NHS England

Clinical Commissioning Policy: Sacral nerve stimulation (SNS) for faecal incontinence (Adult)

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Contact Details for further information	Specialised Services Team NHS England Floor 5 Skipton House London SE1 6LH

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NHS England

Clinical Commissioning Policy: Sacral nerve stimulation (SNS) for faecal incontinence (Adult)

First published: in draft December 2012

Prepared by the NHS England Clinical Reference Group for

Specialised Colorectal Services

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Contents

Policy Statement

The NHS England will commission Sacral Nerve Stimulation (SNS) for the management of faecal incontinence in adults in accordance with the criteria outlined in this document.

In creating this policy the 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 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, 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 they are responsible, including policy development, review and implementation.

Plain Language Summary

Faecal incontinence (FI) may be defined as the uncontrolled loss of faeces (liquid or solid) from the bowel. Severity may vary from occasional seepage to complete loss of rectal contents frequently requiring ‘toilet dependence’. FI is a socially embarrassing and disabling condition.

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.

The scientific evidence supporting this treatment is not particularly strong but 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. Information on the outcome of treatments for these patients will be collected and considered when this policy is reviewed.

1. Introduction

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)[1] and NICE clinical guideline (CG) 49 Faecal Incontinence: the management of faecal incontinence in adults (NICE, 2007).[2] The provision of integrated continence services is also a standard described in the National Service Framework for Older People (Department of Health, 2001).[3]

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.[2]

2. Definitions

Faecal incontinence (FI) may be defined as the uncontrolled loss of faeces (liquid or solid) from the bowel. Severity may vary from occasional seepage to complete loss of rectal contents frequently requiring 'toilet dependence'. FI is a socially embarrassing and disabling condition.[4]

Sacral Nerve Stimulation (SNS) is a new and minimally invasive technique for treating severe FI resistant to conservative treatment. The procedure involves passing low level electric current through selected sacral nerve roots (commonly S3) via an electrode. The electrode is passed through the corresponding sacral foramen and is connected to an electrical pulse generator implanted in the buttock. Chronic low grade electrical stimulation is then used to recruit residual function of the distal colon and rectum, the pelvic floor, and the anal sphincters.

The procedure is tested during an initial screening phase known as Peripheral Nerve Evaluation (PNE). PNE is performed in each patient for 2-3 weeks using an electrode connected to a temporary external stimulator. If significant benefit is achieved then a permanent pulse generator can be implanted. Approximately 60% of patients achieve significant benefit and progress to permanent implantation.[4]

3. Aim and Objectives

The aim of this policy is to outline the clinical criteria which will identify the patients most likely to benefit from SNS and to estimate the cost implications of providing this treatment for the population of England.

4. Criteria for commissioning

In accordance with NICE CG 49 and NICE IPG 64, this treatment should only be offered to patients who meet all of the following criteria:

- The patient has severe, life limiting faecal incontinence which has not responded to conservative management as recommended by the NICE Faecal Incontinence Clinical Guideline 49.[2]

AND

- The patient has been referred to a specialist surgeon at a centre experienced in providing SNS and has discussed:
  - The surgical and non-surgical options appropriate for their individual circumstances
  - The benefits and limitations of each option, with particular attention to long-term results
  - Realistic expectations of the effectiveness of SNS including an acceptance of a 15% risk of complications requiring reoperation and a 5% risk of serious complications requiring device removal.

AND

- Sphincter surgery is deemed inappropriate for the patient, is not necessary or has failed

AND

- The patient has undergone a trial stimulation period of at least 2 weeks, which has demonstrated a reduction of 50% in either the number of episodes of faecal incontinence or the number of days affected by faecal incontinence during the trial period.

AND

- The patient 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).

AND

- The patient does not fall into one of the contraindicated groups. (Appendix A).

Funding for this treatment is subject to prior approval by commissioners.

5. Patient pathway

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

6. Governance arrangements

The procedure should only be performed in specialist units by clinicians with a particular interest in the assessment and treatment of faecal incontinence and expertise in this intervention.

