



Clinical Commissioning Policy: Sacral Nerve Stimulation for Overactive Bladder

Reference: NHS England E10/P/b

NHS England INFORMATION READER BOX

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Medical	Commissioning Operations	Patients and Information
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Publications Gateway Reference:

03725

Document Purpose	Policy
Document Name	E10/P/b Sacral Nerve Stimulation for Urinary Incontinence
Author	Specialised Commissioning Team, NHS England
Publication Date	July 2015
Target Audience	Local Team Assistant Directors of Specialised Commissioning; Regional Team IFR Leads; Finance Leads; Local Team Pharmacists; Chairs of Clinical Reference Groups; Members of Clinical Reference Groups and registered stakeholders; Acute Trust Chief Executives; Acute Trust Medical Directors; Acute Trust Chief Pharmacists
Additional Circulation List	Regional Medical Directors; Regional Directors of Specialised Commissioning; Regional Clinical Directors of Specialised Commissioning; Regional Directors of Nursing
Description	NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
Cross Reference	
Superseded Docs (if applicable)	
Action Required	
Timing / Deadlines (if applicable)	
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Document Status

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1 Executive summary

Policy Statement

NHS England will routinely commission sacral nerve stimulation for overactive bladder in accordance with the criteria outlined in this document.

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

Plain Language Summary

Overactive bladder (OAB) is a condition where the sufferer has to rush to the toilet. The urge to go to the toilet is present but the bladder may contain only a small

amount of urine or may leak small amounts of urine without the person being able to control it.

Physically and socially this can cause problems for people in their daily lives. Doctors use a variety of treatments to be able to control this condition. These include behavioural techniques physiotherapy, medication and operations. Generally these methods are successful for most people.

One of the available treatments for overactive bladder is **Sacral Nerve Stimulation** therapy. This involves placing small electrodes into the back where the bladder nerves are. Electrical impulses then stimulate the nerves and this can help reduce the symptoms of overactive bladder. The electrodes are attached to a small device that can be inserted under the skin. The device can be taken out at any time if the physician and person with the implant decide that it should be removed.

This policy document has been written so that people receiving this treatment will have an understanding of:

- What the treatment is
- Who would benefit
- When it should be used
- The evidence and effectiveness information to support its use

2 Introduction

Overactive bladder is defined by the International Continence Society as a syndrome referring to the urinary symptoms of urgency with or without urge urinary incontinence, and is a debilitating disorder affecting 12-14% of the population¹⁻⁴. Detrusor over activity is the urodynamic diagnosis most commonly associated with the symptoms of OAB.

Although rarely life-threatening, these disorders can have a considerable negative impact on patients' quality of life, restricting their ability to work and function socially. The management of these disorders poses a significant health care burden as the disorders are rarely cured and severity increases progressively with age. The resulting consequences such as urinary tract infections, falls and fractures, and hospitalisations also impose additional costs¹⁻⁴. Incontinence can delay hospital discharge in the older patient or those with a disability. It is often responsible for an increasing level of dependency, i.e. independence to residential home, or residential home to nursing home. It is also a major factor prompting hospital admission in the care of elderly patients.

The provision of integrated continence services is a standard described in the National Service Framework for Older People.⁵ The Good Practice in Continence Services⁶ and the National Service Framework for Older People have called for integrated continence services to be established for people with incontinence. Yet in 2005 and 2006 the National Audit of Continence Care for Older People, sponsored by the Healthcare Commission, reported there has been little progress in the pursuit of truly integrated continence services as envisaged.

The National Audit of Continence Care 2009 commissioned by the Healthcare Quality Improvement Partnership provides the largest, most detailed evaluation of continence care in Europe. It demonstrates that, although the amount of authoritative guidance is increasing, the quality of continence care remains variable and in some respects remains poor.⁷ This is a cause for concern because continued inadequate assessment of incontinence does not indicate high-quality care. Moreover, it is expensive from a financial and a health perspective. Given the great daily cost of containing continence, the audit highlights the importance of assessing, treating and reducing the numbers of incontinent people and the wider associated financial costs.

The current management of OAB involves several levels of treatment. Symptoms are typically managed conservatively by means of behavioural techniques (e.g. bladder training) physical therapies (e.g. pelvic floor exercises) or pharmacotherapy (anti-

muscarinics, Beta-3 agonists). When these approaches are unsuccessful, more invasive procedures such as Botulinum toxin 'A' intra-vesical injections may be used. Percutaneous posterior tibial nerve stimulation should be offered only if the woman does not want botulinum toxin 'A' or sacral nerve stimulation (NICE 2013 Guideline 171). Irreversible surgical procedures include bladder reconstruction (for example, augmentation cystoplasty) and urinary diversion. However, these procedures have associated complications and management requirements such as revisions, ureteric stenosis and hydro-nephrosis.

