



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cailíocht Sláinte

# **Health Technology Assessment of Scheduled Procedures**

## **Spinal Cord Stimulation for chronic pain**

**Draft for Consultation  
August 2013**

*Safer Better Care*



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The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

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- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.
- **Monitoring Healthcare Quality and Safety** – Monitoring the quality and safety of health and personal social care services and investigating as necessary serious concerns about the health and welfare of people who use these services.
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## **1 Spinal cord stimulation for chronic pain**

### **1.1 Scope of health technology assessment**

This health technology assessment (HTA) evaluates the appropriateness and potential impact of introducing clinical referral or treatment thresholds for implantation of a spinal cord stimulation device, a routine scheduled procedure within the publicly funded healthcare system in Ireland. The effectiveness of spinal cord stimulation (SCS) may be limited unless undertaken within strict clinical criteria. This report is one of a series of HTAs of scheduled procedures. Details of the background to the request and general methodology are provided in the separate 'Background and Methods' document.<sup>(1)</sup>

The scope of this HTA is to investigate clinical referral and treatment thresholds for spinal cord stimulation for adults presenting with chronic, intractable pain of neuropathic or ischaemic origin in Ireland. Input from an Expert Advisory Group along with a review of the clinical and cost-effectiveness literature was used to inform the criteria. Additionally, the budget impact and resource implications were assessed, as appropriate.

### **1.2 Surgical indication**

Spinal cord stimulation (SCS) is used to relieve chronic, intractable pain of neuropathic or ischaemic origin. The International Association for the Study of Pain defines chronic pain as persisting beyond normal tissue healing time, assumed to be three months.<sup>(2)</sup> SCS is a form of neuromodulation reserved to treat pain that has failed to respond to conventional measures. It is most commonly used for neuropathic pain (i.e. pain due to damage of peripheral nerves) which is initiated or caused by nervous system damage or dysfunction, and includes conditions such as failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).<sup>(3;4)</sup> Other conditions include phantom limb pain, central pain (e.g. post-stroke pain), diabetic neuropathy and post-herpetic neuralgia.<sup>(3;4)</sup> As those affected often have a complex history with unclear or diverse causes and comorbidities it can be difficult to manage.<sup>(3)</sup> Ischaemic pain is caused by a reduction in oxygen delivery to the tissues, usually due to reduction in blood flow because of constriction or obstruction of a blood vessel.<sup>(3)</sup> Ischaemic pain is commonly felt in the legs or as angina, but it can occur anywhere in the body.<sup>(3)</sup>

Individuals with FBSS continue to have persistent or recurrent back and/or leg pain despite technically and anatomically successful spine surgery.<sup>(3;4)</sup> A specific cause of neuropathic pain can be difficult to identify and FBSS encompasses a broad range of patients who may experience persistent mixed back and leg pain.<sup>(3)</sup>

CRPS (which has been called chronic reflex sympathetic dystrophy, or reflex sympathetic dystrophy syndrome, or causalgia) may occur after a harmful event or period of immobilisation (type I) or nerve injury (type II).<sup>(3;4)</sup> Pain and increased sensitivity to pain are the most significant symptoms and are present in almost all of those with CRPS. Other symptoms can include perceived temperature changes, weakness of movement and changes in skin appearance and condition.<sup>(3)</sup>

Psychological and physical comorbidities and risk factors are common in spinal pain.<sup>(5)</sup> There is extensive evidence associating chronic pain and psychopathology. Consequently, unrecognised and untreated psychopathology can: interfere with the successful management of chronic pain and patient rehabilitation, be predictive of poor surgical outcomes, and may increase pain intensity and disability, thus serving to increase pain-related dysfunction, disability, and costs.<sup>(5)</sup> A multitude of physical elements (including a lack of fitness, poor health, obesity, smoking, drug dependence and other comorbidities such as heart disease, diabetes and thyroid disease) also lead to increased morbidity and mortality in spinal pain patients.<sup>(5)</sup>

### **1.3   Surgical procedure, potential complications and alternative treatments**

Spinal cord stimulation (SCS) is achieved by surgically placing leads in the epidural space and using an implanted pulse generator (implanted subcutaneously) to deliver repetitive electrical impulses to the spinal cord. An external controller is used to alter the pulse width, duration and intensity of stimulation.<sup>(4;5)</sup> This stimulation of the dorsal columns of the spinal cord aims to modify the patient's perception of pain.<sup>(3;4)</sup>

A typical SCS device has four components: an electrical pulse generator device that is surgically implanted under the skin, a lead that connects the electrode(s) contacts to the electrical pulse generator, an extension cable that connects the electrode(s) to the pulse generator, and a remote controller that the patient uses to turn the stimulator on or off and to adjust the level of stimulation.<sup>(3;4)</sup> The electrical pulse generator may be powered by an internal rechargeable or non-rechargeable battery or it may be a radio frequency device (which receives energy in the form of radio frequency pulses from an external device powered by a rechargeable battery).<sup>(3)</sup> There are a number of different SCS devices that have received CE marking including: Genesis IPG 3608, Genesis XP 3609, Genesis XP Dual 3644, Genesis G4, Renew 3408, Renew 3416, Synergy, Synergy Versitrel, Itrel 3 Restore ADVANCED, Restore ULTRA and Prime ADVANCED.<sup>(3)</sup> The choice of SCS system will depend on the person's pain patterns, the stimulation power required and coverage needed, as well as the preferences of the individual person and the clinician.<sup>(3;4)</sup> Pain specialists note that a rechargeable device is typically used in Ireland.<sup>(6)</sup>

The procedure is conducted in two phases as it is common practice for individuals selected for SCS to have a stimulation trial, using externalised leads to mimic the effects of an implanted neurostimulator, before permanent implantation of a neurostimulator.<sup>(3;7;8)</sup> Phase one is typically performed in the outpatient setting with the patient discharged home for five to seven days to assess benefit including treatment tolerability (for example, of the stimulation sensation or the stimulation device), pain relief, improvement in function, and reduction in medication.<sup>(3;7)</sup> If the outcome of the trial is favourable (i.e. tolerable and achieves at least a 50% reduction in pain), then the patient may wish to proceed to the second phase, which is permanent implantation of a pulse generator.<sup>(7)</sup> Of note, a successful trial is not a guarantee of long-term treatment success.<sup>(8)</sup> SCS is not curative for the underlying condition: subsequent to an initial assessment and surgery, patients continue to require follow-up care for as long as they have an implanted SCS system to include battery changes, management of potential complications and adjustment of stimulator settings to optimise benefit.

