



Nerve Stimulation for Urinary or Fecal Incontinence

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P&P # C.5.13

Policy

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. 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; **OR**

- 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 **ONE** of the following:
 - i. a successful 1-week trial of a sacral nerve stimulator (percutaneous sacral nerve evaluation or surgically placed sacral nerve test stimulator) with at least a 50% improvement in **ANY** of the following symptoms:
 - a) Urinary retention; **OR**
 - b) Urinary urge incontinence; **OR**
 - c) Urinary urgency and frequency; **OR**
 - ii. A successful trial of < 1 week if **ALL** the following are met:
 - a) a 1-week trial was intended; **AND**
 - b) a 50% improvement in symptoms was achieved before the end of the 1-week trial; **AND**
 - c) use of test results avoided a surgically placed sacral nerve test stimulator for repeat testing.
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 **ONE** of the following:

- i. a successful 1-week trial of a sacral nerve stimulator (percutaneous sacral nerve evaluation or surgically placed sacral nerve test stimulator) and reports at least a 50% improvement in fecal incontinence; **OR**
- ii. a successful trial of < 1 week if **ALL** the following are met:
 - a) a 1-week trial was intended; **AND**
 - b) a 50% improvement in symptoms was achieved during the reduced testing time; **AND**
 - c) use of test results avoided a surgically placed sacral nerve test stimulator for repeat testing.

C. Criteria for Medical Necessity for The Eclipse System Fecal Incontinence Device

1. The Eclipse System Device Trial

A trial of the Eclipse device is medically necessary for the treatment of fecal incontinence in adults 18 years and older when **ALL** of the following criteria are met:

- a. The individual has fecal incontinence averaging at least 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 **ALL** the following: pelvic floor exercises, biofeedback, dietary, fluid and fiber management; and pharmacotherapy; **AND**
- c. The individual has a structurally intact anal sphincter; **AND**
- d. The prescribing physician is trained in the use and fitting of the Eclipse fecal incontinence device.

2. Permanent Eclipse System Device

The purchase of a permanent Eclipse device is medically necessary for the treatment of fecal incontinence in adults 18 years and older when **ALL** of the following criteria are met:

- a. The patient had a successful trial of the Eclipse device as evidenced by:
 - i. A 50% reduction in baseline fecal incontinence, **AND**
 - ii. No evidence of adverse events that would preclude daily wearing of the device.

3. Eclipse Device Replacement

- a. It is medically necessary for the Eclipse device to be replaced annually.

D. 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 and Investigational: *(Not an all-inclusive list)*

1. Use of sacral nerve stimulation in pregnancy.
2. Perianal electrical stimulation for treatment of fecal incontinence.
3. PeriUse of sacral nerve stimulation for treatment of chronic constipation.
4. Perianal injection of bulking agents for fecal incontinence.
5. Posterior tibial nerve stimulation for the treatment of fecal incontinence.
6. Perianal electrical stimulation for treatment of fecal incontinence.
7. Pelvic floor electrical stimulation for treatment of urinary incontinence.

C. Indications Considered 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. Sacral nerve stimulation for **Fecal Incontinence** due to any of the following:
 - a. The use of injectable/tissue bulking agents (i.e. Solesta);
 - b. Chronic inflammatory bowel;
 - c. Central nervous system disease, e.g., multiple sclerosis, spinal cord injury, cerebrovascular disease (stroke), Parkinson’s disease, or Alzheimer’s disease.

CPT/HCPCS Codes:

64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
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64581	Incision for implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling (when specified as sacral nerve stimulator)
L8699	Prosthetic implant, not otherwise specified (Eclipse)

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