Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP091

Section: Medical Benefit Policy

Subject: Sacral Nerve Stimulation

Applicable Lines of Business

Commercial	**X**	**CHIP**	**X**
Medicare	**X**	**ACA**	**X**
Medicaid	**X**		

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

Medically Necessary — A service, item, procedure, or level of care that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

- Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
- Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
- 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 member 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:
- Urinary urge incontinence
- Urgency-frequency syndrome
- Urinary retention (non-obstructive)
- Fecal incontinence

CRITERIA FOR COVERAGE:

For urinary dysfunction: All must be met
- Medical documentation that the member's urinary incontinence or retention is refractory to all conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and the member 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 member 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 members 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.**

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis.

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. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements

64561 Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64581 Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64585 Revision or removal of peripheral neurostimulator electrodes
64590 Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct of inductive coupling
64595 Revision or removal of peripheral neurostimulator pulse generator or receiver
95970 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
95971 simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95972 electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.
A4290 Sacral nerve stimulation test lead, each
L8679 Implantable neurostimulator pulse generator, any type
L8680 Implantable neurostimulator electrode, each
L8683 radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684 radiofrequency transmitter (external) for use with implantable sacral root neurostimulator receiver for bowel and bladder management replacement
L8685 implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686 implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687 implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688 implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension
L8689 external recharging system for battery (internal) for use with implantable neurostimulator, replacement only
C1767 generator, neurostimulator (implantable), nonrechargeable
C1778 lead, neurostimulator (implantable)
C1787 patient programmer, neurostimulator
C1816 receiver and/or transmitter, neurostimulator (implantable)
C1820 generator, neurostimulator (implantable), non-high frequency, with rechargeable battery and charging system
C1822 generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
C1883 Adaptor/Extension, pacing lead or neurostimulator lead (implantable)
C1897 Lead, neurostimulator test kit (implantable)

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 Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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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), 9/19 (Remove P/A); 9/23 (clarify urinary retention criteria)

Reviewed: 3/06; 3/07, 3/08, 4/09, 5/11, 3/13, 3/14, 10/14, 10/15, 10/16, 9/17, 9/18, 9/20, 9/21, 9/22

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies