I. Policy: Sacral Nerve Stimulation

II. Purpose/Objective:
To provide a policy of coverage regarding Sacral Nerve Stimulation

III. Responsibility:
A. Medical Directors
   B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
A sacral nerve stimulator is composed of a pulse generator that transmits electrical impulses to the sacral nerves through an implanted wire electrode. These electrical impulses cause a contraction of the bladder muscles, giving the patient improved bladder control. After the electrodes are implanted, the insured individual is provided with an external stimulator on a trial basis. If during the trial, it is determined that the stimulation is not effective or is unacceptable to the member, the electrodes are removed. If the trial proves successful, demonstrated by at least 50% decrease in incontinence symptoms, a stimulator and pulse generator are inserted subcutaneously and are connected to the implanted electrodes.

INDICATIONS: REQUIRES PRIOR PLAN AUTHORIZATION. The authorization must be requested and approved prior to the implantation of the electrodes for the trial period.
- Urinary urge incontinence
- Urgency-frequency syndrome
- Urinary retention
- Fecal incontinence

CRITERIA FOR COVERAGE:

For urinary dysfunction: All must be met
- Medical documentation that the insured individual’s urinary incontinence or retention is refractory to all conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and the insured individual is an appropriate surgical candidate such that implantation with anesthesia can occur.
- Demonstration of symptomatic improvement with a temporarily implanted electrode must precede permanent implantation.

For fecal incontinence: All must be met

Physician provided documentation of:
- Two or more fecal incontinence episodes per week for a minimum of 6 months, or for more than 12 months after vaginal childbirth; and
- Failure or intolerance of conventional therapy (e.g., Bowel re-training program, dietary modification, the addition of bulking and pharmacologic treatment); and
- Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury; and
- Fecal incontinence is not related to a treatable medical or surgical condition including, but not limited to congenital anorectal malformation, anal abscess and/or fistula, or visible sequelae of pelvic radiation; and
- the insured individual is an appropriate surgical candidate such that implantation with anesthesia can occur.

For Neurogenic Bladder Secondary to Spinal Cord Injury: All must be met
- The Device must be FDA approved (e.g. Vocare Bladder System / FineTech-Brindley Bladder Control System)
- patients who have clinically complete spinal cord lesions according to ASIA Classification (see: http://www.asia-spinalinjury.org/publications/59544_sc_Exam_Sheet_r4.pdf
- intact parasympathetic innervations of the bladder
- skeletally mature and neurologically stable

Demonstration of at least 50% reduction in incontinent episodes with a temporarily implanted electrode must precede permanent implantation.

NOTE: Services related to component reimplantation or replacement in insured individuals previously approved for the implantation, or members having had the implantation prior to enrollment in the Plan, and who otherwise meet criteria for coverage, do not require prior authorization.”

EXCLUSIONS:
There is insufficient evidence in the peer-reviewed, published medical literature to support the use of sacral nerve stimulation as a treatment of stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications. These applications are considered Experimental, Investigational, or Unproven and are NOT COVERED.
The Innova Feminine Incontinence Treatment System is considered Experimental, investigational or Unproven and is NOT COVERED.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Sacral Nerve Stimulation

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>64561</td>
<td>Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)</td>
</tr>
<tr>
<td>64581</td>
<td>Incision for implantation of neurostimulator electrodes; sacral nerve; (transforaminal placement)</td>
</tr>
<tr>
<td>64585</td>
<td>Revision or removal of peripheral neurostimulator electrodes</td>
</tr>
<tr>
<td>64590</td>
<td>Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct of inductive coupling</td>
</tr>
<tr>
<td>64595</td>
<td>Revision or removal of peripheral neurostimulator pulse generator or receiver</td>
</tr>
<tr>
<td>95970</td>
<td>Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming</td>
</tr>
<tr>
<td>95971</td>
<td>simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming</td>
</tr>
<tr>
<td>A4290</td>
<td>Sacral nerve stimulation test lead, each</td>
</tr>
<tr>
<td>L8679</td>
<td>Implantable neurostimulator pulse generator, any type</td>
</tr>
<tr>
<td>L8680</td>
<td>Implantable neurostimulator electrode, each</td>
</tr>
</tbody>
</table>


LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:
Health Technology Trends, FDA Approves Implantable Electrical Stimulator for Patients with Urinary Incontinence, Vol. 9 No. 11; November 1997


Geisinger Clinic technology Assessment Committee, “Innova Feminine Incontinence Treatment System, April 27, 1994


This policy will be revised as necessary and reviewed no less than annually.
Devised: 8/98

Revised: 7/99, 3/03; 3/04; 2/05; 5/10 (refs); 3/12 (added indication)

Reviewed: 3/06; 3/07, 3/08, 4/09, 5/11, 3/13, 3/14, 10/14, 10/15, 10/16