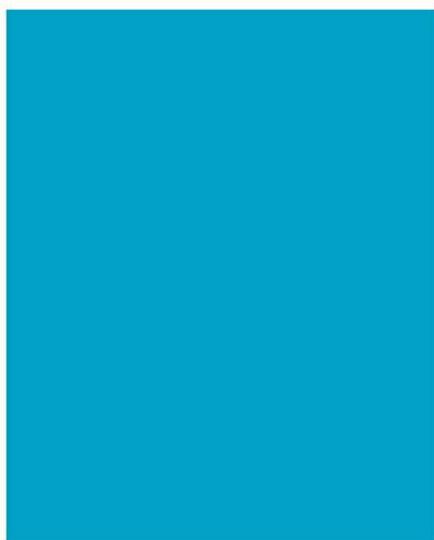


**Clinical Commissioning  
Policy Statement: Sacral  
Nerve Stimulation (SNS) for  
Faecal Incontinence in Adults**

**April 2013**

**Reference: NHSCB/A08/PS/b**



# **NHS Commissioning Board Clinical Commissioning Policy Statement: Sacral Nerve Stimulation (SNS) for Faecal Incontinence in Adults**

First published: April 2013

**Prepared by the NHS Commissioning Board.**

**Specialised Colorectal Services**

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First published April 2013

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<p><b>POLICY STATEMENT:</b></p> <p><b>Sacral Nerve Stimulation (SNS) for Faecal Incontinence in Adults</b></p>	<p><b>Policy Ref:</b></p> <p><b>NHSCB/A8/PS/b</b></p>
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<p><b>Treatment:</b></p>	<p>Sacral Nerve Stimulation (SNS) is a new and minimally invasive technique for treating severe faecal incontinence resistant to conservative treatment. The procedure involves passing low level electric current through selected sacral nerve roots (in the spine) via an electrode.</p>
<p><b>For:</b></p>	<p>Severe faecal incontinence</p>
<p><b>Background:</b></p>	<p>This National Institute for Health and Clinical Excellence (NICE) has published two documents related to this topic: Interventional Procedure Guidance (IPG) 99 Sacral nerve stimulation for faecal incontinence (NICE, 2004)<sup>1</sup> and NICE clinical guideline (CG) 49 Faecal Incontinence: the management of faecal incontinence in adults (NICE, 2007).<sup>2</sup> The provision of integrated continence services is also a standard described in the National Service Framework for Older People (Department of Health, 2001).<sup>3</sup></p> <p>Treatment of faecal incontinence (FI) is primarily conservative (bulking agents, pelvic floor exercises, dietary changes and medication). For some patients conservative measures are ineffective and surgical interventions are required. Overlapping sphincter repair may be undertaken for these patients but early results often deteriorate with time. For failed sphincter repair, creating a new sphincter from the patient's own muscle (dynamic graciloplasty) and artificial sphincter implantation may be considered. These are both major operations with a high morbidity and failure rate. Formation of a permanent stoma is a final surgical option for patients, however the physical and psychological sequelae are considerable.<sup>2</sup></p>
<p><b>Commissioning position:</b></p>	<p>Sacral nerve stimulation is not routinely funded for use in severe faecal incontinence.</p>

<b>Effective from:</b>	1 April 2013
<b>Evidence summary:</b>	<p><b>Systematic Reviews and Health Technology Assessments</b></p> <p>The efficacy of SNS for FI was reviewed by Frazer et al. in 2004 in a health technology assessment (HTA) report commissioned by NICE.<sup>5</sup> In the same year a further two systematic reviews were published by Jarrett et al<sup>4</sup> and Matzel et al.<sup>6</sup></p> <p>Following permanent implantation 47-75% of participants achieved at least a 50% reduction in the number of FI episodes per week.<sup>4,5,6</sup> Most studies reported significant improvement in the ability to defer defecation and all studies reported statistically significant improvements in validated incontinence scores. One of the included studies, a double blind cross over study, reported a reduction in the number of FI episodes per week and demonstrated reversible benefit at 9 months.<sup>7</sup></p> <p>The studies that assessed quality of life used either the Short Form-36 Health Survey (SF-36) or the disease specific, Faecal Incontinence Quality of Life (FIQL) questionnaire. All five of the studies that used the FIQL reported statistically significant improvement in all four domains (lifestyle, coping behaviour, depression and self perception and embarrassment).<sup>5,6</sup></p> <p>Two studies used the SF-36, one showed statistically significant improvements in general health, vitality, social functioning, role-emotional and mental health.<sup>4</sup></p> <p>All of the studies considered within these systematic reviews have substantial methodological limitations. With the exception of one double blind cross over study, all the studies are small case series or prospective cohorts without comparator (the double-blind cross over study had only two participants). The studies all included highly selective study populations. The improvements observed may have occurred by chance or due to bias through selective reporting of results, selection of participants or placebo effect. Measurement of FI was not standardised across the studies. In addition the maximum length of follow up was 99 months. Heterogeneity among the studies prevented a meta-analysis.</p> <p>The authors of the NICE HTA and the two systematic reviews acknowledged the limitations of the evidence; however, the large therapeutic effect observed in these low quality trials</p>

was consistent. The authors of all three reviews concluded that SNS is effective in reducing the number of FI episodes per week, reducing urgency to defecate and improving the quality of life.

