms)  
  **AND**  
  - Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy)  |
Service | Medical Necessity
--- | ---
Permanent implantation, sacral nerve neuromodulation device | Service Medical Necessity

lead may be considered medically necessary in patients who meet all of the following criteria:

- There is a diagnosis of chronic fecal incontinence of more than 2 incontinent episodes on average per week for more than 6 months, or for more than 12 months after vaginal childbirth

AND

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

AND

- The patient is an appropriate surgical candidate (see Definition of Terms)

AND

- The condition is not related to an anorectal malformation (eg, 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

AND

- Incontinence is not related to a spinal cord injury or progressive, systemic neurologic condition (such as multiple sclerosis or diabetic neuropathy)

AND

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

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

- All of the criteria above are met

AND

- A trial stimulation period demonstrates at least 50% improvement in symptoms over a period of at least 48 hours.
<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other applications, urinary incontinence and nonobstructive retention</td>
<td>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).</td>
</tr>
<tr>
<td>Other applications, chronic constipation or chronic pelvic pain</td>
<td>Sacral nerve neuromodulation is investigational in the treatment of chronic constipation or chronic pelvic pain.</td>
</tr>
</tbody>
</table>

### Coding

Sacral nerve neuromodulation involves several steps that are identified by the following codes.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
<td></td>
</tr>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td><strong>HCPCS</strong></td>
<td></td>
</tr>
<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
</tr>
<tr>
<td>E0745</td>
<td>Stimulator electronic shock unit</td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator, pulse generator, any type</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode each (Note: Reported with 1-unit for each contact point on the implanted lead)</td>
</tr>
<tr>
<td>L8685</td>
<td>Implantable neurostimulator pulse generator, single array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8686</td>
<td>Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension</td>
</tr>
<tr>
<td>L8687</td>
<td>Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension</td>
</tr>
<tr>
<td>L8688</td>
<td>Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
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</tr>
</tbody>
</table>

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Definition of Terms

**Inappropriate surgical candidates:** Includes patients with bleeding disorders, anatomical limitations, skin disease at risk for infection, psychiatric disease, or patients who are pregnant.\(^{30}\)

**Overactive bladder (OAB):** The International Continence Society has defined that overactive bladder syndrome as “urinary urgency, with or without urgency urinary incontinence, usually with increased daytime frequency and nocturia...” (available online at [http://wiki.ics.org/Overactive+Bladder](http://wiki.ics.org/Overactive+Bladder), Accessed May 2018).

Evidence Review

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 policy 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.
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 (eg, 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 4 to 7 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. 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 between on and off by placing the control magnet over the area of the pulse generator for 1 to 2 seconds.

**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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

### Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02434874*</td>
<td>Sacral Nerve Stimulation to Treat Urgency Urinary Incontinence with Wireless Neuromodulation</td>
<td>60</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT03261622</td>
<td>Sacral Nerve Stimulation for Fecal Incontinence – Placebo or Clinical Effective (SNS)</td>
<td>75</td>
<td>Nov 2020</td>
</tr>
<tr>
<td>NCT03139734</td>
<td>Sacral Neuromodulation for Pelvic Pain Associated with Endometriosis</td>
<td>50</td>
<td>May 2022</td>
</tr>
</tbody>
</table>

* denotes an industry-sponsored trial
NCT: national clinical trial

**Clinical Input Received from Physician Specialty Societies and Academic Medical Centers**

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies and 2 academic medical centers while this policy was under review in 2012. Reviewers from 2 specialty societies and 2 academic medical centers provided opinions on the possible medical necessity of implantable leads for test stimulation, as part of a 2-stage process for device implantation. All 4 respondents supported the use of implantable leads for test stimulation as an alternative to
percutaneous test stimulation for patients who had failed percutaneous test stimulation and/or for patients with inconclusive percutaneous test stimulation. Reasons for support included a longer period of interrupted treatment with stage-1 stimulation due to less lead migration and a higher rate of positive tests compared with percutaneous test stimulation.

