# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

# Medical technology guidance

# SCOPE

# Senza Spinal Cord Stimulation (SCS) System for the treatment of chronic pain

## 1 Technology

### *1.1 Description of the technology*

The Senza Spinal Cord Stimulation (SCS) System (Nevro Corp; referred to as the Senza SCS system) is a neuromodulation technology that uses an implanted pacemaker-like device to deliver electrical impulses to the spinal cord in people with chronic intractable pain of the trunk or limbs. The Senza SCS system, can be used to deliver low frequency SCS (2 Hz to 1,200 Hz) or a high frequency trademark SCS treatment known as HF10 therapy. This treatment involves the delivery of high frequency (10 kHz), short duration (30 μsec), low-amplitude (1-5 mA) pulses to the T8-T11 spinal epidural space in a specific treatment algorithm.

The Senza SCS system consists of the following:

- Implantable pulse generator (IPG): a rechargeable implantable device with 16 output channels capable of stimulating the spinal cord nerves through electrode leads.
- Trial stimulator: a battery-powered, handheld device capable of providing the same stimulation as the IPG.
- Patient remote: a handheld battery operated unit able to communicate with the IPG or Trial Stimulator.

- Charger: used by the patient to transcutaneously charge the IPG battery. It is a portable device powered by a rechargeable battery and can be held in one hand.

- Programmer: The Clinician Programmer programs the IPG or Trial Stimulator via the Programmer Wand via a graphical user interface (GUI).

- Programmer Wand: The Programmer Wand is the Clinician Programmer interface that allows communication with the IPG or Trial Stimulator.

- Leads: to be used with either the IPG or trial stimulator for use in delivering stimulation.

In line with other SCS systems implantation of the device is performed in two stages. The first stage is known as the 'trial stage' where percutaneous leads are placed appropriately and are temporarily attached to a trial stimulator. The trial stimulator is a battery-powered, handheld device capable of providing the same stimulation as the IPG. During the trial phase of SCS, the patient wears the external trial stimulator for a period of time to evaluate the effectiveness of the stimulation treatment. In order to progress to the permanent implant stage (surgical implantation of the neurostimulator) patients must have experienced a substantial improvement in their pain (for example a 50% or greater reduction in pain score on a visual analogue scale [VAS]). The timescale between the temporary trial and permanent implant varies but is typically one to two weeks.

If the trial is successful, the second permanent, implant stage involves the neurostimulator (IPG) and leads being implanted through a small incision in the patient's back. The procedure is normally performed under general anaesthetic in an operating theatre. An intra-operative image intensifier is used to confirm accurate placement/positioning of the electrodes and leads. The implanted neurostimulator is controlled remotely using the physician/patient controller. The controller adjusts the signal generator to

deliver an appropriate level of electrical stimulation to the spinal cord through the implanted leads.

Unlike conventional low frequency SCS (stimulation frequencies up to 1200 Hz), Senza SCS system does not require paraesthesia mapping during the implantation procedure, which is where patients are brought back to consciousness in the operating theatre and asked iteratively to confirm whether the paraesthesia sensation is aligned to cover the site of their pain. This mapping procedure can vary from a few minutes to over an hour. During the implantation procedure for the Senza SCS system, the leads are placed based on readily identifiable anatomic landmarks with positioning confirmed by imaging. This is designed to ensure that the implantation procedure time is more predictable as mapping is not needed. All device programming is done post-operatively.

Specification of the precise treatment patterns of stimulation and electrical pulses for spinal cord stimulation devices (low and high frequency) is known as 'programming'. For the Senza SCS system, programming is standardised to a limited number of optimised settings which have been developed through clinical studies. The result is that therapy is able to be delivered using the same therapeutic algorithm irrespective of the skill or experience of the person responsible for device programming in the clinical setting.

Removal (explantation) or replacement of the neurostimulator (IPG) requires a surgical procedure, performed in an operating theatre. Explantation is usually performed when the battery powering the Senza SCS System can no longer maintain a sufficient charge. The Senza SCS system has a battery life of approximately 10 years with continuous use. It is therefore expected that the patient will not have to receive a new neurostimulator for at least this period of time. The manufacturer has stated that they expect the device is likely to maintain performance beyond 10 years based on bench testing.

## *1.2 Regulatory status*

The Senza SCS system was CE marked as a class III device in May 2010. It is indicated as an aid in the management of chronic intractable pain of the

trunk and/or limbs, including unilateral or bilateral pain associated with the following: failed back surgery syndrome, intractable low back pain and leg pain.

