



Clinical Review Criteria Sacral Nerve Stimulator for Fecal and Urinary Incontinence

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Criteria For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	Sacral Nerve Stimulator for Urinary Incontinence (230.18)
Local Coverage Determinations (LCD)	None
Local Coverage Article	Sacral Nerve Stimulation for Urinary and Fecal Incontinence (A53017)

For Non-Medicare Members

Kaiser Permanente has elected to use the MCG* Implanted Electrical Stimulator, Sacral Nerve (A-0645) for medical necessity determinations. For access to the MCG Clinical Guidelines criteria, please see the MCG Guideline Index through the provider portal under Quick Access.

***The MCG* are proprietary and cannot be published and/or distributed.** However, on an individual member basis, Kaiser Permanente can share a copy of the specific criteria document used to make a utilization management decision. If one of your patients is being reviewed using these criteria, you may request a copy of the criteria by calling the Kaiser Permanente Clinical Review staff at 1-800-289-1363 or access the MCG Guideline Index using the link provided above.

If requesting these services, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Fecal incontinence is the inability to control the loss of fecal matter from the bowel. Management of fecal incontinence includes conservative therapy, such as dietary and lifestyle changes, antidiarrheal medications, biofeedback therapy, absorbent pads, and anal plugs, as well as surgical interventions, such as direct sphincter repair and implantation of an artificial sphincter (Mowatt 2007, Tan 2011).

Sacral nerve stimulation is a treatment option for patients who have failed or could not tolerate conservative therapy. It involves applying electrical stimulation to a sacral nerve via an electrode that is placed through the corresponding sacral foramen. In order to be a candidate for sacral nerve stimulation, patients must undergo a testing phase known as peripheral nerve evaluation to determine if the treatment might prove effective. The peripheral nerve evaluation determines the feasibility of electrode implantation and involves a 2 to 3-week period of stimulation with a temporary electrode to assess the potential benefits of the therapy. If significant benefit is achieved, patients may undergo permanent implantation. The exact mechanism of action through which sacral nerve stimulation provides its therapeutic effect is unclear (Mowatt 2007, Pettie 2012, Tan 2011).

The InterStim® Therapy System (Medtronic Inc., Minneapolis, MN) is a sacral nerve stimulation device that has been approved by the FDA to treat chronic fecal incontinence in patients who have failed or could not tolerate conservative treatments.

Evidence and Source Documents

[Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence](#)
[Sacral Nerve Stimulator for Fecal Incontinence](#)

Medical Technology Assessment Committee (MTAC)

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence

BACKGROUND

Urinary incontinence (UI) refers to an involuntary leak of urine. There are several types of UI. Stress UI, the most common form, is an involuntary leak on effort or exertion and urge UI is an involuntary leak accompanied or immediately preceded by a sense of urgency. Mixed UI is a combination of stress and urge UI. A related condition is urinary retention, the inability to completely empty the bladder. Another diagnosis is overactive bladder syndrome (OAB), an urge that occurs with us without a leak of urine, and usually occurs with increased urinary frequency and nocturia. The condition is often categorized as either OAB dry (without incontinence) or OAB wet (with incontinence). The prevalence of urinary incontinence in women is approximately 50% when defined as any urine loss and is 8-36% when limited to bothersome urine loss. About half of all cases are stress incontinence. Urinary incontinence that is severe enough it cannot be easily concealed can have a major impact on quality of life, especially if it includes urinary urgency. Severe urinary incontinence has been found to increase the risk of urinary tract infections in post-menopausal women, and the risk of falls and hip fractures in elderly women (Gray, 2005). Treatments for urge incontinence include the use of absorbent pads, bladder training/pelvic floor muscle exercises, treatment with medications (anti-cholinergic agents, antispasmodics, tricyclic antidepressants), topical estrogen, pelvic floor electrical stimulation, and surgery. The most common treatment for urinary retention is self-catheterization. Sacral nerve stimulation using an implantable device (bladder pacemaker) is proposed as an additional alternative to surgery for patients with urge incontinence, urgency-frequency symptoms or urinary retention. (It is not proposed for stress incontinence, the most common form of urinary incontinence). The InterStim Therapy for Urinary Control is an FDA-approved device developed by Medtronic. Consistent with the protocol in clinical trials, patients undergo percutaneous test stimulation in an outpatient setting before implantation. This involves insertion of an electrode into a sacral foramen. An external device produces continuous stimulation. The implantable InterStim system uses an implanted lead stimulating the appropriate sacral nerve root, most commonly S3. The proximal part of the lead is tunneled under the skin and connected to the neurostimulator which is placed in a subcutaneous pocket in the lower abdomen. The physician can use a microprocessor-based console programmer to set stimulation settings. There is also a handheld programmer that patients can use to turn the stimulator on and off, and to adjust the voltage output amplitude. The battery operating the device is expected to last 7 to 9 years. It is challenging to evaluate the efficacy of treatments for urinary incontinence because there is no gold standard for outcome assessment. In addition, there is a high placebo effect in randomized incontinence studies; as many as 30-40% of patients in placebo groups report success. The high placebo effect has been attributed to several factors including the strong subjective component in voiding dysfunction, and potentially therapeutic effects of study design components such as keeping a voiding diary and interacting with study personnel (Dmochowski, 2001). Because of the high placebo effect, in order to show that an intervention is effective, it is necessary to show that it has an impact beyond that of a placebo. Sacral nerve stimulation for urinary incontinence was reviewed by MTAC in February 1999 and February 2001. The technology did not meet MTAC evaluation criteria. An evidence update was conducted outside of MTAC in October 2002. The GHP Urology Department has requested an updated review.