Practice Guidelines and Position Statements

**Urinary Disorders**

**American Urological Association**

In 2014, the American Urological Association updated its guidelines on the diagnosis and treatment of overactive bladder. The guideline stated that sacral neuromodulation may be offered as a third-line treatment in carefully selected patients with severe refractory symptoms or in those who are not candidates for second-line therapy (eg, oral anti-muscarinics, oral β3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery.

**American College of Obstetricians and Gynecologists**

A 2005 practice bulletin on urinary incontinence from American College of Obstetricians and Gynecologists considered sacral nerve neuromodulation to be beneficial for treating chronic voiding dysfunction. An updated 2015 practice bulletin on urinary incontinence from the College did not address sacral nerve stimulation (SNS).

**Fecal Disorders**

**National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence issued guidance on the management of fecal incontinence in 2007. The guidance was reviewed in 2014, and no changes were made. The guidance has recommended:

A trial of temporary sacral nerve stimulation should be considered for people with faecal incontinence in whom sphincter surgery is deemed inappropriate. All individuals should be informed of the potential benefits and limitations of this procedure and should undergo a trial stimulation period of at least 2 weeks to
determine if they are likely to benefit. People with faecal incontinence should be offered sacral nerve stimulation on the basis of their response to percutaneous nerve evaluation during specialist assessment, which is predictive of therapy success.\textsuperscript{38}

**American College of Gastroenterology**

In its 2004 practice guideline on the diagnosis and management of fecal incontinence, the American College of Gastroenterology found limited evidence in favor of SNS.\textsuperscript{39} The College concluded that the precise indication for SNS, its comorbidity, its long-term outcome, and efficacy remain to be defined.

**Pelvic Floor Society**

The Pelvic Floor Society conducted a systematic review as the basis for practice recommendations on the use of SNS for the treatment of constipation.\textsuperscript{40} The systematic review assessed 7 observational studies, all generally of poor quality due to inadequate description of methods. Due to inconsistent reporting on harms and treatment success, and heterogeneity in the patient populations, the Society could not recommend SNS.

**Medicare National Coverage**

Effective 2002, the Centers for Medicare & Medicaid Services covers SNS for the “treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention.”\textsuperscript{41} SNS “involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.”

“The following limitations for coverage apply to all three indications:

- “Patients must be refractory to conventional therapy ... and be appropriate surgical candidates such that implantation with anesthesia can occur.

- “Patients with stress incontinence, urinary obstruction, and specific neurologic diseases ... that are associated with secondary manifestations ... are excluded.

- “Patients must have had successful test stimulation in order to support subsequent implantation. Before patients are eligible for permanent implantation, they must..."
demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.”

**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 Medtronic 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.

**Note:** This policy does not address pelvic floor stimulation, which refers to electrical stimulation of the pudendal nerve. Pelvic floor stimulation is addressed in a separate in policy (see Related Policies).

This policy does not address devices that provide direct SNS in patients with spinal cord injuries. The VOCARE® Bladder System/ FineTech Brindley Bladder Control System, a stimulator implanted in the sacral anterior nerve roots, is one device intended for patients with complete spinal cord injury and neurogenic bladder.

**References**


30. Leong RK, De Wachter SG, Nieman FH, et al. PNE versus 1st stage tined lead procedure: a direct comparison to select the most sensitive test method to identify patients suitable for sacral neuromodulation therapy. Neurourol Urodyn. Sep 2011;30(7):1249-1252. PMID 21404317