Sacral nerve stimulation (SNS) is a minimally invasive treatment which uses electrical impulses to stimulate sacral nerves. It is proposed as a potential treatment for the symptoms of overactive bladder including urge urinary incontinence and urgency-frequency alone or in combination, in patients who have failed or cannot tolerate conservative and medical treatments.

The National Institute for Health and Clinical Excellence (NICE) has published a number of documents related to SNS (www.nice.org.uk):

- NICE Interventional Procedure Guidance on sacral nerve stimulation for urge incontinence and urgency-frequency (IPG64) – normal arrangements.
- NICE Clinical Guideline on Urinary Incontinence in Women (CG171): Recommends sacral nerve stimulation for the treatment of OAB due to detrusor over activity in women who have not responded to conservative management including drugs, who either:
 - Are unable to perform clean intermittent catheterisation, or
 - Who have not responded to botulinum toxin A treatment
- NICE Clinical Guideline on Lower Urinary Tract Syndrome in Men (CG97): Recommends sacral nerve stimulation to manage detrusor over activity only to men whose symptoms have not responded to conservative management and drug treatments.

- **A recent NICE HTA appraisal has also confirmed that Mirabegron, a beta 3 agonist, would be positioned within a complex treatment pathway and potentially offered an additional pharmacological treatment before invasive treatment options were considered.

3 Definitions

The Incontinence MDT is a multidisciplinary team of incontinence specialists. This may include urologists and urogynaecologists with a subspecialist interest in urinary incontinence, specialist nurses, continence advisors and other relevant specialists.

Urge urinary incontinence is one of the most commonly encountered forms of urinary incontinence. It may be defined as the involuntary leakage of urine accompanied by, or immediately preceded by, a sudden desire to void.

Urgency-frequency syndrome is a form of voiding dysfunction characterised by an uncontrolled urge to void, resulting in frequent, small amounts of urine voided many more times than is normally expected (as often as every 15 minutes).

Overactive bladder is defined by the International Continence Society as a syndrome referring to the urinary symptoms of urgency with or without urge urinary incontinence, and is a debilitating disorder affecting 12-14% of the population. It is usually associated with frequency and nocturia in the absence of infection or other obvious pathology. ^{2-4,8}

Sacral Nerve Stimulation therapy involves the use of electrical pulses to stimulate the sacral nerves located in the lower back. Electrodes are placed next to a sacral nerve, usually S3, by inserting the electrode lead into the corresponding foramen of the sacrum. Adequate electrode placement is confirmed by obtaining appropriate motor and sensory responses which help the surgeon to verify that the electrodes are stimulating the correct nerves. The electrodes are subsequently attached to a pulse generator. The procedure is reversible.

Prior to 'permanent' implantation, responsiveness is tested using a test period of treatment using an external stimulator. This involves the use of a temporary wire electrode which is later removed, or using a tined electrode which can be left in permanently.

A decision to proceed with a permanent implantation of the SNS device is made on the basis of the results of test stimulation. A patient is suitable for permanent implant if they report a significant useful clinical response to the test period of treatment (eg at least 50% improvement in symptoms recorded in the bladder diaries). This offers SNS a unique advantage over other surgical options, as the patient outcomes can be assessed before a commitment is made to the permanent procedure.

The permanent implant of the SNS system is minimally invasive, and it provides sustainable symptom relief in carefully-selected patients thereby avoiding repeated treatment with botulinum toxin A, or irreversible surgery. In patients who have failed treatment with SNS or where removal of the device is necessary, the treatment is fully reversible, simply involving an explant of the implanted components. Unlike some alternative treatments, SNS does not preclude further treatment options nor does it pose a delay or waiting period before which further treatment can be prescribed. The battery usually needs to be replaced every 5 to 7 years but may need to have it done sooner if necessary.

4 Aims and objectives

This policy aims to:

- Outline the clinical criteria which will identify the patients most likely to benefit from SNS for overactive bladder.

