

Subject: Implantable Neurostimulator for Sacral Neuromodulation in Treatment of Urinary and Fecal Incontinence		Original Effective Date: 8/4/14
Policy Number: MCP-182	Revision Date(s): 7/18/16	
Review Date: 12/16/15, 6/15/16, 6/22/17, 3/8/18, 9/18/19, 9/16/20		
MCPC Approval Date: 3/8/18, 9/18/19, 9/16/20		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members. ¹

Contents

DISCLAIMER 1

SUMMARY 1

Recommendation 2

Limitations 3

SUMMARY OF MEDICAL EVIDENCE 3

Coding Information..... 4

Resource References 5

GENERAL BACKGROUND SUMMARY

Sacral nerve stimulation (SNS), using the Medtronic InterStim Therapy System, is the application of a mild electrical pulse to the sacral nerves through a surgically implanted neuromodulation system to treat urinary or fecal incontinence. The electrical pulses modulate the sacral nerves that influence the functioning of the bladder, bowel, urinary, and anal sphincters, and the pelvic floor muscles. Stimulation of the sacral nerves (S2-

S4) generally causes a lifting and tightening of the anus, and contraction of the external sphincter. Implantation of the InterStim neurostimulator is a two-phase process. The first phase consists of a trial period to determine if a patient is likely to achieve optimal benefit from long-term implantation. If the patient experiences a decline in urinary or bowel accidents by at least half the number of incontinence episodes in a typical week, the patient may benefit from the InterStim Therapy System. The second phase involves the permanent implantation of the neurostimulator, which requires a surgical procedure under general or local anesthesia, typically performed on an outpatient basis. The sacral nerve neurostimulator (InterStim device) is inserted under the skin through a small incision in the upper buttock, and placed in a subcutaneous pocket. The long-term lead is implanted in the tailbone and modulates a sacral nerve adjacent to the lead. Sacral nerve stimulation is intended as second-line therapy in adults with chronic urinary or fecal incontinence who have not responded favorably to medical therapy, who are not appropriate candidates for conservative treatments, or who are considering a more invasive surgical option. ⁴⁴

The InterStim System for Urinary Control (Medtronic Inc.) is approved by the FDA for the treatment of nonobstructive urinary retention, urinary urge incontinence, and symptoms of urgency-frequency syndrome in patients who have failed or could not tolerate more conservative treatments. The InterStim System also received a premarket application (PMA) approval for the treatment of chronic fecal incontinence in patients who have failed or could not tolerate conservative, noninvasive therapies. ²⁻³

Recommendation 1-5 6-38 39-44

- ❑ SNS with the implantable neurostimulator for the treatment of fecal incontinence may be considered medically necessary when all of the following criteria are met: [ALL]
 - Chronic fecal incontinence with greater than two incontinent episodes on average per week and duration of incontinence greater than six months or for more than twelve months after vaginal childbirth; AND
 - Documented failure or intolerance to conventional therapy (e.g., dietary modification, the addition of bulking and pharmacologic treatment); AND
 - Documented successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms measured through incontinence diaries; AND
 - Condition is not related to 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) 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 with the implantable neurostimulator for the treatment of urinary incontinence may be considered medically necessary when ALL of the following criteria are met: [ALL]
 - ONE of the following chronic clinical conditions with duration of incontinence greater than six months: [ONE]
 - urinary urge incontinence, or
 - nonobstructive urinary retention, or
 - urgency-frequency syndrome; AND

- Documented successful percutaneous test stimulation, defined as at least 50% sustained (more than one week) improvement in symptoms measured through incontinence diaries; AND
- Documented failure or intolerance to conventional therapy (e.g., dietary modification, voiding re-training, and/or pelvic floor physiotherapy exercises, pharmacotherapy)