7. Epidemiology and needs assessment

Current epidemiological studies suggest that between 1% and 10% of adults are affected by faecal incontinence. It is estimated that 1.4% of the population experience regular severe faecal incontinence that greatly affects their quality of life. Prevalence is higher in women, the frail and elderly and in those who are institutionalised.[2]

8. Evidence Base

Systematic Reviews and Health Technology Assessments

The efficacy of SNS for FI was reviewed by Frazer et al. in 2004 in a health technology assessment (HTA) report commissioned by NICE.[5] In the same year a further two systematic reviews were published by Jarrett et al[4] and Matzel et al.[6]

Following permanent implantation 47-75% of participants achieved at least a 50% reduction in the number of FI episodes per week.[4,5,6] 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.[7]

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.).[5,6]

Two studies used the SF-36, one showed statistically significant improvements in

general health, vitality, social functioning, role-emotional and mental health.[4]

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 arms. (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.

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 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.[1]

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.[2]

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.[8]

Only two double blind crossover studies which assessed the effects of SNS for FI were identified. One study enrolled 34 participants[9] and the other enrolled two participants.[7] 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[10], 1 historical case control study[11] and at least 10 additional prospective studies/case series[12-22] 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.[10]

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.

Safety

An HTA commissioned by the Australian Government undertook a review of adverse events in available literature and reported the following:

- During PNE the commonest adverse events reported are electrode migration/lead displacement (10.4% CI: 7.36-14.58) and infection (6.12% CI: 3.85-9.57).
- Following permanent implantation the commonest adverse event reported is reoperation/removal (15.5% CI 11.67-20.29). Re-operations are mainly due to implant/lead problems requiring repositioning or replacement. Permanent device removal (5.0% CI 3.67-9.37) is most commonly due to infection, pain, or diminishing response.[23]

These findings are similar to that of other published HTA and systematic reviews. The complication rates and severity of complications are lower than alternative procedures, such as dynamic graciloplasty or artificial bowel sphincter implantation.[2]

Overall SNS for the treatment of FI appears to be safe in the medium term. Long term data is not available.

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. When indirect non-medical costs were included the ICER was reduced to £12 959 per QALY gained.[24]

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.[26]

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.

Summary of Evidence of Cost Effectiveness

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.[24]

Alternative treatments

For patients with severe intractable FI for whom sphincter surgery is inappropriate or who have failed DGP, artificial bowel sphincter (ABS) and stoma formation represent 'end-stage' treatment options. Both DGP and ABS are associated with substantial morbidity.

Sphincter Repair. No evidence was identified regarding the cost-effectiveness of external sphincter repair. It is one of the lowest cost surgical options, with procedural costs of £3000 per patient. Effectiveness is estimated to be similar to dynamic graciloplasty (DGP), however there appears to be a deterioration of symptoms over time. The reported complication rates are lower and it is likely to be more cost effective.[2]

Dynamic Graciloplasty: In a controlled trial of 403 patients, DGP was associated with an overall infection rate of 28%, with serious infections occurring in 15% of patients. Technical problems occurred in 48% of patients and an additional study reported pain and evacuation difficulties in 69% of patients. A range of ICERs have been published and at best it appears that DGP is borderline cost-effective compared to conservative treatment at £29,000 per QALY gained. Estimated costs for the first year are £18,289 (range £11,731-£26,264) per patient. The annual follow-up costs are estimated to be £1217 (range £795-£1864) per annum. A UK study used Markov modelling to analyse alternative surgical management strategies and reported that DGP was less cost effective than ABS and stoma.[30]

Artificial Bowel Sphincter: ABS is associated with a high rate of serious complications such as infection (33%), cuff erosion (10%), wound dehiscence (9%) and evacuation difficulties (9%).[31] Device removal is required in 19-41% of patients.[32] A case series of patients demonstrated improvements in validated continence scores in patients who avoided serious complications and subsequent device removal.[32] IPG 276 and IPG 66 state that the evidence for safety and efficacy are not adequate. Estimated costs for the first year are £17,424 (range £10,239-£24,772) per patient. The annual follow-up costs are estimated to be £1217 (range £795-£1864) per annum.[30]

Permanent stoma formation: Is the final surgical option. Estimated costs for the first year are £7008 (range £6624 - £8765) per patient. The annual cost of maintaining stoma care per patient is estimated to be £2318 (range £2125-3202) per annum. One UK study demonstrated that over a 5-year time horizon, end stoma formation gave an ICER of £4719/QALY.[30] The same study calculated that stoma formation was more cost effective than ABS and DGP. When compared to SNS, stoma formation has slightly lower initial costs but the annual maintenance costs are higher. In addition stoma formation is associated with significant physical and psychological morbidity.

Direct Cost estimates for England

[Example, direct costs obtained from STH NHSFT on 28/05/09.]