A range of conservative treatment alternatives to implantation of a SCS device are available including education and advice, antidepressants, anticonvulsants, analgesics, non-steroidal anti-inflammatory medication, opioids, intrathecal drug delivery, acupuncture, physiotherapy, transcutaneous electrical nerve stimulation and psychological therapies (including cognitive behavioural therapy and supported self-management).<sup>(3;4)</sup> As complete pain relief is rarely achieved with SCS, it is likely that conservative management will continue to be provided post-implantation.<sup>(3;4;7)</sup>

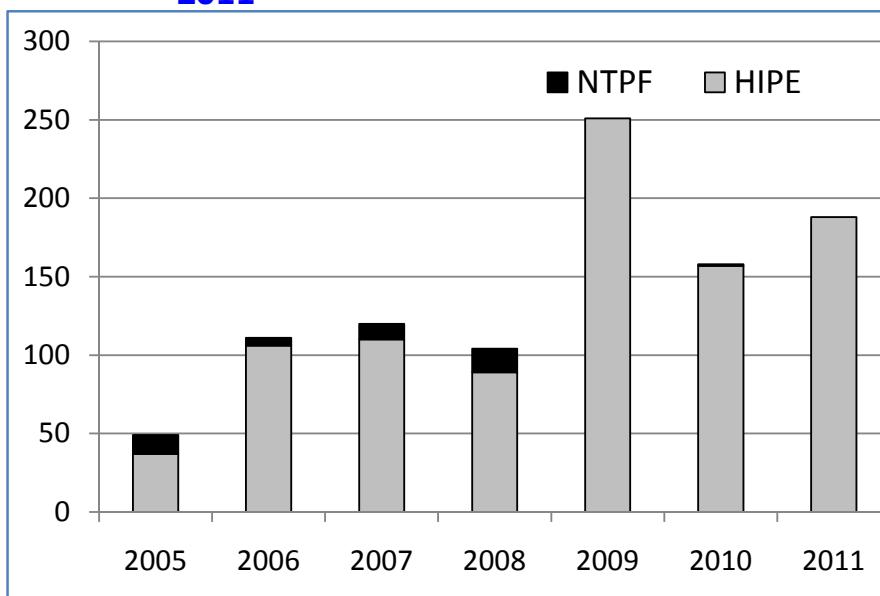
Complications can include both SCS device-related complications such as electrode migration (13%),<sup>(8)</sup> lead fracture (9%),<sup>(8)</sup> lead displacement(12%),<sup>(4)</sup> generator pocket related complications, and other complications related to the surgery such as hematoma, dural puncture, nerve damage, cerebrospinal fluid leak (7%),<sup>(9)</sup> infection (1-6%),<sup>(4;8;9)</sup> and rarely paralysis.<sup>(4;5;7-10)</sup> The reported percentage of implantations requiring surgery (which may include device removal) to resolve a device-related complication ranges from 0% to 38%.<sup>(3;4)</sup>

#### **1.4 Current practice in Ireland**

SCS procedures comprise trial implantations, permanent implantations, battery replacement, device replacement and removal. These procedures differ in length and complexity; however, with the exception of insertion, adjustment, replacement or removal of the epidural electrodes, the current Hospital In-Patient Enquiry (HIPE) data do not provide sufficient detail to allow it to be disaggregated by procedure type. In 2011, data from the HIPE Scheme indicate that there were 188 discharges from public hospitals for patients who had undergone a spinal cord stimulation (SCS) procedure, as identified using the procedure codes specified in Appendix 1.<sup>(11)</sup> Of

these 83 procedures were for adjustment, replacement or removal of the epidural electrodes. No additional procedures were procured by the National Treatment Purchase Fund (NTPF) in 2011. The number of procedures provided through the publicly funded healthcare system has more than trebled since 2005 (Figure 1.1 on the following page). This increase in activity may not all relate to new patients: as already noted, a limited number of procedures each year may relate to battery replacement, device adjustment, removal or replacement in existing SCS patients. A recent Belgian HTA reported the rates for spinal cord stimulation per million as approximately 84.6 in Belgium (2009), 11.35 in France (2010), 54.3 in the Netherlands (2011), 11.7 in Germany (2010) and 21.5 in the UK (2010 to 2011).<sup>(12)</sup> In comparison, the rates in Ireland are estimated as approximately 41 per million based on 2011 HIPE data.<sup>(11)</sup>

**Figure 1.1. Number of spinal cord stimulation procedures\* performed in public hospitals and purchased through the NTPF, 2005-2011<sup>(13)</sup>**



\* HIPE ICD-10AM/ACHI procedure blocks 43 and 58, all procedures. Note: one individual may undergo more than one procedure per year, including a trial implantation.

In Ireland, the trial implantation can be performed as a day case surgery with the patient returning home for five to seven days to assess benefit. Following a successful trial, permanent implantation is typically undertaken as an inpatient procedure. As each permanent implant procedure will have a prior trial procedure, and as not all trials will be successful, the number of day cases performed is expected to exceed the number of inpatient admissions. There has been a large shift towards day case surgery seen in recent years. In 2005, just 40% of procedures were treated as day cases compared to 70% of procedures in 2011. This increase may indicate either an increase in the number of trial implantation procedures

performed relative to permanent implantations or that more trial procedures are being performed as a day case.

Spinal cord stimulation is carried out for a wide variety of indications with low back pain (32%) being the most common indication in 2011 (Table 1.1). This procedure was undertaken in seven hospitals in 2011 primarily by pain specialists (95%), with a small number (3%) of procedures performed by neurosurgeons.<sup>(11)</sup>

**Table 1.1. HIPE reported principal diagnoses for spinal cord stimulation coded as 'all procedures' (2011)**

Principal diagnosis*	Code	Number of procedures	% of total procedures
Low back pain	M545	61	32%
Polyneuropathy, unspecified	G629	23	12%
Episodic and paroxysmal disorders	G40-G47	9	5%
Other soft tissue disorders, not elsewhere classified	M79	7	4%
Complex regional pain syndrome type I, upper limb	G5811	6	3%
Pain in a joint, site unspecified	M2559	6	3%
Other dorsalgia, lumbar region	M5486	6	3%
Complications of surgical and medical care, not elsewhere classified	T80-T88	6	3%
Fitting and adjustment of other devices related to nervous system and special senses	Z462	6	3%
Other*		57	30%

\* Note the remaining principal diagnosis contained five or fewer cases per diagnosis code.

The SCS procedure rate varies across the proposed Health Service Executive (HSE) hospital groups announced in May 2013,<sup>(14)</sup> with the rate in what will become the Dublin East hospital group being the highest in 2011. Variation in procedure rate may be explained by varying availability of specialist pain teams experienced in the provision of an SCS service or differing budget restrictions imposed by individual hospitals. There is also considerable variation in the percentage of day cases between hospital groups, with the Dublin Midlands group having the lowest percentage of day case procedures (Table 1.2).<sup>(11;14)</sup> Given the limited number of SCS procedures provided in some hospital groups, this data should be interpreted with caution. The average length of stay recorded in HIPE for those undergoing an SCS procedure was 11.1 days in 2011 with significant variation noted between hospital groups. Pain specialists providing this service have noted that trial implants are usually completed as a day case while a length of stay of one to two days is usual for patients admitted for permanent implantation of an SCS device.<sup>(15)</sup> Variation in day

case rate may be due to differences in clinical practice, for example, admission of patients for the duration of the trial procedure and completion of the permanent implantation as part of the same admission. Again however, due to the limited number of procedures provided in some hospital groups, this data should be interpreted with caution. The majority of patients (80%) undergoing SCS procedures in 2011 were aged between 30 and 60 years.

