Local Coverage Determination (LCD)

Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence

L39543

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Palmetto GBA	A and B MAC	10111 - MAC A	J - J	Alabama
Palmetto GBA	A and B MAC	10112 - MAC B	J - J	Alabama
Palmetto GBA	A and B MAC	10211 - MAC A	J - J	Georgia
Palmetto GBA	A and B MAC	10212 - MAC B	J - J	Georgia
Palmetto GBA	A and B MAC	10311 - MAC A	J - J	Tennessee
Palmetto GBA	A and B MAC	10312 - MAC B	J - J	Tennessee
Palmetto GBA	A and B and HHH MAC	11201 - MAC A	J - M	South Carolina

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Palmetto GBA	A and B and HHH MAC	11202 - MAC B	J - M	South Carolina
Palmetto GBA	A and B and HHH MAC	11301 - MAC A	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11302 - MAC B	J - M	Virginia
Palmetto GBA	A and B and HHH MAC	11401 - MAC A	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11402 - MAC B	J - M	West Virginia
Palmetto GBA	A and B and HHH MAC	11501 - MAC A	J - M	North Carolina
Palmetto GBA	A and B and HHH MAC	11502 - MAC B	J - M	North Carolina

LCD Information

Document Information

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Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence

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Issue

Issue Description

This LCD outlines limited coverage for this service with specific details under ***Coverage Indications, Limitations and/or Medical Necessity***.

Issue - Explanation of Change Between Proposed LCD and Final LCD

The LCD language regarding length of time for basic testing has been changed to be consistent with FDA language and other payor policies.

CMS National Coverage Policy

Title XVIII of the Social Security Act, §1862(a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member

Title XVIII of the Social Security Act, §1862(a)(7) states Medicare will not cover any services or procedures associated with routine physical checkups

CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 4, §230.18 Sacral Nerve Stimulation for Urinary Incontinence

CMS Internet-Only Manual, Pub. 100-08, Medicare Program Integrity Manual, Chapter 13, §13.5.4 Reasonable and Necessary Provision in an LCD

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Urinary incontinence refers to the involuntary loss of urine.

The overall prevalence of overactive bladder (OAB) in the total United States (U.S.) population was 23.3%, with women reporting OAB almost twice as frequently as men (30.0% vs. 16.4%, respectively).[19] Nearly half of nursing home residents have some degree of incontinence. For noninstitutionalized persons older than 60 years of age, prevalence ranges from 15-35%, with women having twice the prevalence of men.[17]

Sacral nerve stimulation (SNS) delivers nonpainful, electrical pulses to the sacral nerves to modulate reflexes that influence the bladder, sphincter, and pelvic floor to improve or restore function.[4] SNS has been approved for use in treating urinary incontinence in the U.S. since 1997.[2]

In 2011, SNS was U.S. Food and Drug Administration (FDA) approved for the indication of fecal incontinence (FI).[4] The chronic involuntary loss of stool is a life altering circumstance. In the older population, this represents 1 of the single most frequent precipitating factors for entrance into a nursing home.[2] FI is a common symptom, with a prevalence that ranges from

7-15% in community dwelling men and women, but it is often underreported, as providers seldom screen for FI and patients do not volunteer the symptom, even though the symptoms can have a devastating impact on quality of life (QOL).The strongest independent risk factors for FI in the community are bowel disturbances, especially diarrhea, the symptom of rectal urgency, and burden of chronic illness.[3]

Sacral neuromodulation (SNM) is a guideline recommended treatment for voiding dysfunction including urgency, urge incontinence, and nonobstructive retention as well as FI.

SNS is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and urinary retention by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) §230.18 Sacral Nerve Stimulation for Urinary Incontinence. Direct stimulation of the sacral nerve(s) via an electrode array implanted at the level of the sacrum is the only treatment modality covered by the NCD.[1]

Covered Indications

Urinary Incontinence

SNS is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome, and nonobstructive urinary retention. SNS involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in appropriate candidates. Both the test and the permanent implantation are covered.[1]

Limitations

NCD §230.18 Sacral Nerve Stimulation for Urinary Incontinence describes the following limitations for coverage to apply to all 3 indications:

- Patient must be refractory to conventional therapy (documented behavioral (such as bladder training, or pelvic muscle exercise training), pharmacologic and /or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic disease (e.g., diabetes with peripheral nerve involvement, multiple sclerosis, spinal cord injury) which are associated with secondary manifestations of the above 3 indications are excluded.
- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.[1]

Covered Indications /Limitations

Fecal Incontinence (FI)

This A/B Medicare Administrative Contractor (MAC) will cover SNS for FI, when all of the following criteria are met:

- Chronic FI with greater than 2 incontinent episodes on average per week and duration of incontinence greater than 6 months or for more than 12 months after vaginal childbirth; AND
- Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
- A successful percutaneous test stimulation, defined as at least 50% sustained (more than 48 hours) improvement in symptoms; AND
- Condition is not related to anorectal malformation (e.g., congenital malformation, defects of the external anal sphincter over 60 degrees, visible sequelae of pelvic radiation, active anal abscesses and fistulae) and /or chronic inflammatory bowel disease; AND
- Incontinence is not related to another neurologic condition such as peripheral neuropathy or complete spinal cord injury.