LIMITATIONS⁴⁸

- ❑ All of the following clinical conditions are considered not medically necessary, investigational, experimental and unproven: [ALL]
 - as a first-line therapy
 - chronic constipation
 - neurogenic voiding dysfunction and urinary retention
 - other conditions that include: diabetes, interstitial cystitis, chronic pelvic pain, stress incontinence, overactive bladder, and mixed urinary incontinence
 - pediatric use in children

- ❑ Contraindications to SNS for urinary incontinence include: mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture, and/or concurrent use of any form of diathermy.⁴⁸

SUMMARY OF MEDICAL EVIDENCE⁶⁻³⁸

Urinary Incontinence

There is a large body of evidence from both randomized controlled trials (RCTs), prospective and retrospective studies, systematic reviews and large case studies that indicate sacral nerve stimulation (SNS) by an implantable system is safe and effective for the treatment of urinary urge incontinence, nonobstructive urinary retention, and urgency-frequency syndrome in selected individuals who are refractory to standard therapies and who experience a > 50% symptom relief during a trial of percutaneous test SNS. Most of the studies had small to moderate sample sizes, ranging from 51 to 581 patients. Outcome measures varied, but the primary outcome measures usually included incontinence symptom relief measured by patients and recorded in daily voiding diaries. Long-term outcomes from RCTs of SNS are lacking; however, evidence from prospective and retrospective long-term follow-up studies of the available RCT's show sustained control of intractable urinary symptoms for up to 2 years and, in a small patient group, for up to 11 years. The results of the uncontrolled studies were generally positive; several prospective studies reported > 60% clinical efficacy of SNS for patients with chronic urinary voiding symptoms at ≥ 5 years follow-up. Although the results of a few studies indicate that SNS may be effective for some patients with neurogenic urinary retention and mixed urinary incontinence, there is insufficient data for these conditions.²¹⁻³⁸

Fecal Incontinence

There is some evidence from published studies that sacral nerve stimulation using the InterStim Therapy System improves the symptoms of chronic fecal incontinence in adults by reducing the number of fecal incontinence episodes per week and improving some measures of quality of life. The studies include two randomized crossover studies (total n=54), a randomized controlled study (n=120), and six prospective, before-and-after studies (total n=498) and one meta-analysis (n=944). Two studies had overlapping patient populations

and the one reported subsequent long-term follow-up data. The majority of patients were refractory to primary conservative treatment before undergoing permanent implantation of the InterStim device and conducted an initial peripheral nerve evaluation to test efficacy prior to permanent device implantation. Outcome measures were generally related to severity of bowel incontinence following device implantation, and included functional outcomes. A few studies also reported if the ability to completely empty the bowel improved following device implantation. Follow-up periods ranged from 12 to 75 months. The best evidence consisted of two randomized crossover studies in which patients served as their own controls, and one randomized controlled study, which compared InterStim therapy with optimal medical treatment. Two of three randomized studies did not specifically report significant differences in therapeutic effects between treatment and controls. However, the majority of patients experienced improvements in symptoms relative to baseline assessments, including a significant reduction in number of incontinence episodes and significant improvements in physical, social, and emotional functioning. The meta-analysis follow-up ranged from 2 to 35 weeks and the majority of studies reported a decrease in the number of incontinent episodes per week after the procedure.⁶⁻²⁰

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement) including image guidance, if performed
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling

HCPCS	Description
A4290	Sacral nerve stimulation test lead, each
L8680	Implantable neurostimulator electrode, each
L8679	Implantable neurostimulator, pulse generator, any type [when specified as sacral nerve stimulator]
L8680	Implantable neurostimulator electrode, each
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
ICD-10	Procedure Codes
01HY0MZ	Insertion of neurostimulator lead into peripheral nerve, open approach
01HY3MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous approach
01HY4MZ	Insertion of neurostimulator lead into peripheral nerve, percutaneous endoscopic approach
ICD-10	Diagnosis Codes
N39.41	Urge incontinence
R15.0-R15.9	Fecal incontinence (code range)
R33.0-R33.9	Retention of urine (code range)
R35.0	Frequency of micturition
K59.00-K59.09	Constipation (code range)
R10.2	Pelvic and perineal pain