**Table 1.2 2011 HIPE data per proposed HSE hospital group\***

HSE hospital group	Number (%)	ALOS (days)	Inpatient bed days	% day case	Avg. age (years)
Dublin North East	15 (8)	3.5	21	60.0	44.8
Dublin Midlands	26 (14)	5.18	112	19.2	45.6
Dublin East	136 (73)	16.95	494	80.1	48.22
South/South West	10 (5)	1.25	5	80.0	50.65
West/North West	-	-	-	-	-
Midwest	-	-	-	-	-
Acute paediatric services, Dublin	-	-	-	-	-

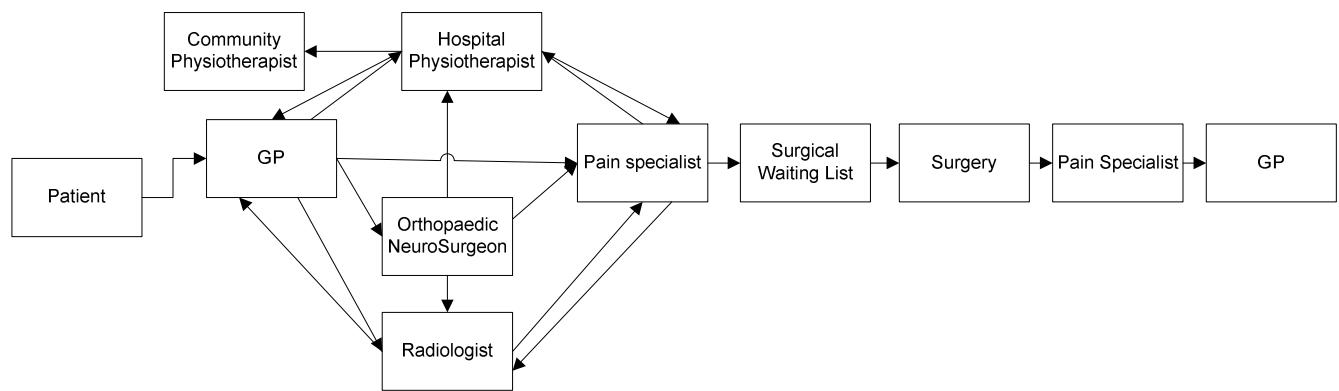
\* Data for hospitals included in the hospital groups.<sup>(14)</sup>

Standard practice in the publicly funded healthcare system is that patients must be referred by their general practitioner (GP), or another consultant, to obtain a hospital outpatient appointment with a pain specialist.<sup>(16)</sup> Specialist pain clinics are available in all major hospitals (and within all the proposed hospital groups) with a number of these centres also offering pain management programmes that provide psychologically based rehabilitative treatment for patients with persistent pain.<sup>(17)</sup> As indications for SCS include intractable pain syndromes such as failed back surgery syndrome, onward referral by orthopaedic and neurological surgeons of patients who have previously undergone surgery is common.

Suitability for SCS implantation surgery is based on clinical and radiological criteria and international guidelines recommend that assessment should include completion of physical and psychological assessments by a multidisciplinary team experienced in chronic pain management and in the assessment and management of patients with SCS devices. Access to this procedure is therefore limited to centres with specialist pain services and teams experienced in SCS management. As SCS is used to treat patients with intractable pain syndromes, patients will typically have exhausted conservative management strategies including physiotherapy and potentially other surgical or interventional procedures prior to being considered for implantation of an SCS device.

The current pathways for the referral, treatment and post-operative follow-up of SCS patients in the publicly funded healthcare system are illustrated in Figure 1.2.

**Figure 1.2. Current referral, treatment and follow-up pathways for publicly-funded patients undergoing spinal cord stimulation**



Delays in the patient journey may arise due to delays in obtaining timely access to physiotherapy, radiology services (particularly MRI) and hospital outpatient appointments. The length of time a patient must wait to be reviewed as an outpatient varies according to the referral pathway and the individual hospital and consultant to which a patient is referred. A breakdown of outpatient waiting time by surgical discipline is not available. At the end of March 2013, it was reported that there were 384,632 patients on the Outpatient Waiting List database collated by the NTPF, 52% of who were waiting less than six months, with 73% waiting less than 12 months.<sup>(18)</sup>

At present, there are no standardised national referral criteria that are routinely used to prioritise outpatient referrals. This can result in unnecessary outpatient appointments and difficulties in triaging patients according to symptom severity. It is suggested that a significant percentage of those referred to outpatient clinics are considered not appropriate for surgical treatment. Pain specialist feedback indicates that the number of appropriate referrals can be dramatically increased by active engagement with primary care practitioners regarding referral criteria at a local level, so that 90% to 95% of those referred are considered appropriate for specialist intervention.<sup>(19)</sup> Back pain triage clinics have also been established by some hospitals to facilitate timely access to appropriate services. These have stated referral criteria and triage processes for accessing orthopaedic, pain specialist, rheumatology and specialist physiotherapy services as appropriate.<sup>(20)</sup> Since March 2012 a spinal triage scheme involving 24 specialist musculoskeletal (MSK) physiotherapists has been in operation nationally (although not all hospitals) as a waiting list reduction initiative by the HSE's Orthopaedic and Rheumatology Clinical Care programmes. Under this

scheme, patients who have been referred to secondary care are initially triaged by the specialist, who can decide which patients are suitable for referral to an MSK physiotherapist for treatment; those whose symptoms persist following treatment are referred back to the specialist while those whose symptoms subside may be referred back to primary care. Although yet to formally report, anecdotally it is noted that only approximately 15% of patients are referred back to the surgeon to be considered for spinal surgery.<sup>(21)</sup> Separately, it has been reported that only 85% of patients referred to a spinal triage programme with initial assessment and management by an MSK physiotherapist were suitable for conservative management (group or individual therapy), 14% were discharged and only 1% required onward referral for specialist opinion. Back pain triage clinics have also been established by some hospitals to facilitate timely access to appropriate services. These use stated referral criteria, standardised referral forms and triage processes for accessing orthopaedic, pain specialist, rheumatology and specialist physiotherapy services. It is recommended that unless urgent, patients access physiotherapy within the primary care system prior to referral to the triage clinic.<sup>(20)</sup> While the use of such stated criteria provide clarity, facilitate timely access and streamline the efficient use of resources, they do not eliminate wait times if need exceeds available capacity.

As of April 2013, 10 people were on surgical waiting lists for spinal cord stimulation, with 60% waiting over six months.<sup>(22)</sup> At a hospital level, based on data submissions from 44 hospitals, average patient waiting time for spinal cord stimulation was reported to range from less than a month to a maximum of four months (n=2 hospitals). Of note, however, waiting lists may not reflect total demand for SCS services. Due to the high acquisition cost of SCS devices, it is reported that restrictive policies are typically implemented at a hospital level limiting the number of new devices that may be implanted in a given year. The number of patients on the waiting list may therefore reflect those prioritised by the pain specialist as being likely to benefit most from an SCS device rather than identifying all patients for whom an SCS device has been considered.<sup>(23)</sup>

## **2 Clinical referral/treatment threshold**

### **2.1 Review of the literature**

A literature search was conducted during May 2013. The approach and general search terms are described in Appendix 1 in the separate Background and Methods document accompanying this document. A summary of the results of this search is included in Table 2.1.