The objectives are to:

- Clarify how the evidence and its quality determines the clinical commissioning position for SNS in the treatment of bladder dysfunction and
- Set out the minimum requirements for the service

5 Epidemiology and needs assessment

The estimated prevalence of OAB is around 10-12% of the adult female population.¹² Further, the prevalence of urinary incontinence in men aged 18 - 64 years is 3%; and over 65 year is 8.5%, with 28.5% of this total comprising men with clinical significant urinary incontinence and most likely to seek treatment (NICE costing template for 'management of lower urinary tract syndrome in men').

The prevalence of urinary incontinence (UI) and OAB increases with age, and some populations, such as those with a higher number of nursing homes, may have a greater prevalence of urinary incontinence than the population as a whole¹⁰.

However, most people with UI and OAB do not report symptoms to their GP¹¹.

Available data from NICE suggest that the standard benchmark rate for a referral into a urinary continence service for women is 0.80%, or 800 per 100,000, of the adult female population (aged 15 years or older) per year. Approximately 25-40% of OAB related cases are refractory to conservative treatment and drug therapy¹² Patients will require second-line therapy. This does require the patient to have had access to appropriate and continued support for proper behavioural therapy support whilst undergoing a trial of pharmacotherapy.

6 Evidence Base

a. Clinical Efficacy

A systematic review of the efficacy and safety of sacral nerve stimulation for urinary urge incontinence and urgency frequency urge urinary incontinence commissioned by NICE was identified.¹³ The review concludes that the results from randomised control trials (RCT) included in the review provide evidence of some benefit from SNS in reducing incontinence episodes, pad usage, and frequency of voids, and in improving bladder capacity and voided volume. Benefits of SNS were reported to persist at follow-up three to five years after implantation of the pulse generator. Although the few data sources available suggest improvement, the impact of SNS on

quality of life of patients with urgency incontinence or urgency-frequency is still to be established.

The efficacy results of the RCTs included in the review are presented for each outcome measure according to the clinical indications for SNS, a) urge urinary incontinence; b) urgency-frequency; or c) a combination of these two conditions.

i. Urge urinary incontinence

Two RCTs reported findings on cure and improvement rates at the six months follow-up in patients with urgency incontinence randomised to a stimulation (n= 16 and 34) or a delayed group (n=22 and n=42).^{14,15} The trials showed that complete continence (completely dry with no incontinent episodes) or improvement of more than 50% in incontinence symptoms was observed in 50% and 80% of patients, respectively, following the procedure.

In the stimulation group of the two trials, the number of leakage episodes per day, severity of leakage, and number of pads used per day were significantly lower six months after implantation compared with baseline.

The two randomised controlled trials used the SF-36 short-form Health Survey to assess the impact of SNS on patients' quality of life. Weil et al¹⁵ found a significant difference in only the emotional role score (See Appendix 2). They also reported that, for the stimulation group at six months, the physical functioning score (67; 95% CI, 55-78) and the overall score for the physical component of the scale (42; 95% CI, 37-57) were significantly higher ($p=0.034$ and $p=0.019$ respectively) than the corresponding baseline values (52; 95% CI, 41-64 and 36; 95% CI, 30-41) (See Appendix 2). Schmidt et al¹⁴ observed a significant between-group difference six months after implantation in the physical health component of the questionnaire ($p=0.0008$) but no significant difference between the treatment groups in the mental health component.

ii. Urgency-frequency symptoms

One RCT (n=50) was identified reporting findings at the six months follow-up in patients with urgency frequency randomised to a stimulation (n=25) or a delayed group (n=25).¹⁶ In the trial a 50% improvement in number of voids was observed in 56% of the patients in the stimulation group and 4% of the patients in the delay group at six months.

The trial also reported a significant decrease in the frequency of voids (from 16.9 to 9.3, $p<0.0001$) and degree of urgency (from 2.2 to 1.6, $p=0.01$) at six months compared to baseline in the stimulation group. Mean volume voided (from 118ml to 226 ml, $p<0.001$) and mean bladder capacity (from 234ml to 325ml, $p=0.008$) were also significantly higher compared with baseline values. In contrast, none of these parameters changed significantly in the delay group.

Hassouna et al¹⁶ used the SF-36 Health Survey to assess the physical and mental health in 23 stimulation and 20 delay group patients at six months (See Appendix 2). Significantly higher scores were observed in the stimulation group for all the subscales of SF-36 with the exception of the emotional role score.

iii. Combination of both urge urinary incontinence and urgency-frequency symptoms

One RCT was identified which compared the efficacy of a 2-stage implant with a 1-stage implant procedure in 22 patients with overactive bladder symptoms (urgency incontinence and urgency-frequency). No significant differences were observed in main clinical symptoms and quality of life between the two procedures.¹⁵

b. Safety

A systematic review of the efficacy and safety of sacral nerve stimulation for urinary urgency incontinence and urgency frequency urge urinary incontinence commissioned by NICE was identified.¹⁷ Adverse events were documented amongst a total of 1015 patients in 27 studies included in the review.

