Policy
The Medical Management Department reviews referral requests for authorization of temporary or permanent Sacral Nerve Stimulation (SNS) for treatment of urinary or fecal incontinence.

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee’s specific plan document must be referenced. The terms of an enrollee’s plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee’s specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

A. Documentation Required:

In order to facilitate the authorization process referral requests must include the following:

1. Documentation of the individual’s diagnosis, medical history and physical exam.
2. Documentation of the individual’s specific history of urinary or fecal incontinence, urinary frequency or non-obstructive urinary retention.
3. Documentation of pharmacotherapies, intermittent catheterization trials and behavioral treatment of symptoms that have been tried in the past 12 months.
4. Results and interpretation of the temporary sacral nerve stimulation.

B. Criteria for Medical Necessity for Sacral Nerve Stimulation:

The TEMPORARY percutaneous application of FDA approved leads for sacral nerve stimulation (SNS) in adults 18 years and older is considered medically necessary for ONE of the following:

1. For treatment of **Urinary Incontinence and Retention** when ALL the following criteria are met:
   a. The individual has urge incontinence, urge frequency, or non-obstructive urinary retention (see Definitions); **AND**

   b. The individual has had symptoms for at least 12 months that have resulted in significant disability limiting the patient’s ability to participate in daily activities; **AND**

   c. The individual has failed at least 12 weeks of conservative treatment for their condition as noted below (i **OR** ii):

   i. For the treatment of urge incontinence or urge frequency:
a) Pharmacotherapies must include at least 2 different anti-cholinergic (anti-muscarinic) drugs or a combination of an anti-cholinergic (anti-muscarinic) and a beta-3 adrenergic receptor agonist if no documented intolerance to these medications; **AND**

b) Behavioral treatments must include a combination of pelvic floor exercise, biofeedback, timed voids, and fluid management.

ii. For the treatment of non-obstructive urinary retention:
   a) Pharmacotherapies must include trials of alpha blockers and anti-cholinergics drugs; **AND**
   b) Behavioral treatments must include a trial of intermittent catheterization;

2. For treatment of **Fecal Incontinence** when **ALL** the following criteria are met:
   a. The individual has fecal incontinence averaging at least two (2) episodes of incontinence per week for 6 consecutive months; **AND**

   b. The individual has failed at least 12 weeks of conservative treatment which includes a combination of pelvic floor exercises, biofeedback, dietary, fluid and fiber management; and pharmacotherapy; **AND**

   c. The individual has a weak but structurally intact anal sphincter; **AND**

   d. The prescribing physician is experienced in the diagnosis and treatment fecal incontinence and trained in use of the sacral nerve stimulation device.

The **PERMANENT** subcutaneous implant of FDA approved leads and a pulse generator for sacral nerve stimulation in adults 18 years and older is considered medically necessary for **ONE** of the following:

1. For treatment of **Urinary Incontinence and Retention** when **ALL** the following Criteria are met:
   a. The individual meets all of the criteria for trial of temporary percutaneous sacral nerve stimulation listed in **Procedure B.1** above; **AND**

   b. The individual is clinically appropriate to undergo a surgical procedure; **AND**

   c. The individual has undergone a successful 1-week trial of a percutaneous sacral nerve stimulator with at least a 50% improvement in **ANY** of the following symptoms:
      i. Urinary retention; **OR**
      ii. Urinary urge incontinence; **OR**
      iii. Urinary urgency and frequency.

2. For treatment of **Fecal Incontinence** when **ALL** the following criteria are met:
   a. The individual meets all of the criteria for trial of temporary percutaneous sacral nerve stimulation listed in **Procedure B.2** above; **AND**

   b. The individual is clinically appropriate to undergo a surgical procedure; **AND**

   c. The individual has undergone a successful 2-3 week trial of a percutaneous sacral nerve stimulator and reports at least a 50% improvement in fecal incontinence.
C. Criteria for Medical Necessity for Posterior Tibial Nerve Stimulation:

The Posterior Tibial nerve stimulation (PTNS) in adults 18 years and older is considered medically necessary when ALL the following criteria are met:

1. The individual has overactive bladder, urge incontinence or urge/frequency incontinence; **AND**
2. The individual has had symptoms for at least 12 months that have resulted in significant disability limiting the patient’s ability to participate in daily activities; **AND**
3. The individual has failed at least 12 weeks of conservative treatment for their condition including **BOTH** of the following:
   a. Pharmacotherapies must include at least 2 different anti-cholinergic drugs or an anti-cholinergic and a beta-3 adrenergic receptor agonist; **AND**
   b. Behavioral treatments must include a combination of pelvic floor exercise, biofeedback, timed voids, and fluid management.

**NOTE:**
- Initial treatment of up to 12 sessions occurring weekly is considered medically necessary when criteria have been met.
- Monthly maintenance therapy treatments are considered medically necessary for patients who report improved symptoms during initial treatment course.
- PTNS therapy is limited to up to 2 years total treatment from initiation of therapy (start of initial treatment sessions).
- Requests for continuation of PTNS therapy beyond 2 years of treatments (initial + maintenance) must be approved by the Medical Director.

C. Indications Considered Experimental, Investigational or not Medically Necessary: *(Not an all-inclusive list)*

1. Sacral nerve stimulation for Urinary Incontinence and/or Retention due to **ANY** of the following:
   a. Obstruction;
   b. Voiding dysfunction due to neurologic conditions (e.g., detrusor hyperreflexia, complete spinal cord injury, diabetic neuropathy, multiple sclerosis);
   c. Stress incontinence;
   d. Chronic pelvic pain;
   e. Bilateral sacral nerve stimulation.
2. Use of sacral nerve stimulation in pregnancy.
3. Sacral nerve stimulation for **Fecal Incontinence** due to **EITHER** of the following:
   a. The use of injectable/tissue bulking agents (i.e. Solesta); **OR**
   b. Chronic inflammatory bowel
5. **Peri** Use of sacral nerve stimulation for treatment of chronic constipation.
6. Eclipse™ Vaginal Bowel Control System for fecal incontinence

**CPT/HCPCS Codes:**

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<thead>
<tr>
<th>Code</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>
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<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)</td>
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<tr>
<td>64590</td>
<td>Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct of inductive coupling (when specified as sacral nerve stimulator)</td>
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</tbody>
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**References**

CMS Pub 100-03 National Coverage Determination for Sacral Nerve Stimulation for Urinary Incontinence; Section 230.18.


UpToDate® Fecal Incontinence in Adults: Management; Robson K, Lembo A, August 10, 2016

UpToDate® Treatment of Urinary Incontinence in Women; Lukacz E, January 6, 2017

UpToDate® Urinary Incontinence in Men; Clemmens J, January 6, 2017

UpToDate® Chronic Urinary Retention in Women; Rickey L, January 22, 2016

Medscape, Urinary Incontinence Medication, Vasavada S, November 28, 2016