**Table 2.1 Included Evidence Sources.**

Publication type	Number	References
Clinical guidelines	6	(3;5;7;8;10;24)
Health technology assessments	3	(4;12;25)
Systematic review	2	(9;26)
Cost-effectiveness studies	1	(27)

## **2.2 Clinical evidence**

For spinal cord stimulation (SCS) to be indicated, a patient should have failed a structured conservative management programme, and be clinically suitable for surgery. Six clinical guidelines relating to the adult population were found that specifically mention referral criteria for spinal cord stimulation (Appendix 2).<sup>(3;5;7;8;10;24)</sup> Within the UK's National Health Service (NHS), a number of primary care trusts (PCTs) have set their reimbursement policy for spinal cord stimulation through the creation of defined clinical referral criteria. Some examples of these referral thresholds are included in Appendix 2.<sup>(28-32)</sup>

According to the published guidelines,<sup>(3;5;7;8;10;24)</sup> SCS is recommended for those with failed back surgery syndrome (FBSS) or complex regional pain syndrome (CRPS) Type 1 (CRPS attributed to a traumatic event or a period of immobilisation) that has failed to respond to conservative treatment. There is good quality evidence that SCS is more effective than continued conservative management or repeat operation in reducing pain at six months and 12 months, for individuals with FBSS and CRPS Type 1.<sup>(3;4;8;9)</sup> It should be noted that as trials comparing stimulation to conservative management cannot be blinded (as individuals can sense the stimulation) this will probably lead to some overestimation of benefits of SCS.<sup>(33)</sup>

Generally, SCS is used as part of an overall treatment strategy and only after the more conservative treatments have failed.<sup>(4)</sup> Treatment success for SCS is defined in the literature as a 50% reduction in pain as measured by a validated tool. As patients are likely to experience continued pain following implantation of a SCS device, the use of SCS should be seen as part of the ongoing treatment programme. There is randomised controlled trial (RCT) evidence that combining SCS with conservative management, such as physiotherapy, is more effective than conservative management alone in reducing pain at six months and at two years, but not at long-term follow up (five years), in individuals with FBSS and in those with CRPS.<sup>(3-5;33)</sup> Detailed guidelines produced by the British Pain Society recommend that SCS should be delivered, with other therapies, through a multidisciplinary pain management team.<sup>(7)</sup>

Two guidelines<sup>(7;10)</sup> recommend that all patients being considered for spinal cord stimulation receive a psychological assessment to determine their suitability for a screening trial before permanent implantation. A literature review,<sup>(26)</sup> suggests that psychological factors such as depression, anxiety, and poor coping, are predictors of poor outcome; however, the authors found insufficient evidence that psychological assessment leads to improved treatment outcomes. Psychological assessment can also be useful as a means to discuss the patient's beliefs, expectations, and understanding of the treatment.<sup>(7)</sup>

Although the specific suggestions about timing of referral are not clear from the literature, criteria developed by the UK primary care trusts include conservative management of at least six months duration.<sup>(28-32)</sup> This agrees with the NICE recommendation.<sup>(3)</sup> However, for indications well supported by evidence, the British Pain Society suggests SCS may be considered when first-line therapies for chronic pain have failed.<sup>(7)</sup>

There is weaker evidence from poor quality studies that SCS is effective for other neuropathic pain including: CRPS Type II (that is CRPS due to nerve injury), peripheral nerve injury, diabetic neuropathy, post-herpetic neuralgia, stump or phantom limb pain, partial spinal cord injury, chronic low back pain, chronic back and leg pain, ischaemic limb pain and angina pain.<sup>(4)</sup> However, not all guidelines recommend the use of SCS for these conditions.<sup>(5;8)</sup> For chronic pain of ischaemic origin, the British Pain Society accepts that there is no high quality RCT evidence to support the use of SCS;<sup>(7)</sup> this agrees with the NICE guidelines suggesting that SCS is not recommended for chronic pain of ischaemic origin except in the context of research as part of a clinical trial.<sup>(3)</sup>

NICE issued guidance in 2013 on peripheral nerve-field stimulation for chronic low back pain stating that current evidence on the efficacy for chronic low back pain is limited in both quantity and quality, and duration of follow up is limited.<sup>(34)</sup> It also reports that evidence on safety is also limited and there is a risk of complications from any implanted device and that this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

A new peripheral neurostimulation technique which uses subcutaneous target stimulation delivers electrical stimulation at the site of maximum pain via electrodes implanted subcutaneously. However, further literature is required to support its use, this technique is not assessed further in this report at this time.<sup>(33)</sup>

## **2.3 Cost-effectiveness evidence**

The direct and indirect financial costs of back pain are substantial in all developed countries.<sup>(35)</sup> The cost-effectiveness of SCS has been considered for both failed back surgery syndrome (FBSS) and chronic regional pain syndrome (CRPS). Although the initial healthcare acquisition costs for SCS can be high, these are offset by a reduction in post-implant healthcare resource demand and costs, which have led to SCS been considered cost-effective for both FBSS and CRPS.<sup>(5;36)</sup>

A recent Belgian HTA (2012) conducted a systematic review of the literature on the cost-effectiveness of SCS.<sup>(12)</sup> It reported on 14 studies (some of which are summarised in Appendix 2<sup>(4;10;37-40)</sup>) stating that at the time there was only low quality evidence on cost-effectiveness of neuromodulation. However, it concluded that in patients with FBSS, and based on low quality evidence, SCS could to be cost-effective at generally referred thresholds when compared to conventional care or re-intervention. In patients with CRPS, and based on low quality evidence, SCS used in combination with conventional care or physical therapy could to be cost-effective at generally referred thresholds, when compared to conventional care or physical therapy alone.

Cost-effectiveness of SCS in the UK was considered in a 2008 NICE technology appraisal. For patients with FBSS, SCS combined with conservative management was considered cost-effective when compared to conservative management alone assuming a device longevity of four years, and a device cost of up to GBP £13,000.<sup>(3;4)</sup> SCS combined with conservative management was also considered cost-effective when compared to re-operation, assuming a device longevity of four years and a device price up to £15,000.<sup>(3;4)</sup> For CRPS, SCS combined with conservative management was considered cost-effective when compared to conservative management alone, when a device longevity of four years and a device price of up to £8,000 were assumed.<sup>(3;4)</sup> These results have been extrapolated to the Irish setting where it was indicated that to be considered cost-effective at a €20,000/QALY threshold, the device would need to cost €16,000 or less and have a longevity of four years.<sup>(27)</sup>

The results from the cost-effective studies indicate that the results are sensitive to the device price, thus where different SCS systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered.

The remaining cost-effectiveness studies retrieved are summarised in Appendix 2.

## **2.4 Budget impact and resource implications**

Chronic pain is an emotional, social and economic burden on those living with it. Over 14m working days are lost in Ireland each year at an annual cost of €1.5 billion with the direct cost of musculoskeletal disorders at work estimated to be at least €750 million.<sup>(41)</sup> This is estimated to cost the Irish economy €750 million a year and includes €275 million in illness benefit which equates to approximately one third of all payments by the Department of Social Protection. It also includes approximately €500 million in overtime payments, loss of productivity and cost to the health service.<sup>(41;42)</sup>

The number of spinal cord stimulation procedures has increased three-fold since 2005 although a small number of procedures each year may relate to the continued follow up and support of those with existing implants including routine device and battery replacement, and unplanned procedures arising from device failure or complications. As evidence of its use and effectiveness for other indications increases, there may be additional demand for procedures. As noted in Section 1.4, based on 2011 data, the current rate of SCS procedures is estimated at 41 per million population which compares well to rates reported in other European countries (approximately 84.6 in Belgium [2009], 11.35 in France [2010], 54.3 in the Netherlands [2011], 11.7 in Germany [2010] and 21.5 in the UK [2010 to 2011]). The current estimated annual national cost of spinal stimulation procedures is €1.7 million, based on the latest Casemix costs (Table 2.2). Pain specialists note that due to the high acquisition cost of the SCS devices, restrictive policies are in place in a number of hospitals that limit the number of new devices that may be implanted in a given year, so that current activity and expenditure likely reflects these policies rather than total demand.