## *1.3 Claimed benefits*

The benefits to patients claimed by the company compared with low frequency SCS are:

- Clinically superior pain relief (almost twice as much when measured using a VAS score) for the majority of patients with predominant back pain, as well as those with predominant leg pain.
- Increased achievement of a successful outcome (greater than or equal to a 50% reduction in pain) compared with low frequency SCS.
- A significantly better functional outcome.
- The delivery of treatment without paraesthesia can therefore be continued during sleep and while driving or operating machinery.
- Sustained and long term improvement in pain relief and function (RCT follow-up data currently to 24 months).
- May reduced the need for concomitant pain medication and potentially follow-up attendance at pain clinics.

The benefits to the healthcare system compared with low frequency SCS claimed by the sponsor are:

- Avoidance of the need for paraesthesia mapping facilitating shorter and more predictable implantation procedural times
- May reduce the need for concomitant pain medication and potentially follow-up attendance at pain clinics.

## *1.4 Relevant diseases and conditions*

The Senza SCS system is intended for use in the management of chronic intractable pain of the trunk and/or limbs, including unilateral or bilateral pain associated with failed back surgery syndrome as well as intractable low back and leg pain.

Pain that persists for more than several months, or beyond the normal course of a disease or expected time of healing, is often defined as chronic. Chronic pain can affect people of all ages, although in general, its prevalence increases with age. Estimates of the prevalence of this condition in the UK vary from less than 10% to greater than 30% depending on the specific definition of chronic pain used. Chronic pain is accompanied by physiological and psychological changes such as sleep disturbances, irritability, medication dependence and frequent absence from work. Emotional withdrawal and depression are also common, which can strain family and social interactions

## *1.5 Current management*

NICE technology appraisal guidance on spinal cord stimulator implantation for chronic pain of neuropathic or ischaemic origin recommends spinal cord stimulation as a treatment option for adults with chronic pain of neuropathic origin who continue to experience chronic pain for at least 6 months despite appropriate conventional medical management, and who have had a successful trial of stimulation as part an appropriate multidisciplinary team assessment. If different spinal cord stimulation systems are considered to be equally suitable for a person, the least costly should be used. Spinal cord stimulation is not recommended as a treatment option for adults with chronic pain of ischaemic origin except in the context of research. This NICE Technology Appraisal guidance was last reviewed in February 2014 at which time newer devices such as Senza SCS were identified but no new evidence was identified which was judged likely to change the recommendations which don't specify individual devices.

Conventional medical management involves a multidisciplinary approach and may include pharmacological interventions such as non-steroidal anti-inflammatory drugs, tricyclic antidepressants, anticonvulsants, analgesics and opioids as well as physiotherapy, psychological support, transcutaneous electrical nerve stimulation (TENS) and acupuncture.

NICE guideline on low back pain and sciatica in over 16s: assessment and management recommends exercise, pharmacological interventions, radiofrequency denervation, epidurals and surgical intervention. Manual

therapy should be considered but only as part of a treatment package including exercise, with or without psychological therapy.

# 2 Reasons for developing guidance on Senza SCS system for chronic pain

The Committee concluded that Senza SCS may offer benefits to patients through improved chronic pain management without the provocation of paraesthesia. The Committee also concluded that Senza SCS may offer benefits to the healthcare system through a reduction in operative time resulting from the avoidance of intra-operative mapping. This may enable costs savings through an increase in the number of patients treated on surgical lists.

The Committee noted that the most robust evidence currently available for Senza SCS is for the treatment of patients who have chronic pain despite previous back surgery. It considered, however, that an evaluation should include other subgroups of patients with chronic neuropathic pain.

# 3 Statement of the decision problem

| | **Scope issued by NICE** |
|---|---|
| Population | Patients undergoing spinal cord stimulation for chronic pain in line with NICE Technology Appraisal 159 |
| Intervention | HF10 therapy using the Senza spinal cord simulation system |
| Comparator(s) | Low frequency spinal cord stimulation ( up to 1200 Hz) |
| Outcomes | The outcome measures to consider include:<br>• Pain scores (for example VAS score)<br>• Duration of pain relief<br>• Patient satisfaction relating for example to frequency of battery recharging.<br>• Health-related quality-of-life<br>• Functional disability measures e.g. disability Index Score, Oswestry Disability Index and functional improvement including ability to drive and perform work-related activities<br>• Opioid and other analgesic use<br>• Device-related adverse events<br>• Implantation time in theatre<br>• Incidence of paraesthesia<br>• Implant lifetime |

| | | |
|---|---|---|
| | • Reason for implant removal<br>• Follow up appointments including attendance at pain clinics<br>• Staff conducting device programming | |
| Cost analysis | Comparator(s):<br>• Low frequency spinal cord stimulation (up to 1200 Hz)<br><br>Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. This will include the trial and permanent implantation phases of the care pathway.<br>Sensitivity analysis will be undertaken to address uncertainties in the model parameters. | |
| Subgroups to be considered | • Previous back surgery / failed back surgery syndrome<br>• Chronic pain involving the limbs<br>• Chronic pain involving the back<br>• Complex regional pain syndrome | |
| Special considerations, including those related to equality | People likely to benefit from this technology may have disabilities causing issues with mobility. They may be considered to be disabled if their condition has a substantial and long-term negative effect on the ability to do normal daily activities. Disability is a protected characteristic under the Act. | |
| | Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics? | No |
| | Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality? | No |
| | Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance? | No |