N39.3	Stress incontinence (male or female)
N39.42	Incontinence without sensory awareness

RESOURCE REFERENCES

Government Agency:

- Centers for Medicare & Medicaid Services (CMS). Medicare Coverage Database. National Coverage Determination (NCD) for Sacral Nerve Stimulation for Urinary Incontinence (230.18). Available at: <https://www.cms.gov/medicare-coverage-database/>
- U.S. Food and Drug Administration (FDA) Premarket Approval. Medtronic™ Interstim™ system for urinary control: treatment of urinary retention and symptoms of urgency/frequency. Summary of Safety and Effectiveness. No. P970004. Rockville, MD: FDA. April 15, 1999.
- U.S. Food and Drug Administration (FDA) Premarket Approval. Interstim sacral nerve stimulation system (fecal). Summary of Safety and Effectiveness. No. P080025. Rockville, MD: FDA. March 14, 2011.
- Agency for Healthcare Research and Quality. Rockville, MD:
 - Evidence Report Technology Assessment. No 161. Prevention of Urinary and Fecal Incontinence in Adults. Dec 2007. Available at: <http://archive.ahrq.gov/downloads/pub/evidence/pdf/fuiad/fuiad.pdf>
 - Comparative Effectiveness Review No. 165. Treatments for Fecal Incontinence. AHRQ Publication No. 15(16)-EHC037-EF.; March 2016.
- Brasure M, Fink HA, Risk M, et al. Chronic urinary retention: Comparative effectiveness and harms of treatments. Report, AHRQ Comparative Effectiveness Reviews; Rockville, MD 2014.

Peer Reviewed Publications

- Wexner SD, Collier JA, Devroede G, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. *Ann Surg.* 2010a;251(3):441-449.
- Wexner SD, Hull T, Edden Y, et al. Infection rates in a large investigational trial of sacral nerve stimulation for fecal incontinence. *J Gastrointest Surg.* 2010b;14(7):1081-1089.
- Mellgren A, Wexner SD, Collier JA, et al.; SNS Study Group. Long-term efficacy and safety of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum.* 2011;54(9):1065-1075.
- Leroi AM, Parc Y, Lehur PA, et al. Efficacy of sacral nerve stimulation for fecal incontinence: results of a multicenter double-blind crossover study. *Ann Surg.* 2005;242(5):662-669.
- Michelsen HB, Krogh K, Buntzen S, Laurberg S. A prospective, randomized study: switch off the sacral nerve stimulator during the night? *Dis Colon Rectum.* 2008;51(5):538-540.
- Tjandra JJ, Chan MK, Yeh CH, Murray-Green C. Sacral nerve stimulation is more effective than optimal medical therapy for severe fecal incontinence: a randomized, controlled study. *Dis Colon Rectum.* 2008;51(5):494-502.
- Chan MK, Tjandra JJ. Sacral nerve stimulation for fecal incontinence: external anal sphincter defect vs. intact anal sphincter. *Dis Colon Rectum.* 2008;51(7):1015-1024; discussion 1024-1025.