**Table 2.2. HSE inpatient and day case acute hospital activity and costs summarised by diagnosis-related group (based on 2011 costs and activity)<sup>(43)</sup>**

<b>DRG code</b>	<b>Description</b>	<b>% of Spinal cord stimulation procedures</b>	<b>Cost/inpatient (€)</b>	<b>Cost/day case (€)</b>
A12Z	Insertion of neurostimulator device	43%	27,564	10,001
I10B	Other back and neck procedures W/O catastrophic or severe CC	33%	4,917	1,537
B03B	Spinal procedures W/O catastrophic or severe CC	15%	9,504	1,105
Z01B	OR procedures W diagnoses	3%	4,322	1,501

	of other contacts W health services W/O cat/sev CC			
801C	OR procedures unrelated to principal diagnosis W/O CC	2%	7,379	1,759
B03A	Spinal procedures W catastrophic or severe CC	2%	1,105	21,491
-	Other procedures*	3%	-	-
-	Outpatient appointment	-	-	130

\* Note the remaining diagnosis-related groups accounted for 1% or fewer of the procedures.

Data summary from HSE National Casemix Programme Ready Reckoner, 2013 based on the 2011 inpatient and day case activity and costs reported by 38 hospitals participating in the programme that year.

### **3 Advice on clinical referral/treatment threshold**

There is a need for clear surgical referral and treatment criteria for patients. The current international guidelines and evidence suggest that spinal cord stimulation should only be considered after conservative management has been exhausted and then only for patients with failed back surgery syndrome and complex regional pain syndrome Type 1, in whom there has been a successful trial of stimulation. There is no clear evidence however on the optimal timeline for referral.

Therefore, the following criteria are advised:

The decision to offer a patient surgery should be based on consideration of their clinical symptoms, and their potential for functional benefits.

Implantation of a spinal cord stimulation device in adults with chronic, intractable, neuropathic pain is justified and appropriate in the following situations:

- failure of an improvement in symptoms following at least six months of conservative management
- successful completion of a physical and psychological assessment
- successful outcome from a trial of stimulation as part of the assessment by a multidisciplinary team experienced in chronic pain management and the management and ongoing support of those with spinal cord stimulation devices

AND

- clinical symptoms and diagnostic imaging compatible with failed back surgery syndrome

OR

- clinical symptoms and diagnostic imaging compatible with complex regional pain syndrome Type 1.

A patient should not be referred for spinal cord stimulation if:

- The patient's quality of life or ability to function is not compromised.

At present there is insufficient evidence to support the use of SCS for other indications. Patients who are not offered SCS should remain under the care of their primary care practitioner (general practitioner, community physiotherapist) and be reassessed as appropriate.

## **4 Discussion**

Spinal cord stimulation has been shown to be an effective additional treatment to conservative management for individuals with failed back surgery syndrome (FBSS) and chronic regional pain syndrome (CRPS) Type 1. Spinal cord stimulation is expected to reduce rather than cure an individual's chronic pain, thus careful management of expectations and continued primary care treatment is essential. Evidence suggests that there should be a trial period with a temporary stimulation device to ensure the patient is satisfied and tolerant of the stimulation device prior to permanent implantation. As spinal cord stimulation is indicated after structured conservative management has been exhausted and is available only in a limited number of tertiary services, patients undergoing this procedure may have had multiple interactions with a range of primary and specialist services prior to being considered for this treatment. Due to capacity constraints in the public healthcare system, patients will inevitably have experienced some waiting time for physiotherapy, radiological imaging, outpatient appointments and surgery.

The number of spinal cord stimulation procedures performed in the publicly funded system is not expected to reduce as a result of implementing stated treatment thresholds. Consistent with international trends, there has been a substantial increase in the number of SCS procedures undertaken in Ireland. Although a relatively infrequent procedure in the publicly funded system, current activity levels compare well with international activity. There is some evidence of regional variation in activity levels, day case rates and average length of stay which may indicate differences in access or clinical practice with potential differences in how patients are prioritised at a local level. Implementing standardised national referral and treatment criteria should reduce regional variation and improve access for those with the greatest clinical need. As evidence of the use and effectiveness of SCS for other indications increases, there may be additional demand for procedures.

The suggested referral criteria reflect existing best practice in Ireland. Consistent application of the criteria throughout the healthcare system through the use of stated thresholds that are integrated into agreed national referral guidelines should assist patient triage, bring greater transparency, ensure equity of access based on clinical need and allow maximal benefit to be gained from existing resources.

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## **Appendix 1 – Coding**

<b>Block</b>	<b>Procedure code</b>	<b>Description</b>
43	39130-00	Percutaneous insertion of epidural electrodes
	39139-00	Insertion of epidural electrodes by laminectomy
	39131-00	Adjustment of epidural electrodes
	39137-00	Replacement of epidural electrodes
	39136-01	Removal of epidural electrodes
58	39121-00	Functional spinal stereotactic procedure

## Appendix 2 – Examples of international clinical referral thresholds

Guideline	Scope	Spinal cord stimulation thresholds	Evidence
Belgian Health Care Knowledge Centre (2012) <b>Belgium</b> <sup>(12)</sup>	<b>Indications:</b> severe chronic pain <b>Population:</b> adults	In patients with failed back surgery syndrome: <ul style="list-style-type: none"> <li>▪ Low quality evidence that SCS was more effective than repeated lumbosacral spine surgery at three years in relieving pain.</li> <li>▪ Low quality evidence that SCS was more effective than conventional medical management at six months in providing leg pain relief.</li> </ul> In patients with complex regional pain syndrome: <ul style="list-style-type: none"> <li>▪ There was low quality evidence that SCS plus physical therapy was more effective in reducing pain than physical therapy alone.</li> <li>▪ 38% of patients with SCS had needed a re-intervention at two years.</li> </ul>	<b>Literature review:</b> Systematic <b>Grading system:</b> Cochrane's risk of bias tables for RCTs, AMSTAR checklist for systematic reviews <b>Key references:</b> xx
British Pain Society (2009) <b>UK</b> <sup>(7)</sup>	<b>Indications:</b> FBSS, CRPS, Neuropathic pain secondary to peripheral nerve damage, pain associated with peripheral vascular disease, RAP, Brachial plexopathy: traumatic (partial, not avulsion), post-irradiation <b>Population:</b> adults	There is clinical evidence from randomised controlled trials to support use of SCS in pain from failed back surgical syndrome (FBSS), complex regional pain syndrome (CRPS), neuropathic pain, and ischaemic pain.  The BPS believes that the available evidence (from controlled trials, observational studies, and clinical experience) supports the use of SCS when individuals are carefully assessed by multidisciplinary teams of healthcare professionals experienced in using the technology.  SCS should be considered early in the patient's management when simple first-line therapies have failed. SCS should not necessarily be considered a treatment of last resort.	<b>Literature review:</b> Systematic <b>Grading system:</b> None <b>Key references:</b> North et al. 2007, Kemler et al. 2006, Malis-Gagnon et al 2004, Taylor et al. 2005, Turner et al. 2004
American Society of Interventional Pain Physicians (2007) <b>US</b> <sup>(5)</sup>	<b>Indications:</b> persistent (at least sub-acute in duration) low back pain. (non-spinal low back pain) and thoracic or cervical	There is fair quality evidence of a moderate benefit for patients with FBSS with persistent radiculopathy  In patients with persistent and disabling radicular pain following surgery for herniated disc and no evidence of a persistently compressed nerve root, it is recommended that clinicians discuss risks and benefits of SCS as an option (weak recommendation, moderate-quality evidence).	<b>Literature review:</b> Systematic <b>Grading system:</b> Modified level 1-5 <b>Key references:</b> North et al. 2007, Kemlar et al. 2006, Raphael et al., Turner