# 4 Related NICE guidance

### Published

- Low back pain and sciatica in over 16s: assessment and management. NICE guideline 59 (2016). Available from www.nice.org.uk/guidance/NG59
- Spinal injury: assessment and initial management. NICE guideline 41 (2016). Available from www.nice.org.uk/guidance/NG41

- Percutaneous transforaminal endoscopic lumbar discectomy for sciatica. NICE interventional procedure guidance 556 (2016). Available from www.nice.org.uk/guidance/IPG556
- Percutaneous interlaminar endoscopic lumbar discectomy for sciatica. NICE interventional procedure guidance 555 (2016). Available from www.nice.org.uk/guidance/IPG555
- Percutaneous intradiscal radiofrequency treatment of the intervertebral disc nucleus for low back pain. NICE interventional procedures guidance IPG545 (2016). Available from www.nice.org.uk/guidance/IPG545
- Percutaneous electrothermal treatment of the intervertebral disc annulus for low back pain and sciatica. NICE interventional procedures guidance IPG544 (2016). Available from www.nice.org.uk/guidance/IPG544
- Percutaneous coblation of the intervertebral disc for low back pain and sciatica. NICE interventional procedures guidance IPG543 (2016). Available from www.nice.org.uk/guidance/IPG543
- Insertion of an annular disc implant at lumbar discectomy. NICE interventional procedures guidance IPG506 (2014). Available from www.nice.org.uk/guidance/IPG506
- Neuropathic pain in adults: pharmacological management in non-specialist settings. NICE clinical guideline 173 (2013). Available from www.nice.org.uk/guidance/CG173
- Peripheral nerve-field stimulation for chronic low back pain. NICE Interventional procedures guidance IPG451 (2013). Available from www.nice.org.uk/guidance/IPG451
- Transaxial interbody lumbosacral fusion NICE Interventional procedures guidance IPG387 (2011). Available from www.nice.org.uk/guidance/IPG387
- Non-rigid stabilisation techniques for the treatment of low back pain NICE interventional procedures guidance IPG366 (2010). Available from www.nice.org.uk/guidance/IPG366.
- Therapeutic endoscopic division of epidural adhesions NICE interventional procedures guidance IPG333 (2010). Available from www.nice.org.uk/guidance/IPG333.

- Lateral (including extreme, extra and direct lateral) interbody fusion in the lumbar spine) NICE Interventional procedures guidance IPG321 (2009). Available from www.nice.org.uk/guidance/IPG321
- Prosthetic intervertebral disc replacement in the lumbar spine NICE interventional procedures guidance IPG306 (2009). Available from www.nice.org.uk/guidance/IPG306
- Percutaneous endoscopic laser cervical discectomy. NICE interventional procedures guidance IPG303 (2009). Available from www.nice.org.uk/guidance/IPG303
- Percutaneous endoscopic laser lumbar discectomy. NICE interventional procedures guidance IPG300 (2009). Available from www.nice.org.uk/guidance/IPG300
- Spinal cord stimulation for chronic pain of neuropathic or ischaemic origin. NICE technology appraisal guidance TA159 (2008). Available from www.nice.org.uk/guidance/TA159
- Automated percutaneous mechanical lumbar discectomy NICE interventional procedures guidance IPG141 (2005). Available from www.nice.org.uk/guidance/IPG141
- Percutaneous endoscopic laser thoracic discectomy NICE interventional procedures guidance IPG61 (2004). Available from www.nice.org.uk/guidance/IPG61

**Under development**

None identified.

# 5 External organisations

## *5.1 Professional organisations*

### 5.1.1 Professional organisations contacted for expert advice

Expert advice was received from 5 relevant specialists.

### 5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of Occupational Health Nurse Practitioners
- British Association of Spinal Surgeons
- British Chiropractic Association
- British Institute of Musculoskeletal Medicine
- British Orthopaedic Association
- British Osteopathic Association
- British Pain Society
- British Society for Rheumatology
- British Society of Rehabilitation Medicine
- Chartered Society of Physiotherapy
- College of Occupational Therapists
- Royal College of Nursing
- Royal College of Physicians
- Royal College of Surgeons
- Society for Back Pain Research (SBPR)

## *5.2 Patient organisations*

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Back Care

- British Orthopaedic Association - Patient Liaison group
- Fighting Back UK
- Action on Pain
- British Pain Society
- Pain Association Scotland
- Pain Concern
- Pain Relief Foundation
- Pain UK