BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 05/07/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

SACRAL NERVE NEUROMODULATION AND STIMULATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Sacral Nerve Modulation/Stimulation (SNM):
SNM has been investigated as a treatment for urinary and fecal incontinence. The SNM device consists of an implantable pulse generator that delivers controlled electrical impulses. The pulse generator is attached to wire leads that connect to the sacral sensory nerves. Two external components of the system help control the electrical stimulation. A control magnet is kept by the individual and can be used to turn the device on or off. Prior to implantation, a peripheral nerve stimulation test is conducted to determine if the individual is an appropriate candidate for the device.

SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Definitions:

Urgency-Frequency:
Uncontrollable urge to urinate that results in very frequent, small volumes.

Urinary Retention:
Inability to completely empty the bladder of urine.

Urinary Stress Incontinence:
Involuntary loss of urine from the urethra due to increased intra-abdominal pressure.

Urinary Urge Incontinence:
Leakage of urine when there is a strong urge to void.

Criteria:

Urinary Incontinence:

- A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. **ONE** of the following diagnoses:

     - Urinary urge incontinence
     - Non-obstructive urinary retention
     - Overactive bladder
     - Urgency-frequency syndrome

  2. Documented failure or intolerance to at least two conventional conservative treatments (e.g., behavioral training such as bladder training, prompted voiding, pelvic muscle exercise training, pharmacologic treatment for at least a sufficient duration to fully assess its efficacy and/or surgical corrective therapy)
  3. Incontinence is not related to a neurologic condition
  4. Individual is an appropriate surgical candidate

SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Criteria: (cont.)

Urinary Incontinence: (cont.)

- Permanent implantation of a sacral nerve neuromodulation device is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Trial period criteria above are met
  2. Trial stimulation demonstrates at least 50% improvement in symptoms over a period of at least one week

- Sacral nerve neuromodulation for all other urinary indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These urinary disorders include, *but are not limited to:*

  - Stress or urge urinary incontinence due to a neurologic condition (e.g., detrusor hyperreflexia, multiple sclerosis, spinal cord injury or other types of chronic voiding dysfunction

Fecal Incontinence:

- A trial period of sacral nerve neuromodulation with either percutaneous nerve stimulation or a temporarily implanted lead is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Chronic fecal incontinence of greater than two incontinent episodes on average per week with duration greater than 6 months or for more than 12 months after vaginal childbirth
  2. Failure or intolerance to conservative therapy (e.g., dietary modification, the addition of oral bulking and pharmacologic treatment for at least a sufficient duration to fully assess its efficacy, performed more than 12 months [or 24 months in case of cancer] previously)
  3. Individual is an appropriate surgical candidate
  4. Condition is not related to an anorectal malformation (e.g., congenital anorectal malformation; defects of the external anal sphincter over 60 degrees; visible sequelae of pelvic radiation; active anal abscesses and fistulae) or chronic inflammatory bowel disease
  5. Incontinence is not related to another neurologic condition

SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Criteria: (cont.)

Fecal Incontinence: (cont.)

- Permanent implantation of a sacral nerve neuromodulation device is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Trial period criteria above are met
  2. Trial stimulation demonstrates at least 50% improvement in symptoms over a period of at least one week

- Sacral nerve neuromodulation/stimulation for all other fecal indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These indications include, *but are not limited to:*

  - Treatment of chronic constipation
  - Chronic pelvic pain

SACRAL NERVE NEUROMODULATION AND STIMULATION (cont.)

Resources:

Resources prior to 05/22/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.69 BCBS Association Medical Policy Reference Manual. Sacral Nerve Neuromodulation/ Stimulation. Re-issue 04/10/2014, issue date 11/01/1998.

FDA Premarket Approval Database for Interstim® Therapy:

- FDA-approved indication: Sacral nerve stimulation. For the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

FDA 510K Summary for Urgent PC Neuromodulation System:

- FDA-approved indication: To treat patients with Overactive Bladder (OAB) and associated symptoms of urinary urgency, urinary frequency and urge incontinence.