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	<b>spine pain</b> <b>Population:</b> adults	<p>It is recommended that shared decision making regarding SCS include a discussion about the high rate of complications following spinal cord stimulator placement</p> <p>The guideline is not intended to guide evaluation or management of patients with back pain associated with major trauma, tumour, metabolic disease, inflammatory back disease, fracture, dislocation, major instability, or major deformity; patients with progressive or severe neurologic deficits; children or adolescents with low back pain; pregnant women, patients with low back pain from sources outside the back.</p>	et al 2004, Cameron
NICE (2008) UK <sup>(3)</sup>	<b>Indications:</b> chronic pain of neuropathic or ischaemic origin <b>Population:</b> adults	<p>1.1 SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who:</p> <ul style="list-style-type: none"> <li>■ continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm visual analogue scale) for at least six months despite appropriate conventional medical management.</li> <li>■ who have had a successful trial of stimulation as part of the assessment specified in recommendation 1.3.</li> </ul> <p>1.2 SCS is not recommended as a treatment option for adults with chronic pain of ischaemic origin except in the context of research as part of a clinical trial. Such research should be designed to generate robust evidence about the benefits of SCS (including pain relief, functional outcomes and quality of life) compared with standard care.</p> <p>1.3 SCS should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of individuals with SCS devices, including experience in the provision of ongoing monitoring and support of the person assessed.</p> <p>1.4 When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with SCS. Tests to assess pain and response to SCS should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties and may need to be adapted.</p>	<b>Literature review:</b> Systematic <b>Grading system:</b> NICE <b>Key references:</b> Simpson et al. 2008

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		<p>1.5 If different SCS systems are considered to be equally suitable for a person, the least costly should be used. Assessment of cost should take into account acquisition costs, the anticipated longevity of the system, the stimulation requirements of the person with chronic pain and the support package offered.</p> <p>1.6 Individuals who are currently using SCS for the treatment of chronic pain of ischaemic origin should have the option to continue treatment until they and their clinicians consider it appropriate to stop.</p>	
European Federation of Neurological Societies (2007) <b>EU</b> <sup>(8)</sup>	<b>Indications:</b> neuropathic pain <b>Population:</b> adults	Spinal cord stimulation (SCS) is efficacious in failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS) type I.	<b>Literature review:</b> Systematic <b>Grading system:</b> EFNS <b>Key references:</b> Cameron 2004, Taylor 2005, Taylor 2006
American Academy of Pain Medicine (2007) <b>US</b> <sup>(10)</sup>	<b>Indications:</b> Chronic neuropathic pain <b>Population:</b> Adults	Neuropathic Pain Indications for spinal cord stimulation include: <ul style="list-style-type: none"> <li>■ Failed back surgery syndrome (FBSS)</li> <li>■ Complex regional pain syndrome (CRPS) I and II</li> <li>■ 'Other' (peripheral neuropathic pain, phantom limb/post-amputation syndrome, post-herpetic neuralgia, root injury pain, spinal cord injury/lesion)</li> </ul>	<b>Literature review:</b> Systematic <b>Grading system:</b> Own modified <b>Key references:</b> North et al. 2005, Kemleret al. 2006
Siaarti (Italian Society of Anaesthesia, Analgesiam Resuscitation, and Intensive Care) 2006 <b>Italy</b> <sup>(24)</sup>	<b>Indications:</b> Chronic non cancer pain <b>Population:</b> Adults	Spinal cord stimulation techniques were shown to be effective in patients with FBSS	<b>Literature review:</b> Systematic <b>Grading system:</b> Own modified <b>Key references:</b> Gybels 1998, Spincemaille 2000, De La Porre 1993

Key: CRPS – complex regional pain syndrome; FBSS – failed back surgery syndrome; RCT – randomised controlled trial; SCS – spinal cord stimulation; VAS – visual analogue scale.

Study	Description	Sample size (n)	Finding
Simpson et al. (2009) <sup>(4)</sup>	Health technology assessment	11 RCTs	This report addressed the question 'What is the clinical and cost-effectiveness of spinal cord stimulation (SCS) in the management of chronic neuropathic or ischaemic pain?' The evidence suggested that SCS was effective in reducing the chronic neuropathic pain of FBSS and CRPS type I. For ischaemic pain, there may need to be selection criteria developed for chronic limb ischaemia; SCS may have clinical benefit for refractory angina in the short term. Further trials of other types of neuropathic pain or sub-groups of ischaemic pain, may be useful.
American Pain Society (2009) <sup>(9)</sup>	Evidence review	3 systematic reviews, 72 case series	For chronic back and leg pain or failed back surgery syndrome, lower-quality evidence from multiple case series estimated that approximately half of patients experienced decreased pain after spinal cord stimulator implantation, and about 40% returned to work (level of evidence: poor). Spinal cord stimulation is associated with frequent complications, especially related to electrode or lead problems. Although most complications appear minor, infections (6% of complications) and cerebrospinal fluid leak (7%) have been reported (level of evidence: poor).
National Centre for Pharmacoeconomics (2012) <sup>(27)</sup>	Economic review and evaluation	9 economic evaluations	Extrapolating the UK results (NICE) to the Irish setting, it was found that the average device price would need to be approximately 16,000 or less in order to be deemed cost effective (based on four-year longevity). While spinal cord stimulation appears to be effective in some patients there is considerable uncertainty associated with factors such as efficacy (trial data), effectiveness (real life data), device longevity, and device costs and patient selection. For this reason, the current average cost for private health insurers for a spinal cord stimulator appears to not represent value for money.
Belgian Health Care Knowledge Centre (2012) <sup>(12)</sup>	HTA and systematic review of cost-effectiveness analysis	14 SCS studies	There is only low quality evidence on cost-effectiveness of neuromodulation. However:  In patients with FBSS, and based on low quality evidence, SCS could be cost-effective at generally referred thresholds when compared to conventional care or re-intervention.  In patients with CRPS, and based on low quality evidence, SCS used in combination with conventional care or physical therapy could to be cost-effective at generally referred thresholds, when compared to conventional care or physical therapy alone.