SNS is considered experimental, investigational for the treatment of chronic constipation or chronic pelvic pain (CPP).

Summary of Evidence

Wexner, et al.[2] conducted a multicentered prospective trial to determine the safety and efficacy of SNS in a large population under the rigors of FDA approved investigational protocol. Patients showing ≥50% improvement during test stimulation received chronic implantation of the InterStim™ Therapy (Medtronic; Minneapolis MN). The primary efficacy objective was to demonstrate that ≥50% of subjects would achieve therapeutic success, defined as ≥50% reduction of incontinent episodes per week at 12 months compared with baseline. At 12 months, 83% of subjects achieved therapeutic success (95% confidence interval: 74%-90%; P<0.0001), and 41% achieved 100% continence. Therapeutic success was 85% at 24 months. Incontinent episodes decreased from a mean of 9.4 per week at baseline to 1.9 at 12 months and 2.9 at 2 years. There were no reported unanticipated adverse device effects associated with InterStim™ Therapy. They concluded that SNS using InterStim™ Therapy is a safe and effective treatment for patients with FI.

Noblett, et al.[4] reviewed the history, mechanism of action, evolution, and landmark literature for this treatment modality. They concluded that the treatment of neuromodulation for the treatment of refractory voiding and bowel dysfunction has provided an effective alternative therapy for patients who have failed more conservative treatments. Data supports the long-term efficacy and safety of SNS for the treatment of bladder and bowel dysfunction.

Siegel, et al.[7] conducted a multicenter clinical trial to measure the effectiveness of SNS in 10 patients with chronic intractable pelvic pain. They performed a prospective nonrandomized study to characterize the safety and efficacy of SNS for chronic intractable pelvic and /or urogenital pain in 10 patients with a history of pelvic pain that persisted for at least 6 months and was refractory to conventional treatment. Due to their small sample size they did not anticipate that the data from this study would be suitable for statistical analysis. They concluded that the data in their feasibility study implied that transforaminal SNS decreases the severity, number of hours, and rate of pain in patients with chronic intractable pelvic pain. From a clinical viewpoint, 6 of 10 patients reported substantial benefit from treatment. A multicenter, statistically powered study should be performed to evaluate the validity of these trends.

Paquette, et al.[8] conducted an organized search of Medline, PubMed, Embase, and the Cochrane Database of Collected Reviews. The scope of this updated practice parameter was to address the evaluation and management of patients with FI based on a thorough review of the published literature. SNM is thought to modulate rectal sensation by activating or deactivating chemical mediating receptors, stimulating the afferent pathway, and changing brain activity relevant to the continence mechanism. SNM has been consistently shown to result in a reduction in frequency of FI episodes. Pooled analysis of all studies to date indicates that 79% (69-83%) of patients experience ≥50% improvements in weekly FI episodes in the short term (0-12 months) and 84% of patients experience ≥50% improvement at long-term (>36 month) follow-up when a per protocol analysis is followed (only patients who received a full system implant are analyzed). SNM may be considered as a first line surgical option for incontinent patients. Grade of Recommendation: Strong recommendation based on moderate quality evidence, 1B.

Mahran, et al.[9] performed a systematic review study that comprised a systematic search and summary of the literature related to the use of SNM in improving the symptoms of CPP. The search was conducted using online databases: Medline, Embase, Cochrane, Web of Science, and Scopus for articles that studied the efficacy of SNM in treating CPP. The primary outcome was pain improvement on a 10-point visual analog scale (VAS) in patients with CPP. Fourteen of 2175 studies, evaluating 210 patients were eligible for further analysis. The main finding of this systematic review is that SNM is an acceptable treatment option for CPP in selected patients. While the implantation rate is lower than it is for other indications, based on their analysis, the improvement in VAS pain score obtained by using SNM ranges between 35-52%. Pain improvement was better in patients with CPP due to etiologies other than interstitial cystitis/bladder pain syndrome (IC/BPS). They concluded, SNM is a promising treatment option for refractory CPP. Randomized prospective studies are warranted to compare SNM versus other modalities for CPP treatment.