### **NICE Interventional Procedural Guidance and Full Guidance on Faecal**

#### **Incontinence**

In response to the commissioned HTA, NICE issued Interventional Procedural Guidance (IPG 99) in November 2004. IPG 99 states that current evidence on the safety and efficacy of SNS for FI appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.<sup>1</sup>

NICE Guidance for the management of adults with FI published in 2007, states that PNE should be considered for patients for whom sphincter repair is inappropriate. The authors of both publications acknowledged the complete lack of high quality evidence and made recommendations based on low quality evidence and expert opinion.<sup>2</sup>

#### **Cochrane Review 2007**

In 2007 a Cochrane review assessed SNS for FI and constipation in adults. The authors included only randomised or quasi-randomised trials that have a SNS intervention arm and a comparator arm.<sup>8</sup>

Only two double blind crossover studies which assessed the effects of SNS for FI were identified. One study enrolled 34 participants<sup>9</sup> and the other enrolled two participants.<sup>7</sup> In the larger study, following the crossover period, participants, while still blinded, chose the period of stimulation they had preferred. The outcomes were reported separately for the 19 participants who preferred the “on” and the five who preferred the “off” period.

In patients who preferred the “on” period there was a statistically significant reduction in the median number of episodes of FI and the validated continence scores, compared to patients who preferred the “off” period. The difference was small compared with the reduction observed between the ‘on’ period and the baseline period. This may suggest substantial placebo response.

The five patients who preferred the “off” period experienced an increase in the number of episodes of FI per week during

the “on” period. Both studies reported statistically significant improvements in quality of life measures (FIQL and SF-36).

The authors concluded that the studies identified provided very limited evidence that SNS can lead to a significant improvement in continence in some (but not all) selected patients with severe FI. However, temporary PNE for a 2–3-week period does not always successfully identify those for whom a permanent implant will be beneficial.

### **Recent Evidence**

Since the Cochrane review published in 2008, 1 RCT<sup>10</sup>, 1 historical case control study<sup>11</sup> and at least 10 additional prospective studies/case series<sup>12-22</sup> have been published.

A recent RCT (2008) compared optimal medical therapy for severe faecal incontinence in 120 patients, aged 39 – 86 years. Highly significant results were reported in the intervention arm (n=60) compared to the control arm (n=60), with mean FI episodes per week decreasing from 9.5 to 3.1 (p<0.0001) and perfect continence was reported in 25 patients (47.2%). There was significant improvement in all quality of life domains measured. Although this RCT provides some of the highest quality evidence to date, there are important methodological limitations. Due to a lack of blinding the observed effect may have been overestimated due to placebo response. Furthermore, the study lacks descriptions of sample size, intention to treat analysis or flow of patients through the trial.<sup>10</sup>

### **Summary of Evidence of Effectiveness for SNS**

Despite the paucity of high quality evidence there is a large body of lesser quality studies which consistently demonstrate than SNS results in significant improvements in continence and quality of life in adults with severe FI that is refractory to conservative treatment.

### **Evidence of Cost Effectiveness**

Dudding and colleagues undertook a full economic evaluation in the UK in 2008. Direct medical and non-medical costs were ascertained using the 2005/2006 national tariff, national statistics and the costs of SNS devices, medication and pads. Based on direct medical and non-medical costs the incremental cost effectiveness ratio (ICER) for SNS was £25,070 per QALY gained (£6028 - £30,783). A detailed one-way sensitivity analysis demonstrated the effect on the ICER with varying direct medical and non-medical costs.

	<p>When indirect non-medical costs were included the ICER was reduced to £12 959 per QALY gained.<sup>24</sup></p> <p>An additional cost consequences analysis reported an ICER of €16181per QALY gained. The authors concluded that lower costs were due to performing the procedure under local anaesthetic.<sup>26</sup></p> <p>Optimising the stimulator parameters in order to maximise the battery life is essential. Inappropriately high stimulator settings cause the battery to deplete in under 5 years. Battery replacement costs £5400, and this has a significant impact on costs. Explicit training and understanding of this issue is essential and should be a prerequisite for any potential provider.</p> <p><b>Summary of Evidence of Cost Effectiveness</b></p> <p>There appears to be evidence that SNS is a cost effective treatment for FI, at a willingness to pay of £30,000 per QALY gained. Recent evidence from a methodologically robust economic evaluation in the UK calculated an ICER of £25,070. Costs may potentially be mitigated through use of local anaesthetic and careful selection of patients.<sup>24</sup></p>
<b>Equality impact:</b>	<p>The NHS CB 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. The NHS CB is committed to ensuring equality of access and non-discrimination, irrespective of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation. In carrying out its functions, the NHS CB 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 they are responsible, including policy development, review and implementation.</p>
<b>Responsible CRG:</b>	Specialised Colorectal Services CRG
<b>Date approved by NHSCB Board:</b>	April 2013
<b>Policy review date:</b>	During 2013

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