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Celestin et al. (2009) <sup>(26)</sup>	Systematic review	25 studies	This review examined the relationship between pre-surgical predictor variables and treatment outcomes, investigating the benefit of psychological screening prior to lumbar surgery or SCS. Twenty five studies were identified, of which none were RCT and only four SCS studies. The methodological quality of the studies varied and some important shortcomings were identified. A positive relationship was found between one or more psychological factors and poor treatment outcome in 92% of the studies reviewed. In particular, pre-surgical somatization, depression, anxiety, and poor coping were most useful in helping to predict poor response to lumbar surgery and SCS.
Kemler et al. (2010) <sup>(37)</sup>	Decision-analytic model	2 SCS RCTs	This study assessed the cost-effectiveness of the addition of spinal cord stimulation (SCS) compared with conventional management alone (CMM) in patients with complex regional pain syndrome (CRPS), and to determine the cost-effectiveness of non-rechargeable versus rechargeable SCS implanted pulse generators (IPGs). The incremental cost-effectiveness of SCS compared with CMM was £3,562 per QALY (GBP 2008), a finding that was robust across sensitivity analyses with an 87% probability that SCS is cost-effective at a willingness-to-pay threshold of £30,000. When the longevity of an IPG is four years or less, a rechargeable (and initially more expensive) IPG is more cost-effective than a non-rechargeable IPG.
Kumar et al. (2013) <sup>(25)</sup>	Markov model	SCS compared to conventional medical management (CMM)	The study compared SCS and conventional medical management (CMM) with CMM alone for patients with failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS). It predicted the ICER for SCS as: CAN\$ 9,293 (FBSS) and CAN\$ 11,216 (CRPS) per QALY gained, stating that SCS provided the optimal economic path. It also noted that the probability of SCS being cost-effective compared with CMM was 75-95% depending on pathology.
Kumar et al. (2009) <sup>(38)</sup>	Comparative analysis of costs (US / Canada)	Retrospective analysis of 197 cases (1995-2006)	It reported that the cost of implanting a SCS system in Canada is \$21,595 (CAD), in US Medicare \$32,882 (USD), and in US Blue Cross Blue Shield (BCBS) \$57,896 (USD). The annual maintenance cost of an uncomplicated case in Canada is \$3,539 (CAD), in US Medicare \$5,071 (USD), and in BCBS \$7,277 (USD). The mean cost of a complication was \$5,191 in Canada (range \$136-18,837 [CAD]). In comparison, in the US the figures were \$9,649 (range \$381-28,495) for Medicare and \$21,390 (range \$573-54,547) for BCBS (both USD). Using these calculations a formula was derived which predicted that for budgeting purposes the institution should first calculate the initial implantation costs that then can be 'grossed up' by 18% per annum which covers the costs associated with annual maintenance and complications for every actively managed patient.

Manca et al. (2008) <sup>(44)</sup>	RCT	N=100	This study assessed the quality of life, resource consumption and costs of spinal cord stimulation (SCS) versus conventional medical management (CMM) in neuropathic pain patients with failed back surgery syndrome (PROCESS trial). Resource consumption was costed using UK and Canadian 2005-2006 national figures. The six-month mean total healthcare cost in the SCS group (CAN\$19,486; €12,653) was significantly higher than in the CMM group (CAN\$3994; €2,594), with a mean adjusted difference of CAN\$15,395 (€9,997) ( $p<0.001$ ). However, the gain in HRQoL with SCS over the same period of time was markedly greater in the SCS group, with a mean EQ-5D score difference of 0.25 [ $p<0.001$ ] and 0.21 [ $p<0.001$ ], respectively at three and six months after adjusting for baseline variables. It concluded that the addition of SCS to CMM in patients with neuropathic leg and back pain results in higher costs to health systems but also generates important improvements in patients' EQ-5D over the same period.
Bala et al. (2008) <sup>(45)</sup>	Systematic review of cost-effectiveness	2 RCTs, 1 retrospective cohort study, 13 case series	This study reported on a systematic review to assess the (cost)effectiveness of spinal cord stimulation (SCS) for chronic pain due to failed back surgery syndrome (FBSS). It reported that the studies show that SCS is effective in the treatment of FBSS in terms of pain reduction. The effect was consistent in all analysed studies. Improvements were also reported for other outcomes, such as quality of life and functional status. All the studies reported some complications, most of which were technical problems. Three studies met inclusion criteria (cost-effectiveness) and all concluded that SCS is both more effective and less costly in the long term, but there is an initial high cost associated with device implantation and maintenance.
North et al. (2007) <sup>(46)</sup>	Cost-effectiveness and cost utility analysis based on a randomized, controlled trial	1 RCT (n=42)	This study assessed spinal cord stimulation (SCS) for failed back surgery syndrome compared to reoperation. The mean per-patient costs were US \$31,530 for SCS versus US \$38,160 for re-operation (intention to treat), US \$48,357 for SCS versus US \$105,928 for re-operation (treated as intended), and US \$34,371 for SCS versus US \$36,341 for re-operation (final treatment). SCS was dominant (more effective and less expensive) in the ICERs and incremental cost-utility ratios.
Taylor (2010) <sup>(40)</sup>	Decision-analytic model		This study assessed spinal cord stimulation (SCS) for failed back surgery syndrome compared to non-surgical conventional medical management (CMM). It reports on the 2008 NICE's previously unavailable analysis details and an analysis of the impact on SCS cost effectiveness of rechargeable implanted pulse generators (IPGs). The incremental cost-effectiveness of SCS compared with CMM was £5,624 per QALY, with 89% probability that SCS is cost effective at a willingness-to-pay threshold of £20,000. Compared with reoperation, the ICER of SCS was £6,392 per QALY, with 82% probability of cost-effectiveness at the £20,000 threshold. When the longevity of an IPG is four years or less, a rechargeable (and initially more expensive) IPG is more cost-effective than a non-rechargeable IPG.

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Taylor et al. (2006) <sup>(47)</sup>	Systematic review of clinical and cost-effectiveness	1 RCT (n=25) and 1 CE study	This review evaluated the clinical and cost effectiveness of spinal cord stimulation (SCS) in the management of patients with complex regional pain syndrome (CRPS). It reported that SCS appears to be an effective therapy in the management of patients with CRPS type I (Level A evidence) and type II (Level D evidence). There is evidence to demonstrate that SCS is a cost-effective treatment for CRPS type I.
Taylor et al. (2005) <sup>(48)</sup>	Decision-analytic model and cost-effectiveness analysis.	2 RCTs	This study assessed spinal cord stimulation (SCS) for failed back surgery syndrome compared to non-surgical conventional medical management (CMM), outcome data of SCS and CMM sourced from two-year follow-up data of two RCTs. At a two-year time horizon, SCS gave more health gain but at an increased cost relative to CMM. The two-year cost-effectiveness of SCS ranged from €30,370 in the base case to €63,511 in the worst case scenario (2003).
Taylor et al. (2004) <sup>(39)</sup>	Systematic review of cost-effectiveness	14 studies	This review evaluated cost-effectiveness studies for spinal cord stimulation (SCS) for the treatment of chronic pain. 14 studies were included, it found that across a range of medical indications, the initial healthcare acquisition costs of SCS implantation are consistently offset by a reduction in post-implant healthcare resource demand and costs. It concludes that further research is required to formally examine the cost-effectiveness of SCS.

Examples of UK PCT thresholds	Scope	Threshold	Evidence
Berkshire PCTs <sup>(28)</sup>	<b>Indications:</b> neuropathic pain <b>Population:</b> adults	<p>SCS is recommended as a treatment option for adults with chronic pain of neuropathic origin who:</p> <ul style="list-style-type: none"> <li>■ continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm VAS) for at least six months despite appropriate conservative management</li> <li>■ have had a successful trial of stimulation.</li> </ul> <p>SCS should be provided only after an assessment by a multidisciplinary team experienced in chronic pain assessment and in the management of those with SCS devices, including experience in the provision of ongoing monitoring and support of the person assessed.</p> <p>In selecting patients with FBSS for treatment, the following criteria may be helpful:</p> <ul style="list-style-type: none"> <li>■ The patient must have had previous surgery for radiologically proven nerve compression from a herniated intervertebral lumbar disc.</li> <li>■ The surgery was technically successful.</li> </ul>	<b>Key references:</b> NICE TA159, 2008.