01/2001: MTAC REVIEW

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence

Evidence Conclusion: The Schmidt et al. study found a significant improvement in urinary incontinence symptoms at 6 months among patients who received an InterStim device compared to patients receiving standard medical treatment. This study has several threats to validity including substantial selective loss to follow-up, self-report data and lack of blinding or intention-to-treat analysis. Moreover, the research team had financial ties to the manufacturer of the device. Due to the potential biases in this study, the existing data are insufficient to permit conclusions about the effectiveness of this technology.

Articles: Eleven articles were identified. Six articles were not directly relevant, did not include clinical outcomes or were review articles; five articles presented empirical data on clinical outcomes. Articles were selected based on study type. There were three randomized controlled trials (RCTs) and two case series. The three RCTs were done by a single group of investigators. Only one of the 3 RCTs were examining urinary incontinence as the

outcome. An evidence table was created for this RCT: Schmidt RA, Jonas U, Oelson KA, Janknegt RA, Hassouna MM, Siegel SW, Kerrebroek for the Sacral Nerve Stimulation Study Group. *J Urol* 1999; 162: 352-57. See [Evidence Table](#).

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/2002: MTAC REVIEW

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence

Evidence Conclusion: The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the Interstim device to standard medical treatment for 6 months, among patients who demonstrated during a 3-7-day testing period that they responded to the Interstim device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) Treatment was not blinded and did not allow for a placebo effect of the Interstim device and; 3) The intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing).

Articles: The search yielded 17 articles, many of which were review articles, opinion pieces, dealt with technical aspects of the procedures or addressed other, similar treatments. There were three articles on a single randomized controlled trial and five case series. The three RCT articles reported on different patient populations enrolled in the same trial (those with urge incontinence, urgency-frequency and non-obstructive urinary retention) and were all critically appraised. The Schmidt study was included in the February 2001 MTAC review. Evidence tables were created for the following articles: Schmidt RA, Jonas U, Oleson KA et al. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. *J Urol* 1999; 162: 352-357. See [Evidence Table](#). Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. *J Urol* 2000; 163: 1849-1854. See [Evidence Table](#). Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. *J Urol* 2001 165: 15-19. See [Evidence Table](#).

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

10/01/2007: MTAC REVIEW

Bladder Pacemaker /Sacral Nerve Stimulation for Treatment of Urinary Incontinence

Evidence Conclusion: The RCT that generated the three reports was done by the same multinational research team and was funded by Medtronic, the device manufacturer. All of the three first authors had financial relationships with Medtronic. The articles reviewed included the identical intervention for urology patients with different presenting symptoms (urge incontinence, urgency-frequency and non-obstructive urinary retention) and were limited by the same biases. The RCT compared implantation of the InterStim device to standard medical treatment for 6 months, among patients who demonstrated in a 3-7-day testing period that they responded to the device. All found that sacral nerve stimulation was superior to standard medical care during the 6 months before patients in the control group were offered implantation. Bias was introduced because 1) only patients who were shown to respond to the device were included (about 45% of otherwise eligible patients); 2) treatment was not blinded and did not allow for a placebo effect of the InterStim device and; 3) the intervention was compared to standard medical treatment, which the patients had already failed. A more valid comparison would be to implant the device in all eligible patients and randomly assign patients to receive active stimulation or no stimulation (this type of placebo control group was used in studies of biventricular pacing). An alternative study design to evaluate the effectiveness of InterStim among patients who respond to a test trial would be to compare InterStim to a different treatment that patients had not already failed. Especially in a non-blinded study with some subjective outcomes, bias can be introduced if one group perceives that they are receiving a new and innovative treatment and the other group is receiving the same treatment they have already received. There are no new RCTs to supplement the above data.