13. Altomare DF, Ratto C, Ganio E, Lolli P, Masin A, Villani RD. Long-term outcome of sacral nerve stimulation for fecal incontinence. *Dis Colon Rectum*. 2009;52(1):11-17.
14. Brouwer R, Duthie G. Sacral nerve neuromodulation is effective treatment for fecal incontinence in the presence of a sphincter defect, pudendal neuropathy, or previous sphincter repair. *Dis Colon Rectum*. 2010;53(3):273-278.
15. Leroi AM, Lenne X, Dervaux B, et al. Outcome and cost analysis of sacral nerve modulation for treating urinary and/or fecal incontinence. *Ann Surg*. 2011;253(4):720-732.
16. Tan E, Ngo NT, Darzi A, Shenouda M, Tekkis PP. Meta-analysis: sacral nerve stimulation versus conservative therapy in the treatment of faecal incontinence. *Int J Colorectal Dis*. 2011;26(3):275-294.
17. Haddad M, Besson R, Aubert D, et al. Sacral neuromodulation in children with urinary and fecal incontinence: a multicenter, open label, randomized, crossover study. *J Urol*. 2010;184(2):696-701.
18. Humphreys MR, Vandersteen DR, Slezak JM, et al. Preliminary results of sacral neuromodulation in 23 children. *J Urol*. 2006;176(5):2227-2231.
19. Roth TJ, Vandersteen DR, Hollatz P, Inman BA, Reinberg YE. Sacral neuromodulation for the dysfunctional elimination syndrome: a single center experience with 20 children. *J Urol*. 2008;180(1):306-311; discussion 311.
20. Mowatt G, Glazener C, Jarrett M. Sacral nerve stimulation for fecal incontinence and constipation in adults. *Cochrane Database Syst Rev*. 2008;(3):CD004464.
21. Schmidt RA, Jonas U, Oleson KA, et al.; Sacral Nerve Stimulation Study Group. Sacral nerve stimulation for treatment of refractory urinary urge incontinence. *J Urol*. 1999;62(2):352-357.
22. Siegel SW, Catanzaro F, Dijkema HE, et al. Long-term results of a multicenter study on sacral nerve stimulation for treatment of urinary urge incontinence, urgency-frequency, and retention. *Urology*. 2000;56(6 Suppl 1):87-91.
23. Janknegt RA, Hassouna MM, Siegel SW, et al. Long-term effectiveness of sacral nerve stimulation for refractory urge incontinence. *Eur Urol*. 2001;39(1):101-106.
24. Jonas U, Fowler CJ, Chancellor MB, et al. Efficacy of sacral nerve stimulation for urinary retention: results 18 months after implantation. *J Urol*. 2001;165(1):15-19.
25. Groenendijk PM, Lycklama à Nyevelt AA, et al. Urodynamic evaluation of sacral neuromodulation for urge urinary incontinence. *BJU Int*. 2008;101(3):325-329.
26. Weil EH, Ruiz-Cerdá JL, Eerdmans PH, Janknegt RA, van Kerrebroeck PE. Clinical results of sacral neuromodulation for chronic voiding dysfunction using unilateral sacral foramen electrodes. *World J Urol*. 1998;16(5):313-321.
27. Weil EH, Ruiz-Cerdá JL, Eerdmans PH, Janknegt RA, Bemelmans BL, van Kerrebroeck PE. Sacral root neuromodulation in the treatment of refractory urinary urge incontinence: a prospective randomized clinical trial. *Eur Urol*. 2000;37(2):161-171.
28. Bosch JL, Groen J. Sacral nerve neuromodulation in the treatment of patients with refractory motor urge incontinence: long-term result of a prospective longitudinal study. *J Urol*. 2000;163(4):1219-1222.
29. Aboseif S, Tamaddon K, Chalfin S, Freedman S, Kaptein J. Sacral neuromodulation as an effective treatment for refractory pelvic floor dysfunction. *Urology*. 2002;60(1):52-56.
30. Volker G, Ubi V, Udo J. Long-term follow up (36 months) of unilateral sacral nerve stimulation for treatment of urinary retention. *Eur Urol Suppl*. 2002;1(1):144.