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		<ul style="list-style-type: none"> <li>■ The patient must nevertheless have severe pain, worse in the radicular distribution than in the back itself.</li> <li>■ The patient must have exhausted treatment by a pain management team and all other reasonable treatment alternatives must have been tried with an unsatisfactory outcome.</li> <li>■ The patient must have been assessed physically and psychologically by a multidisciplinary pain team and deemed suitable for SCS.</li> </ul> <p>Referral must be made by a pain consultant able to verify that the above conditions are met.</p>	
Hull PCT <sup>(29)</sup>	<b>Indications:</b> chronic pain <b>Population:</b> adult	<p>SCS is commissioned for adults with chronic neuropathic pain who:</p> <ul style="list-style-type: none"> <li>■ continue to experience chronic pain (measuring at least 50 mm on a 0 –100 mm VAS) for at least six months despite all other reasonable treatment alternatives having been tried with an unsatisfactory outcome.</li> <li>■ have had a successful SCS trial (this determines suitability for permanent implantation by assessing tolerability and the degree of pain relief likely to be achieved by full implantation).</li> </ul> <p>SCS is NOT commissioned for adults with chronic pain of ischaemic origin:</p> <ul style="list-style-type: none"> <li>■ except in the context of research as part of a clinical trial (due to lack of evidence of clinical effectiveness) after an assessment by a multidisciplinary team experienced in chronic pain assessment and management of those with SCS devices, including experience in the provision of ongoing monitoring and support.</li> </ul>	<b>Key references:</b> NICE TAG 159
North Central London <sup>(30)</sup>	<b>Indications:</b> back pain – neuropathic pain <b>Population:</b> adult	<p>NCL will fund SCS for neuropathic pain for FBSS or CRPS if the patient has:</p> <ul style="list-style-type: none"> <li>■ experienced chronic pain (measuring at least 50mm on a 0-100mm VAS) for at least six months despite appropriate conventional medical management</li> <li>■ completed a successful trial of stimulation as part of an assessment by an experienced multidisciplinary chronic pain management team.</li> </ul> <p>SCS is not recommended as a treatment option for adults with chronic pain of ischemic origin except in the context of research as part of a clinical trial. Such research should be designed to generate robust evidence about the benefits of SCS (including pain relief, functional outcomes and quality of life) compared with standard care.</p> <p>NCL will not routinely fund healthcare interventions that NICE has not recommended they should only be undertaken in the context of research. Clinicians wishing to undertake such procedures should ensure they fulfil the normal requirements for undertaking research.</p>	<b>Key references:</b> Simpson E et al. 2009  NICE TA 159, 2008

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North East Lincolnshire <sup>(31)</sup>	<b>Indications:</b> chronic pain <b>Population:</b> adult	SCS is recommended as a possible treatment for adults with chronic pain of neuropathic origin if they: <ul style="list-style-type: none"> <li>■ continue to experience chronic pain (measuring at least 50 mm on a 0–100 mm VAS) for at least six months despite standard treatments and</li> <li>■ have had a successful trial of SCS as part of an assessment by a specialist team.</li> </ul> Treatment with SCS should only be given after the person has been assessed by a specialist team experienced in assessing and managing those receiving treatment with SCS. Patients outside of these criteria will require prior approval.	<b>Key references:</b> NICE TA 159, 2008
NHS North Somerset <sup>(32)</sup>	<b>Indications:</b> <b>Population:</b> adult	SCS is recommended for the treatment of patients who continue to experience chronic pain of neuropathic origin for at least six months despite appropriate conventional medical management. The PCT will agree to fund a surgical referral where the patient: <ul style="list-style-type: none"> <li>■ has had previous surgery for radiologically proven nerve compression from a herniated intervertebral lumbar disc and the surgery was technically successful</li> <li>■ has severe pain, as defined below, worse in the radicular distribution than in the back itself.</li> <li>■ All other reasonable treatment alternatives must have been tried with an unsatisfactory outcome.</li> <li>■ Continue to experience chronic pain (measuring at least 50 mm on a 0-100mm VAS) for at least six months despite appropriate conventional medical management.</li> </ul> Have had a successful trial of stimulation as part of the assessment by a multidisciplinary team experienced in chronic pain management and management of those with SCS devices.	<b>Key references:</b> NICE TA 159, 2008
<b>Examples of other international thresholds</b>	<b>Scope</b>	<b>Threshold</b>	<b>Evidence</b>
Anthem <sup>(2013)</sup> <b>(US)</b> <sup>(33)</sup>	<b>Indications:</b> implanted (epidural and subcutaneous) spinal cord stimulators (SCS) <b>Population:</b> adult	A temporarily implanted epidural spinal cord stimulator for the treatment of chronic (greater than six-month duration) intractable neuropathic pain is considered medically necessary when all of the following criteria are met: <ul style="list-style-type: none"> <li>■ Documentation in the medical record of the failure of six months of conservative treatment modalities (pharmacologic, surgical, psychologic or physical), if appropriate and not contraindicated.</li> <li>■ Further surgical intervention is not indicated.</li> <li>■ Psychological evaluation has been obtained and there is documentation clearly stating the pain is not psychologic in origin.</li> </ul>	<b>Key references:</b> Burchiel et al. 1996, Cameron T 2004, Kemler et al 2000, Klomp et al. 2009,

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		<ul style="list-style-type: none"> <li>■ No contraindications to implantation exist such as sepsis or coagulopathy.</li> <li>■ Objective documentation of pathology in the medical record.</li> </ul> <p>A permanently implanted epidural spinal cord stimulator for the treatment of chronic (greater than six-month duration) intractable neuropathic pain is considered medically necessary when a temporary trial of SCS has been successful. Successful is defined as:</p> <ul style="list-style-type: none"> <li>■ 50% reduction in pain for at least two days.</li> <li>■ Improvement in function documented in the medical record.</li> </ul> <p>Implantable epidural SCSs for the treatment of chronic intractable neuropathic pain that do not meet all the applicable criteria listed as medically necessary are considered investigational and not medically necessary. Treatment of all other diseases and disorders by an implanted epidural spinal cord stimulator (both temporary and permanent) is considered investigational and not medically necessary.</p>	Kumar et al. 2008, Meglio M. 2004, North, et al. 1994, Taylor RS 2006, Mailis-Gagnon et al 2004, NICE. TA 159. 2008.
Belgian Health Care Knowledge Centre (2012) <sup>(12)</sup>	<b>Indications:</b> implanted spinal cord stimulators (SCS) <b>Population:</b> adult	Belgium: long lasting neurogenic pain syndrome. Specific causes of neurogenic pain are not formally defined, but: <ul style="list-style-type: none"> <li>■ FBSS: in practice, CRPS: excluded, other (if accepted by advisory physician).</li> </ul> France: intractable chronic pain of neuropathic origin secondary to: <ul style="list-style-type: none"> <li>■ radicular pain, CRPS, phantom pain, peripheral nerve injury.</li> </ul> The Netherlands: intractable chronic pain of neuropathic origin secondary to: <ul style="list-style-type: none"> <li>■ FBSS, CRPS, phantom pain, peripheral nerve injury, traumatic brachial, plexus injury, spinal lesion.</li> </ul> Germany: intractable chronic pain of neuropathic origin secondary to: <ul style="list-style-type: none"> <li>■ FBSS, CRPS, phantom pain, brachial plexus injury, diabetic, polyneuropathy, post-herpetic neuralgia, other.</li> </ul> UK: intractable chronic pain of neuropathic origin secondary to: <ul style="list-style-type: none"> <li>■ FBSS, CRPS, other.</li> </ul>	-

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