GUIDELINES
This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder contract. Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards. This guideline is solely for explaining correct procedure reporting and does not imply coverage and reimbursement.

DESCRIPTION
Sacral nerve stimulation (SNS) is the implantation of a permanent device that stimulates the sacral nerves and is a treatment for urinary voiding dysfunction and fecal incontinence in which electrical impulses are delivered to sacral nerve fibers S2, S3, or S4 to modulate the neural pathways that influence the functioning of the bladder, bowel, urinary, and anal sphincters, and the pelvic floor muscles. Patients who have failed behavioral and/or pharmacologic therapies for urinary voiding dysfunction and fecal incontinence would be candidates for SNS. A temporary test stimulation is initially completed to determine if an implantable stimulator would be effective and if so then a permanent implantation is performed.

The InterStim® System for Urinary Control (Medtronic, Inc., Minneapolis, MN), was investigated in a large multicenter, randomized clinical trial that demonstrated that the device was effective in significantly reducing urinary symptoms in those with urge incontinence, urgency frequency and non-obstructive urinary retention. The InterStim Neurostimulator was cleared by the Food and Drug Administration in 1998 for urinary incontinence and received additional labeled approval for urinary retention in 1999.

The Food and Drug Administration (FDA) cleared the Interstim Therapy (Medtronic, Inc., O’Fallon, IL) device for the application of fecal incontinence on March 14, 2011, subject to a 5 year post-approval study. The post-approval study will be called the InterStim Sacral Nerve Stimulation Therapy for Bowel Control: Fecal Incontinence Post Approval Study (FI-PAS). The primary objective is to continue evaluation of incontinent episodes per week at yearly intervals through five years postimplant. Both device and therapy adverse events will be tracked during this ongoing study period.

POLICY
SNS for urinary and fecal incontinence does not require prior authorization.

HMO, PPO, Individual Marketplace, Elite, Advantage
Urinary Voiding Dysfunction:
Paramount covers a percutaneous screening trial of SNS as medically necessary for an individual with urinary voiding dysfunction and failure of, contraindication to, or intolerance to conservative medical management for ANY of the following indications:
- urinary urge incontinence
- nonobstructive urinary retention
- urinary urgency/frequency syndrome

Paramount covers permanent SNS implantation as medically necessary when BOTH of the following criteria are met:
- the individual has met the criteria for a percutaneous screening trial of SNS
- the individual experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms

Fecal Incontinence:
Paramount covers a percutaneous screening trial of SNS for fecal incontinence as medically necessary when ALL of the following criteria are met:
- failure of, contraindication to, or intolerance to conservative medical management
- sphincter surgery is either not indicated or is contraindicated
- absence of a significant anorectal malformation or chronic inflammatory bowel disease involving the anus
- fecal incontinence is not secondary to another neurological condition such as peripheral neuropathy or complete spinal cord injury
Paramount covers permanent SNS implantation for fecal incontinence as medically necessary when BOTH of the following criteria are met:

- the individual has met the criteria for a percutaneous screening trial of SNS
- the individual experienced a beneficial clinical response to a percutaneous screening trial of SNS as evidenced by at least a 50% improvement in reported symptoms

Paramount does not cover SNS for the treatment of any other indication because it is experimental, investigational or unproven.

**CODING/BILLING INFORMATION**
The appearance of a code in this section does not necessarily indicate coverage. Codes that are covered may have selection criteria that must be met. Payment for supplies may be included in payment for other services rendered.

<table>
<thead>
<tr>
<th>CPT CODES</th>
<th>Description</th>
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<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling</td>
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</tbody>
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<table>
<thead>
<tr>
<th>HCPCS CODES</th>
<th>Description</th>
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<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
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<tr>
<td>C1767</td>
<td>Generator, neurostimulator, implantable, non-rechargeable</td>
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<tr>
<td>C1778</td>
<td>Lead, neurostimulator, implantable</td>
</tr>
<tr>
<td>C1897</td>
<td>Lead, neurostimulator, test kit (implantable)</td>
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<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
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<tr>
<td>L8682</td>
<td>Implantable neurostimulator radiofrequency receiver</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, non-rechargeable, 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 extension</td>
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**TAWG REVIEW DATES:** 07/18/2014, 06/18/2015, 08/20/2015

**REVISION HISTORY EXPLANATION**
07/18/14: Policy created after TAWG review of the most current clinical evidence and determination of coverage made.
06/18/15: Policy reviewed and updated to reflect most current clinical evidence per TAWG.
08/20/15: SNS for urinary and fecal incontinence no longer requires a prior authorization per TAWG determination.

**REFERENCES/RESOURCES**
Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services
Ohio Department of Medicaid http://jfs.ohio.gov/
American Medical Association, Current Procedural Terminology (CPT®) and associated publications and services
Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets
Industry Standard Review
Hayes, Inc.