- Among 860 patients 283 (33%) underwent surgical revision of the SNS implant. The most common reasons for reoperation were relocation of the neurostimulator because of pain at the implant site; revision of the lead system for suspected or detected lead migration; and infection.
- Pain was reported in 162 out of 663 tested patients (24%) and included pain at the generator site, pain at lead site, stimulation related pain, and new pain.
- Lead related complications were observed in 130 out of 807 (16%) patients and were mainly lead migration, lead breakage, loosened connection between extension lead and electrode, and electrode insulation defects.
- Forty-two out of 279 patients (15%) required replacement or relocation of the pulse generator mainly because of pain at the implant site, upgrade or reprogramming of an early pulse generator (Itrel I), battery failure, infection, or technical failure.
- Overall, wound problems (e.g. seroma, haematoma, partial wound dehiscence) occurred in 20 out of 283 tested patients (7%).
- Modifications of bowel function or adverse bowel function were documented in 20 out of 353 implanted patients (6%).
- Infection was reported in 35 out of 739 of patients (5%)
- Problems related to the implanted pulse generator (e.g. battery exhaustion) occurred in 5% of the patients who received SNS.
- No major neurological complications were documented apart from a suspected case of nerve injury and a case of generalised fasciculation whose aetiology could not be established.

c. Cost Effectiveness

In an economic model comparing SNS with botulinum toxin 'A' over a five-year period with a societal perspective, Leong et al.¹⁸ reported a greater gain in quality adjusted life years (QALY) and a greater associated cost when SNS was performed prior to botulinum toxin 'A' treatment. As the QALY gain from botulinum toxin 'A' injection was less due the repeated loss of effect with reinjections over time, SNS was demonstrated to become cost-effective after five years compared with botulinum toxin A, with an incremental cost-effectiveness ratio of 27,991 Euros, which is within the accepted NICE threshold of £20,000 to £30,000.

A 10-year Markov model from the Spanish healthcare system perspective also compared SNS with botulinum toxin 'A', in addition to optimal medical therapy.¹⁹ Similarly, these authors found that although the initial costs of SNS were higher than those of alternative treatments, reduced follow-up costs over the long-term in combination with sustained clinical effectiveness made SNS the dominant option over 10 years compared with the alternatives.

In the recently updated NICE Clinical Guideline for Urinary Incontinence in Women (CG 171), the health economic model used in the recommendations showed that SNS had a lower probability of being cost effective than botulinum toxin 'A' at a £20,000 per QALY threshold. Therefore the NICE recommendations state that "botulinum toxin 'A' should be offered first to women who are able to catheterize. For women who are unable to catheterize, SNS was a cost-effective option compared with no treatment."

d. Guidelines

SNS is recommended in European and International guidelines:

- International Consultation on Incontinence (ICI) Guidelines: Recommends neuromodulation as part of the specialised management of patients with mixed incontinence and urgency incontinence due to detrusor over activity if initial therapy fails.

- European Association of Urologists (EAU) Guidelines: Recommends neuro-stimulation as a specialised treatment to be used after failure of initial therapy in women with bladder hypersensitivity and overactive bladder. Recommend neuro-stimulation in men for the same conditions, with the exception of bladder hypersensitivity.
- American Urology Association (AUA) Guidelines: FDA-Approved: Clinicians may offer SNS as third line treatment in a carefully selected patient population characterised by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. (Recommendation; Evidence strength – Grade C; Benefits outweigh risks/burdens).

7 Rationale behind this policy statement

In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

8 Criteria for commissioning

SNS treatment will be routinely commissioned by NHS England for adult patients with urinary urgency incontinence, urinary urgency-frequency syndrome or double incontinence (urinary and faecal) who meet the following criteria:

1. A confirmed diagnosis defined by a quality controlled² conventional urodynamic assessment or ambulatory urodynamics when indicated. If the urodynamic diagnosis is inconclusive, a decision for further management including SNS must be made at an incontinence MDT.