31. Ruiz-Cerdá JL, Arlandis S, González-Chamorro F, et al. Spanish experience in sacral nerve stimulation: case register of the Spanish Sacral Neuromodulation Group (GENS). *Eur Urol Suppl.* 2003;2(1):142.
32. Datta SN, Chaliha C, Singh A, et al. Sacral neurostimulation for urinary retention: 10-year experience from one UK centre. *BJU Int.* 2008;101(2):192-196.
33. Deng DY, Gulati M, Rutman M, et al. Failure of sacral nerve stimulation due to migration of tined lead. *J Urol.* 2006;175(6):2182-2185.
34. Kessler TM, Buchser E, Meyer S, et al. Sacral neuromodulation for refractory lower urinary tract dysfunction: results of a nationwide registry in Switzerland. *Eur Urol.* 2007;51(5):1357-1363.
35. van Kerrebroeck PE, van Voskuilen AC, Heesakkers JP, et al. Results of sacral neuromodulation therapy for urinary voiding dysfunction: outcomes of a prospective, worldwide clinical study. *J Urol.* 2007;178(5):2029-2034.
36. Brazzelli M, Murray A, Fraser C. Efficacy and safety of sacral nerve stimulation for urinary urge incontinence: a systematic review. *J Urol.* 2006; 175(3 Pt 1):835-841.
37. Herbison GP, Arnold EP. Sacral neuromodulation with implanted devices for urinary storage and voiding dysfunction in adults. *Cochrane Database Syst Rev.* 2009;(2):CD004202.
38. Siegel S, Noblett K, Mangel J, et al. Results of a prospective, randomized, multicenter study evaluating sacral neuromodulation with InterStim therapy compared to standard medical therapy at 6-months in subjects with mild symptoms of overactive bladder. *Neurourol Urodyn* 2015; 34:224.

Professional Society Guidelines

39. ACOG Gynecology and the American Urogynecologic Society Practice Bulletin No. 63: Urinary Incontinence in Women American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2016;126:e66–81. Accessed at: <https://www.contemporaryobgyn.net/obstetrics-gynecology-womens-health/acog-guidelines-urinary-incontinence-women>
40. National Institute for Health and Care Excellence (NICE). Multiple guidance documents for sacral nerve stimulation for urinary and fecal incontinence. Updated 2015. Available at: <http://www.nice.org.uk/Search?area=NICE.search&q=Sacral+nerve+stimulation>.
41. Gormley EA, Lightner DJ, Faraday M, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU guideline amendment. *J Urol.* 2015; 193(5):1572-1580.
42. Satish SCR. American College of Gastroenterology Practice Parameters Committee. Diagnosis and management of fecal incontinence. American College of Gastroenterology Practice Parameters Committee. *Am J Gastroenterol.* 2004 Aug;99(8):1585-604.
43. American Society of Colon and Rectal Surgeons (ASCRS) clinical practice guideline on treatment of fecal incontinence. *Dis Colon Rectum* 2015 Jul;58(7):623

Other Resources

44. Hayes a Tract Manager Company: Winifred Hayes Inc. Lansdale, Pa.
 - Health Technology Assessment: Implantable Sacral Nerve Stimulation for Urinary Voiding Dysfunction. Updated 2014. [archived].
 - Health Technology Assessment. Staged Approach to Sacral Nerve Stimulation for Treatment of Fecal Incontinence. Dec. 2015, Updated April, 2020.
45. UpToDate: [website]: Waltham, MA: Walters Kluwer Health; 2020.

- Robson K, Lembo A. Fecal incontinence in adults.
- Lukacz E. Treatment of urinary incontinence in women.
- Rickey L. Chronic urinary retention in women.

46. Medtronic Sacral Neuromodulation. Indications, Safety and Warnings. [website]. Available at:
<http://professional.medtronic.com>

Revision/Review History:

8/4/14: New Policy

12/16/15: Policy reviewed, clinical criteria has not changed.

7/18/16: Policy was reviewed and updated with new medically necessary criteria for both urinary and fecal incontinence. Summary of medical evidence and reference sections were updated.

6/22/17 & 3/8/18: Policy reviewed, clinical criteria has not changed.

9/18/19: Policy reviewed, clinical criteria has not changed. Updated guidelines, coding tables and references.

9/16/20: Policy reviewed, no changes. Updated references.