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/02/99</td>
<td>Add to Surgery Section - New Policy</td>
</tr>
<tr>
<td>01/04/00</td>
<td>Replace Policy - Content updated; policy statement revised to include new FDA approved indications.</td>
</tr>
<tr>
<td>09/21/00</td>
<td>Replace Policy - Policy updated with reference to 2000 TEC assessment; policy statement unchanged.</td>
</tr>
<tr>
<td>04/09/02</td>
<td>Replace Policy - CPT code; policy statement unchanged.</td>
</tr>
<tr>
<td>05/13/03</td>
<td>Replace Policy - Policy updated; policy statement unchanged. New references added.</td>
</tr>
<tr>
<td>09/14/04</td>
<td>Replace Policy - Policy revised and expanded to address neuromodulation to treat fecal incontinence and constipation as investigational.</td>
</tr>
<tr>
<td>08/09/05</td>
<td>Replace Policy - Policy updated with literature search; no changes in policy statement.</td>
</tr>
<tr>
<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
</tr>
<tr>
<td>06/09/06</td>
<td>Disclaimer and Scope update - No further changes.</td>
</tr>
<tr>
<td>04/10/07</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>11/13/07</td>
<td>Replace Policy - Policy updated with literature search; no changes in policy statement; references added; codes added</td>
</tr>
<tr>
<td>05/13/08</td>
<td>Code Updates - Code 787.6 added.</td>
</tr>
<tr>
<td>07/14/09</td>
<td>Replace Policy - Policy updated with literature search. Policy statement updated and clarified with selection criteria. References added.</td>
</tr>
<tr>
<td>08/10/10</td>
<td>Replace Policy - Policy updated with literature review through March 2010; references added and reordered. Policy statement on fecal incontinence has been changed from “investigational” to “may be medically necessary under specific conditions.”</td>
</tr>
<tr>
<td>07/12/11</td>
<td>Replace Policy - Policy updated with literature search through March 2011. References 7, 24, 26, 27, 29, 30, 34, and 36 added; other references reordered or removed. Policy statements unchanged. ICD-10 codes added to policy.</td>
</tr>
<tr>
<td>09/23/11</td>
<td>Related Policies updated; 2.01.27 added.</td>
</tr>
<tr>
<td>06/12/12</td>
<td>Replace policy. Policy updated with literature search through February 2012. Rationale and Policy Guidelines re-written. References 5, 13, 14 and 19-24 added; other</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>09/28/12</td>
<td>references reordered or removed. Clinical input added. Implantable lead stimulation added as alternative stimulation method for eligible patients within medically necessary policy statements. Medically necessary policy statement for urinary incontinence changed to 2-part statement (has criteria for test stimulation and for permanent implantation). Material on methods of trial test stimulation added to Background and Rationale sections. Title changed to Sacral Nerve Neuromodulation/Stimulation. Code 64590 removed as it does not apply to this policy.</td>
</tr>
<tr>
<td>06/10/13</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014. Add Related Policy 8.03.01. Replace policy. Policy updated with literature search through March 13, 2013. Length of successful percutaneous test stimulation in medically necessary statements changed from at least 2 weeks to at least 1 week. Fecal incontinence policy statement separated into 2 statements; 1 on trial stimulation and 1 on permanent implantation. Edits made to statements so that criteria for fecal and urinary incontinence are similar, when applicable. References 12, 13, 16, 17 and 20 added; other references renumbered or removed.</td>
</tr>
<tr>
<td>01/28/14</td>
<td>Minor updated. CPT codes 95972 and 95973 listed within the Policy Guidelines extended to the Coding table to reflect consistency. Scope updated to indicate that this policy not part of Medicare Advantage.</td>
</tr>
<tr>
<td>03/21/14</td>
<td>Update Related Policies. Delete 7.01.106 and replace with 7.01.553. Annual Review. Policy updated with literature review through March 5, 2014. References 5, 9, 12, 21, 30-31, and 34-35 added. Overactive bladder added to medically necessary statement on urinary incontinence. ICD-9 and ICD-10 diagnosis and procedure codes removed; this is performed inpatient.</td>
</tr>
<tr>
<td>06/27/14</td>
<td>Update Related Policies. Change title to 1.01.17. Interim Update. Clarification added as #6 criteria under subheading “A” Fecal Incontinence. Specified the length of time after surgery when a trial of sacral nerve neurostimulation may be considered medically necessary. No new references added. Policy statement clarified as noted.</td>
</tr>
<tr>
<td>09/08/15</td>
<td>Update Related Policies. Remove 7.01.553 as it was archived. Annual Review. In both subheadings titled “B.2” the medically necessary statements that were changed from 1 week to “at least 48 hours” for the trial stimulation period. Policy updated with literature review through June 8, 2015; references 6, 16, 20, and 32 added. Policy statements revised as noted.</td>
</tr>
<tr>
<td>12/16/15</td>
<td>Update Related Policies. Remove 2.01.58 as it is archived. Annual Review, approved May 10, 2016. Policy updated with literature review; reference added. No change to the policy statement. Updated the coding table.</td>
</tr>
<tr>
<td>01/29/16</td>
<td>Minor update. Added HCPCS code L8679.</td>
</tr>
<tr>
<td>06/01/16</td>
<td>Annual Review, approved May 10, 2016. Policy updated with literature review; reference added. No change to the policy statement. Updated the coding table.</td>
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<tr>
<td>Date</td>
<td>Comments</td>
</tr>
<tr>
<td>------------</td>
<td>--------------------------------------------------------------------------</td>
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<tr>
<td>03/01/17</td>
<td>Coding Update. Removed CPT code 95973 as it was deleted as of 01/01/2016.</td>
</tr>
<tr>
<td>08/25/17</td>
<td>Coding update, removed CPT codes 95970 and 95972. Moved into new format, no changes to policy statement.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; reference 40 added. Minor editorial changes to the Policy section; statements unchanged. Removed CPT codes 64585 and 64590.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