2. Symptoms which are refractory to behavioural and lifestyle modification, pelvic floor exercises and pharmacological therapy; at least two anticholinergics followed by a B3 agonist (NICE TA; <http://guidance.nice.org.uk/TA290>), unless such treatments are contraindicated.
3. Female patients who have been offered intra-vaginal oestrogens for the treatment of symptoms of OAB in postmenopausal women with symptoms of vaginal atrophy where clinically appropriate.
4. Patients not suitable for treatment with Botulinum toxin 'A' bladder injections, including any of the following:
 - a) The patient is unable to perform clean intermittent catheterization
 - b) There is a medical contraindication to Botulinum toxin treatment
 - c) Botulinum toxin bladder injections have not had a therapeutically useful effect
 - d) An incontinence MDT has recommended that SNS is a more appropriate treatment
5. Referred to a specialist surgeon at a centre experienced in providing SNS and after review by the incontinence MDT
6. Patients who have been counselled about
 - a) The surgical and non-surgical options appropriate for their individual circumstances.
 - b) The benefits and limitations of each option, with particular attention to long- term results.
 - c) Realistic expectations of the effectiveness of SNS including the risk of failure, the long term commitment, the risk of complications requiring reoperation and device removal and possible adverse effects.
7. Does not have a physical or mental disability which prevents a safe level of cooperation with the technical demands of the procedure. (Formal evaluation should be performed if necessary).

8. Does not have a known condition likely to necessitate future MRI scanning (as MRI contraindicated after SNS treatment, except MRI of head)

SNS **will not** be routinely commissioned for patients:

1. For the treatment of stress urinary incontinence (the involuntary leakage of urine during physical activity, coughing etc)
2. Who have failed to demonstrate a positive response to the test phase of stimulation (ie patients who continue to experience significant symptoms and feel that further treatment would be required); For example, patients experiencing a 50% or less reduction in their main symptom would usually be considered to have a negative response to test stimulation.
3. Who are unable to operate the neuro-stimulator

Contraindications to SNS:

1. Pregnancy
2. Progressive neurological conditions, spina bifida and congenital sacral abnormalities

Cautions:

- Women undertaking horse riding as the leads may break or migrate
- Cardiac pacemaker
- Only bipolar diathermy may be used in patients with an implanted SNS device undergoing pelvic and abdominal surgery
- Patients undergoing Lithotripsy treatment
- Radiotherapy over the device

This policy has been agreed on the basis of NHS England's understanding of the likely price of care associated with enacting the policy for all patients for whom NHS England has funding responsibility, as at the time of the policy's adoption. Should these prices materially change, and in particular should they increase, NHS England

may need to review whether the policy remains affordable and may need to make revisions to the published policy.

9 Patient Pathway

Patients will have undergone assessment and management of their symptoms in primary care without success before referral to secondary and tertiary services.

Initial treatment should be as per current NICE guidance.

Patients with refractory symptoms should be referred to a specialised unit for assessment. This assessment should include multichannel urodynamic testing followed by discussion of the patient's clinical and urodynamic findings at an incontinence MDT.

Patients should be counselled fully about the benefits and limitations of all available treatments. Patients, apart from patients who are unable to self-catheterise, should progress from conservative management to more specialised treatments like Botulinum toxin, SNS and surgery in a clear treatment progression. SNS is generally considered to be a third line treatment for overactive bladder.

10 Governance arrangements

The procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment of OAB, and expertise in this intervention with appropriate facilities and support (e.g. Medical Physics). The physician performing the implant must be trained in the use of the SNS device.

Centres that provide SNS for faecal incontinence may have shared expertise and facilities.

11 Mechanism for funding

Since April 2013 NHS England has been responsible for commissioning in line with this policy on behalf of the population of England.

12 Audit requirements

Performance management of this commissioning policy should be based on the NICE CG 171 audit criteria. This policy is subject to prior approval. In line with the service specification for specialised gynaecology, all SNS implants must be recorded on the national database (British Society of Urogynaecology/British Association of Urological Surgeons).

13 Documents which have informed this policy

NICE Clinical Guideline on Urinary Incontinence in Women (CG171)

NICE Clinical Guideline on Lower Urinary Tract Syndrome in Men (CG97)

14 Links to other policies

This policy follows the principles set out in the ethical framework that govern the commissioning of NHS healthcare and those policies dealing with the approach to experimental treatments and processes for the management of individual funding requests (IFR).

Clinical commissioning policy for Sacral nerve stimulation for faecal incontinence (www.nhs.uk)

15 Date of review

This policy will be reviewed in March 2017 unless information is received which indicates that the proposed review date should be brought forward or delayed.

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