Articles: The ideal study would be a randomized controlled trial comparing InterStim therapy to a placebo and/or established alternative intervention. At the time of the 2002 evidence review, conducted outside of the MTAC meeting, there were several RCTs by the same group of investigators. The RCTs compared InterStim to standard medical therapy. No new RCTs evaluating the efficacy and/or safety of the InterStim device were identified. There

was one additional publication on the original RCT, evaluating psychosocial outcomes in a subset of the study population (Das et al., 2004; Urol). One new RCT was identified on a related topic, comparing two methods for predicting which patients would proceed to device implantation (Borawski et al., 2007). The study did not compare the effectiveness of InterStim treatment compared to placebo or an alternative treatment and was thus not reviewed further. In addition, there were several new case series with sample sizes of approximately 30 patients. Since higher grade evidence has been published, the small case series were not reviewed. *The RCTs on InterStim that have been critically appraised are:* Schmidt RA, Jonas U, Oelson KA et al. for the Sacral Nerve Stimulation Study Group. J Urol 1999; 162: 352-57. See [Evidence Table](#). Hassouna MM, Siegel SW, Lycklama AAB et al. Sacral neuromodulation in the treatment of urgency-frequency symptoms: A multicenter study on efficacy and safety. J Urol 2000; 163: 1849-1854. See [Evidence Table](#). Jonas U, Fowler J, Chancellor B et al. Efficacy of sacral nerve stimulation for urinary retention: Results 18 months after implantation. J Urol 2001 165: 15-19. See [Evidence Table](#).

The use of sacral nerve stimulation for the treatment of urinary incontinence does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Sacral Nerve Stimulator

2/11/2013: MTAC REVIEW

Evidence Conclusion: Based on evidence from one randomized controlled trial and several observational studies, the Kaiser Medical Technology Assessment Team found that the evidence on the safety and efficacy of sacral nerve stimulation for treating severe fecal incontinence is of insufficient quality and quantity to determine whether sacral nerve stimulation is medically appropriate for the treatment of fecal incontinence. The best evidence comes from the randomized controlled trial conducted by Tjandra and colleagues (see below) (Kaiser 2011).

Results from a RCT that included 120 patients with severe fecal incontinence suggest that compared to optimal medical therapy patients who were treated with sacral nerve stimulation had significantly fewer incontinence episodes per week, days with incontinence, days with straining, and significantly better quality of life at 12 months. Adverse events included pain at implant site, seroma, and excessive tingling in the vaginal region. All patients in the sacral nerve stimulation group needed the program readjusted. The mean number of readjustments per person was three. Adjustments included changes in the electrode used for stimulation as well as changes in amplitude and rate. This study had several limitations: power was not assessed, results are only applicable to patients with severe incontinence, and patients included in the study were refractory to medical therapy and pelvic floor exercises, which was the control group treatment (Tjandra 2008).

Outcomes at 12 months (Tjandra 2008)

	SNS	Control	P-value
	mean ± standard deviation		
Incontinence episodes/week	3.1±10.1	9.4±11.8	<0.05
Days with incontinence/week	1.0±1.7	3.1±1.8	<0.05
Days with straining/week	1.4±2.0	4.5±2.3	<0.05
Days using pads/week	2.2±3.0	3.2±3.1	0.085
Fecal incontinence quality of life (FIQL) index*			
Lifestyle	3.3±0.7	2.3±0.9	<0.05
Coping/behavior	2.7±0.9	1.9±0.9	<0.05
Depression/self-perception	3.3±0.8	2.6±0.8	<0.05
Embarrassment	2.8±0.9	1.8±0.6	<0.05

Abbreviations: SNS= sacral nerve stimulation.

* FIQL score range= 1 to 4 with a higher score indicating better quality of life.

Conclusion: There is limited evidence on the safety and efficacy of sacral nerve stimulation for the treatment of fecal incontinence.

Articles: In February 2011, Kaiser Permanente's Medical Technology Assessment Team reviewed implantable sacral nerve stimulators for fecal incontinence. The randomized controlled trial that was included in the Kaiser technology assessment was also selected for review as this was the highest quality study assessing the effects of sacral nerve stimulation for the treatment of fecal incontinence. Since the Kaiser Technology Assessment, several observational studies were identified that evaluated the effects of sacral nerve stimulation. None of these studies were selected for review as they did not compare sacral nerve stimulation to other treatments.

The following study and technology assessment were selected for review: Kaiser Permanente. Implantable sacral nerve stimulators for severe fecal incontinence. February 2011;

http://pkc.kp.org/national/cpg/intc/topics/03_19_125.html

Accessed November 6, 2012.

The use of Sacral Nerve Stimulation for Fecal Incontinence meets the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
HCPC Codes	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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Date Created	Date Reviewed	Date Last Revised
3/5/2013	03/05/2013 ^{MDCRPC} , 11/03/2013 ^{MPC} , 09/02/14 ^{MPC} , 11/04/2014 ^{MPC} , 09/01/2015 ^{MPC} , 07/05/2016 ^{MPC} , 06/06/2017 ^{MPC} , 04/03/2018 ^{MPC} , 04/02/2019 ^{MPC} , 04/07/2020 ^{MPC} , 04/06/2021 ^{MPC} , 04/05/2022 ^{MPC} , 04/04/2023 ^{MPC}	04/18/2023

^{MDCRPC} Medical Director Clinical Review and Policy Committee

^{MPC} Medical Policy Committee

Revision History	Description
11/04/2014	MPC approved to adopt MCG* Implanted Electrical Stimulator, Sacral Nerve (A-0645) for medical necessity determinations for non-Medicare members
12/09/2015	Added LCA and CPT codes
04/07/2020	Added CPT codes 64590 and 64595
04/18/2023	Updated Medicare Billing and coding A53017