Dinning, et al.[12] conducted the first randomized, dual center, controlled trial to evaluate the efficacy of permanent SNS in patients with slow transit constipation. Using the specific

primary outcome of the proportion of patients who, on more than 2 days/week for at least 2 of 3 weeks, report a bowel movement associated with a feeling of complete evacuation during suprasensory stimulation, they found no significant difference in the response rate between permanent suprasensory SNS (30%) and sham stimulation (21%). They found no significant difference in response rate between subsensory permanent SNS (25%) and sham (25%). When compared with sham, active stimulation had no significant impact on any of the tertiary outcome measures (QOL, stool frequency, global satisfaction and bothersome scores, days/week laxative use, number of defecating episodes associated with straining, and /or a feeling of complete evacuation). They found a response rate of 21-30% in each treatment arm whether it be subsensory, suprasensory, or sham, which are rates that are traditionally expected from a placebo response. They concluded in patients with refractory slow transit constipation SNS did not improve the frequency of complete bowel movements over the 3-week active period.

Amundsen, et al.[13] assessed whether onabotulinumtoxinA is superior to SNM in controlling refractory episodes of urgency urinary incontinence. They conducted a multicenter open-label randomized trial (February 2012 - January 2015) at 9 U.S. medical centers involving 381 women with refractory urgency urinary incontinence. In this comparative effectiveness trial, onabotulinumtoxinA had a greater mean daily urgency urinary incontinence episode reduction over 6 months than did the SNM group, -3.9 vs. -3.3 episodes per day, a statistically significant but small difference. Urinary tract infections and need for self-catheterization were more frequent among women who received onabotulinumtoxinA. They concluded among women with refractory urgency urinary incontinence, treatment with onabotulinumtoxinA compared with SNM resulted in a small daily improvement in episodes that although statistically significant is of uncertain clinical importance. In addition, it resulted in a higher risk of urinary tract infections and need for transient self-catheterizations.

Hull, et al.[14] conducted a study to assess the outcome of SNS, or SNM, focusing on the long-term durability of the therapy. Five-year data were analyzed. This prospective, nonrandomized, U.S. FDA - regulated study was conducted in 14 centers in the US, 1 in Canada, and 1 in Australia from 2002 through 2012. Patients with chronic FI in whom conservative treatments had failed or who were not candidates for more conservative treatments received SNS with the use of InterStim™ Therapy (FDA-approved in March 2011, Medtronic, Minneapolis, MN) and were thereafter followed at predetermined intervals to evaluate the efficacy and safety of the therapy. Patients were assessed with a 14-day bowel diary and Fecal Incontinence Quality of Life and Fecal Incontinence Severity Index questionnaires. Therapeutic success was defined as ≥50% improvement over baseline in FI episodes per week. At 5 years post implantation, 89% (64/72) of patients contributing bowel diary data had at least a 50% improvement from baseline in weekly incontinent episodes ($p<0.0001$). In addition, 35% (26/72) of patients at 5 years post implantation had achieved

total continence. The average number of weekly incontinent episodes decreased from 9.1 at baseline to 1.7 at 5 years ($p<0.0001$). This improvement from baseline was observed past 5 years. This study has multiple strengths including its long-term follow-up, the number of patients, the quality of the data, and the use of accepted tools to objectively study the patients before and after therapy. A limitation of this study is that it was not a randomized study with a control arm. Although that would have added to the credibility of the data, the present FDA-sanctioned study still used a rigorous design with strict collection of data at baseline and then regularly through and past 5 years. Another limitation of this study is that there were no prescribed program settings for the device. Patients were able to adjust the stimulation as they needed with portable programmers between visits. They concluded that this prospective study looking at the durability of SNS therapy has shown that the therapeutic effect and improvements in QOL are maintained through 5 years post implantation.

Siegel, et al.[16] evaluated the therapeutic success rate, and changes in the QOL and safety in subjects using SNM (InterStim™ System) at 36 months. The InSite trial was designed to be implemented in 2 phases. Phase 1 was a prospective, multicenter, randomized trial comparing SNM to standard medical therapy with a 6-month follow-up period. It provided level 1 evidence for the objective and subjective superiority of SNM over standard medical therapy among OAB refractory patients and confirmed the safety of currently used devices and techniques for SNM. The second phase of the InSite trial is a prospective evaluation of the safety and efficacy of SNM in 5 years. They concluded the 36-month follow-up data from the multicenter study demonstrate sustained safety, effectiveness and improved QOL in subjects implanted with InterStim™, without requiring failure of all medications. They reported results for all implanted subjects up to 3 years. Subjects will continue to be followed for 5 years to collect additional long-term data. The InSite trial is an ongoing, large, prospective multicenter study designed to evaluate the long-term safety and efficacy of SNM for subjects with refractory symptoms of OAB. They reported the results after 3 years of therapy demonstrating that implanted subjects maintained improvements in OAB symptoms with QOL. The strength of the InSite study include the large number of subjects with protocol mandated follow-up, and the rigorous modified completer analysis with ongoing inclusion of subjects withdrawn for lack of benefit or device related complications as failures. The weaknesses of this InSite study include the homogeneous population, with a minority of male subjects, which could detract from generalizability. Furthermore, centers were allowed to follow individual protocols regarding perioperative antibiotics, lead choice, and procedure techniques.