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Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs. You may need to take action by certain deadlines to keep your health coverage or help with costs.

You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaarket nag lagion nga Itapate nga Impormasion. Daytoy a pakdaarka mabalin nga adda ket lagion nga itapate nga impormasion maiapanggip iti aplikasyonono yowo coverage babena iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaarka. Mabalin nga adda rumbeng nga aramidencyo nga addang sabilay dagiti partikular a naituding nga adlaw tapno mapatgalainedyo ti coverage ti salun-atyo wenno tulong kadagiti gastos. Adda karbenganyo a mangala ti daytoy nga impormasion ken tulong ti bukodyo a pagasasao nga awan ti bayadanyo. Tumawg ti numero nga 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
Este aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

Tagalog (Tagalog):
Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon. Ang paunawa na ito ay maaaring naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaring magana ang iyong pagsakop o kahalagahan sa tulungan ng 800-722-1471 (TTY: 800-842-5357).

ไทย (Thai):
ประกาศนี้อาจมีข้อมูลที่สําคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และคุณมีสิทธิ์ในการได้รับการแจ้งเตือนในกรณีที่คุณจะต้องดําเนินการภายในกําหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่คุณอาจได้รับ. โปรดติดต่อที่ 800-722-1471 (TTY: 800-842-5357)เพื่อขอข้อมูลเพิ่มเติม.

Română (Romanian):

Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Español (Spanish):
Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas claras en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

اللغة السعودية (Arabic):
يتم تقديم هذه الرسالة لتوفر المعلومات الهامة والضرورية لضمان استكمال الرغبة في مواصلة الاستمتاع بالسياسة أو الإعانة. يمكن للمرء الاتصال بالرقم (800-722-1471 TTY: 800-842-5357) للحصول على مزيد من المعلومات.

日本語 (Japanese):
この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれている場合があります。この通知には記載されている情報が重要な日付をご確認ください。健康保険や無料サービスを維持するには、特定の期限までに行動を取らなければならない場合があります。貴重な言語による情報とサポートが無料で提供されます。800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리고 Premera Blue Cross를 통해 커버리지에 관한 정보를 포함하고 있는 것입니다. 본 통지서에는 백신이 되는 병마다 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 비용을 절감하기 위해서 일정한 만료일까지 조치를 취해야 할 필요가 있을 것입니다. 귀하는 이러한 정보와 득을 귀하의 안락도 비용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)으로 전화하시십시오.

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