Direct costs for PNE;

- Insertion of temporary wires for PNE (HRG-AAZ1Z):£660

Direct costs for permanent implantation and follow-up;

- Pulse generator and wires: £8,482
- Day case procedure (HRG-AB01Z): £886
- Follow-up at 2 weeks, 4 weeks, 3 months, 6 months, 1 year and annually thereafter
- Battery replacement £5,400 and presumed day-case procedure to fit: £5,400 +886: £6286 every 7 years (NICE)

Occurrence and costs of complications estimated from current literature:

PNE

Complication	**Prevalence**	**Cost**	**Expected Cost per patient**
Lead migration/lead displacement	10.4% (CI:7.36-14.58).[23]	£1233[24]	Probability x Cost: £1233 x 0.1: £123.3.[24]
Infection	6.12% (CI:3.85-9.57).[23]	£1383[24]	Probability x Cost: £1383 x 0.06 £83[24]

Permanent Implantation

Complication	Prevalence	Cost	Expected Cost per patient	
Reoperation Due to implant/lead repositioning or replacement.	15.5% (CI:11.67-20.29). [23]	Repositioning: £717[24] Migration: £1233[24]	Probability x Cost: £717 x 0.1: ££71.7. [24] £1233 x 0.02: £24.66[24]	Total cost of complications after permanent implantation £ 96.36
Removal (explanted) Due to pain, infection, diminishing response	5.0% (CI:3.67-9.37). [23]	£2844	Probability x Cost: £2844 x 0.04: £113.76 [24]	Cost of removal £113.76[24]

Estimated total cost per patient of complications during PNE: £206

Estimated total cost per patient of complications after permanent implantation: £210

It is assumed that the costs of complications from permanent implantation are spread over the first 2 years (£105 each of year 0 and year 1). Therefore, the overall cost per patient in the first 12 months is estimated to be £10,535. From the studies reviewed the estimated annual cost per patient in years 1-7 is £1200 – 2400 per annum and £660 - £1000 per annum thereafter taking into account deterioration of the battery and replacement at 7 years.

Costs to the England may be calculated based on the above and economic modelling of data from the literature, and can be seen in tables 1 and 2. The prevalence of severe faecal incontinence from current literature is estimated to be 1.4%. According to literature, 50% fail conservative treatment and then proceed to PNE. The estimated number of incident cases requiring full SNS implantation is 1 per 100,000 per year. This is based upon approximate costs from the numbers of requests received by PCTs, discussion with surgeons and data from current evidence. Please note that this does therefore assume that the country as a whole has the same FI experience as that of these PCTs. The first two years include the full costs of PNE, cost of device and implantation, the cost of six follow up appointments, and costs (cost*probability) of associated complications (infection, pain etc). None of these figures account for the number of patients who try but fail SNS (13%).

Table 1: Costs to treat based on incidence rates.

Year	Annual cost to treat (year 0) then follow up (1-7) of one case (£)	Incidence 530/yr £000s
0	10,500	5,565
1	1200	636
2	1200	636
3	1200	636
4	1200	636
5	1200	636
6	1200	636
7	1200	636

Table 2: Crude projected costs for England (£000s)

	Year 0	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Cohort 1	5,565	636	636	636	636	636	636	636
Cohort 2		5565	636	636	636	636	636	636
Cohort 3			5565	636	636	636	636	636
Cohort 4				5565	636	636	636	636
Cohort 5					5565	636	636	636
Cohort 6						5565	636	636
Cohort 7							5565	636
Cohort 8								5565
Total annual costs (£)	5,565	6,201	6,837	7,473	8,109	8,745	9,381	10,017

* assumes 1 per 100,000 per patient/yr

9. Rationale behind the policy statement

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.

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.

In accordance with NICE CG 49 and NICE IPG 64, this treatment should only be offered to patients who meet all of the criteria outlined in section 4 of this document.

Funding for this treatment is subject to prior approval.

10. Mechanism for funding

As per NHS England policy.

11. Audit Requirements

Performance management of this commissioning policy should be based on the NICE CG 49 audit criteria. This policy is subject to prior approval.

12. Documents which have informed this policy

East Midlands Policy. The use of Sacral Nerve Stimulation (SNS) for faecal incontinence in adults. EMSCGP033V1. Ratified March 2010. Available from: http://www.emscg.nhs.uk/Library/150411EMSCGP033V1CommissioningPolicyFaecalIncontinence.pdf. Accessed November 2012.