Benson, et al.[18] conducted the ARTISAN-SNM study a single-arm, prospective, multi-center, pivotal study that was designed to evaluate the safety and efficacy of the Axonics® System for the treatment of urinary urgency incontinence (UUI). The Axonics® System provides SNM therapy for the treatment of OAB, nonobstructive urinary retention, and FI. With an

approved functional life of at least 15 years, the Axonics® System is the first rechargeable SNM system available for use in the U.S. The Axonics® System is approved for full body magnetic resonance imaging (MRI) scans. A total of 129 eligible participants were implanted with a quadripolar tined-lead and neurostimulator in a single procedure. Efficacy data were collected using a 3-day bladder diary, a validated QOL questionnaire (ICIQ-OABqol), and a participant satisfaction questionnaire. At 1 year, 89% of the participants were therapy responders. The average UUI episodes per day reduced from 5.6 ± 0.3 at baseline to 1.4 ± 0.2. Participants experienced an overall clinically meaningful improvement of 34 points on the ICIQ-OABqol questionnaire. All study participants (100%) were able to recharge their device at 1 year, and 96% of participants reported that the frequency and duration of recharging was acceptable. The strengths of this study include the conservative data analysis methods. In addition, the collection of recharging usability data provides insight into the patient charging experience, showing high patient satisfaction. Study limitations include that this was a nonrandomized study, with no comparator or placebo arm. However, given that SNM is a widely accepted treatment with well-known efficacy, the use of a placebo was considered unnecessary.

Siegel, et al.[20] evaluated the therapeutic success rate, changes in QOL, and safety of SNM 5 years after InterStim™ implantation. This prospective study demonstrated the sustained efficacy and safety of SNM in subjects with OAB after 5 years of treatment. The therapeutic success rate was 82% at 5 years and 85% at 1 year, which strongly demonstrates long-term durability in patients with SNM in clinical practice. Limitations include the homogeneous population with a minority of male subjects. Centers could follow individual protocols regarding perioperative antibiotics, lead choice, and procedure techniques. Although this approximates what is occurring in general practice with SNM therapy, this lack of standardization along with the potential impact on infection rates, device related complications, and ultimate therapy success or failure rates may have impacted the overall study results. They concluded statistically significant treatment effects from baseline to 5 years were found in the cardinal symptoms of OAB (leaks and/or voids) and in QOL. In addition, the InSite for OAB study showed an InterStim™ therapy safety profile that indicates a low rate of serious device related AEs (adverse events) and types of devices related AEs that are consistent with product labeling and the published literature.

Analysis of Evidence (Rationale for Determination)

The analysis of evidence reviewed for the SNS for the treatment of urinary and FI included a multicentered prospective nonrandomized trial, a systematic review study that comprised a systematic search and summary of the literature, randomized dual center-controlled trial, multicenter open-label randomized trial, and single-arm prospective multi-center pivotal study.

The literature supports the long-term efficacy and safety of SNS for the treatment of bladder and bowel dysfunction. The InSite trial for OAB success rate was 82% at 5 years and 85%

at 1 year, which strongly demonstrates long-term durability in patients with SNM in clinical practice.

The literature reviewed concluded that SNS is a safe and effective treatment for patients with FI. A Grade 1B recommendation.

The literature did not support the use of SNM for chronic intractable pelvic pain. Further studies are warranted to compare SNM versus other modalities for CPP treatment.

The literature reviewed did not support the use of sacral neurostimulation for chronic constipation.

General Information

Associated Information

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this Local Coverage Determination (LCD) (see *Coverage Indications, Limitations and/or Medical Necessity*).

The documentation must include the following:

1. All documentation must be maintained in the patient's medical record and made available to the A/B MAC upon request.
2. Complete history and physical examination (including voiding diaries, urodynamic studies for urinary incontinence).
3. Patient must be refractory to conventional therapy.
4. Patient must have had a successful test stimulation in order to support subsequent implantation.

Sources of Information

N/A

Bibliography

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Revision History Information

N/A

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A59332 - Billing and Coding: Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence

A59520 - Response to Comments: Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence

LCDs

DL39543 - Sacral Nerve Stimulation for the Treatment of Urinary and Fecal Incontinence (MCD Archive Site)

Related National Coverage Documents

NCDs

230.18 - Sacral Nerve Stimulation For Urinary Incontinence

Public Versions

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