13. Links to other policies

The mechanism operated by the NHS England for funding requests outside of the clinical criteria in this policy is through the Individual Funding Request process for exceptional clinical cases.

14. Date of Review

To be confirmed

15. Glossary

Term/Abbreviation	Meaning
Sphincter	A muscular constriction at the entrance or exit to a cavity or body organ. (www.bapras.org.uk/page.asp).
Stoma	An opening into the body from the outside created by a surgeon. (Medicinenet.com).
Sequalae	The consequences of a particular condition or therapeutic intervention.
NICE	NICE is an independent organisation responsible for providing national guidance on promoting good health and preventing and treating ill health. (NICE, 2010)
NICE Clinical Guideline	NICE guidance on the treatment and care of people with a specific disease or condition in the NHS (NICE, 2010).
NICE Interventional Procedure Guideline	NICE guidance about whether an interventional procedure is safe enough and works well enough to be used in the NHS. The term 'interventional procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or a body cavity. (NICE, 2010)
Clinical effectiveness	How well a specific test or treatment works when used in the 'real world' (for example, when used by a doctor with a patient at home), rather than in a carefully *controlled clinical trial*. Trials that assess clinical effectiveness are sometimes called management trials. (NICE, 2010).
Systematic Reviews	A review, in which evidence from scientific studies has been identified, appraised and synthesized in a methodical way according to predetermined criteria. It may include a *meta-analysis* (NICE, 2010).
Morbidity	The number of cases of an illness, injury or condition within a given time. (NICE, 2010).
Health Technology Assessments	A multi-disciplinary field of policy analysis, which studies the medical, social, ethical and economic implications of development, diffusion and use of health technology. The aim of an HTA is to provide a bridge between scientific evidence, the judgement of health professionals, the views of patients and the general public, and the needs of policymakers. (NHS Quality Improvement Scotland).
Cochrane reviews	Cochrane Reviews are internationally recognised as the highest standard in evidence-based health care. They are systematic reviews of primary research in human health care

	and health policy. They investigate the effects of interventions for prevention, treatment and rehabilitation.(www.cochrane.org).
Placebo	A beneficial (or adverse) effect resulting from someone thinking they have been given a treatment. This can occur when people in the *control group* of a study take a *placebo*. (NICE, 2010).
Prevalence	The proportion of individuals in a population having a disease. (library.thinkquest.org/3564/glossary/p.htm).
Methodology	Describes how research is done, including how information is collected and analysed, and why a particular method has been chosen. The overall approach taken by a research project: for example, the study could be a *randomised controlled trial* of 200 people over 1 year. (NICE, 2010).
QALY	A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or *intervention* and weighting each year with a quality of life score (on a zero to one scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance. (NICE, 2010)
Therapeutic	Part of medicine concerned specifically with the treatment of disease. The therapeutic dose of a drug is the amount needed to treat a disease. (Medicinenet.com).
Randomised Control Trial (RCT)	A study in which a number of similar people are randomly assigned to two (or more) groups to test a specific drug or treatment. One group (the experimental group) receives the treatment being tested, the other (the comparison or *control group*) receives an alternative treatment, a dummy treatment (*placebo*) or no treatment at all. The groups are followed up to see how effective the *experimental treatment* was. *Outcomes* are measured at specific times and any difference in response between the groups is assessed statistically. This method is also used to reduce *bias*. (NICE, 2010).
Case series	Description of several cases of a given disease, usually covering the course of the disease and the response to treatment in each case. There is no comparison (*control*) group. (NICE, 2010).
Prospective studies	A research study in which the health or other characteristic of participants is monitored (or 'followed up') for a period of

	time, with events recorded as they happen. This contrasts with *retrospective* studies. (NICE, 2010).

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Appendix A: Contraindications to SNS

Sacral nerve stimulation is not deemed appropriate in the patient groups listed below. It will not therefore be funded in such circumstances.

Contraindications:

- Present external rectal prolapse (full thickness)
- Crohn's Disease and active Ulcerative Colitis
- Altered bowel habit associated with abdominal pain suggestive of functional bowel disease.
- Pregnancy
- Anatomical limitations preventing placement of an electrode
- Skin disease risking infection (e.g pilonidal sinus)
- Severe or uncontrolled psychiatric disease
- Overflow faecal incontinence secondary to constipation
- Congenital anorectal malformation.

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