NICE National Institute for Health and Care Excellence

Adoption support resource – insights from the NHS

Implementation support
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1 Introduction

This resource has been developed to provide practical information and advice on NICE medical technologies guidance on the Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain for NHS organisations wishing to adopt this technology.

NICE's adoption team worked with contributors in NHS organisations who use spinal cord stimulation systems, including Senza, to gather learning and experiences.

The information presented in this resource is intended for the sole purpose of supporting the NHS in adopting, evaluating the impact of adopting, or further researching this technology. It is complementary to the guidance and was not considered by the medical technologies advisory committee when developing its recommendations.

The learnings gained from existing users are not presented as best practice but as real-life experiences of how contributors have adopted this technology.

As Senza is 1 of several available spinal cord stimulation (SCS) devices contributors explained that the choice of device is determined by a multidisciplinary assessment, taking into account patients' needs and preferences.

The benefits of using Senza for appropriate patients as reported by NHS contributors to this resource include:

- avoiding the paraesthesia associated with many SCS devices which can disrupt sleep and daily activities
- good conversion rate from a trial of Senza to a permanent implant
- improved quality of life through better pain management when compared with conventional medical management
- enabling more predictable procedure time because paraesthesia mapping is not needed, which may improve theatre planning and increase capacity
- providing another option for SCS.

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2 Summary of NICE recommendations

The case for adopting Senza spinal cord stimulation (SCS) for delivering HF10 therapy as a treatment option for chronic neuropathic back or leg pain after failed back surgery is supported by the evidence. HF10 therapy using Senza SCS is at least as effective as low-frequency SCS in reducing pain and functional disability, and avoids the experience of tingling sensations [paraesthesia] (recommendation 1.1).

Senza SCS for delivering HF10 therapy should be considered for patients:

- with residual chronic neuropathic back or leg pain (at least 50 mm on a 0 mm to 100 mm visual analogue scale) at least 6 months after back surgery despite conventional medical management and
- who have had a successful trial of stimulation as part of a wider assessment by a multidisciplinary team (recommendation 1.2).

Patients with other causes of neuropathic pain were included in the evaluation and may be considered for HF10 therapy using Senza SCS but any additional benefits compared with low-frequency SCS are less certain. Cost modelling indicates that, over 15 years, HF10 therapy using Senza SCS has similar costs to low-frequency SCS using either a rechargeable or non-rechargeable device (recommendation 1.3).

Clinicians implanting SCS devices including Senza should submit timely and complete data to the UK Neuromodulation Registry (recommendation 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 (recommendation 1.5).

The specific recommendations on individual technologies made by NICE medical technologies guidance are not intended to limit use of other relevant technologies which may offer similar advantages.

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3 Current practice

For low back pain and sciatica, the NICE guideline on low back pain and sciatica in over 16s recommends self-management, exercise, psychological therapy and pharmacological therapies. If these are not effective, the guideline recommends invasive treatments including surgery. It does not refer to spinal cord stimulation (SCS).

NICE technology appraisal guidance on spinal cord stimulation recommends SCS as a treatment option for chronic pain of neuropathic origin that continues for at least 6 months despite conventional medical management (including pharmacological treatment, physiotherapy and psychological support) in adults who have had a successful trial of stimulation as part of a wider assessment by a multidisciplinary team. 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 needs of the person with chronic pain and the support package offered. SCS is not recommended for chronic pain of ischaemic origin, except in the context of research. A review of the guidance in 2013 concluded that more recent evidence (including evidence on Senza) would be unlikely to change the recommendations and the guidance was placed on the static list.

The British Pain Society publication Spinal cord stimulation for the management of pain: recommendations for best practice (2009) supports the use of SCS only after a multidisciplinary assessment by healthcare professionals experienced in using the technology.

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4 Tips for adopting the Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain

NHS contributors to this resource considered the following to be important:

- Ensure staff have the appropriate skills in programming Senza, including training for nurse specialists. Consider extending training to cover more complicated programming and checks after implantation.
- Take measurements before, during and after implementation to show the benefits and impact of adopting Senza. Before implementation, plan how data will be collected and by whom.
- Pilot the use of Senza before full implementation across the service.
- Ensure that the decision to use Senza is made by a specialist multidisciplinary team. Senza is most beneficial with careful patient selection.

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5 How to implement NICE's guidance on the Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain

To implement this technology in routine practice, contributors to the resource suggest the following steps.

Project management

This technology can be best adopted using a project management approach. NICE has produced resources to help you put guidance into practice, which sets out the most common steps taken when putting evidence-based guidance into practice.

Implementation team

The first step is to form a local project team who will work together to implement the technology and manage any changes in practice.

Individual NHS organisations will determine the membership of this team and how long the project will last. Consider the following membership so that the guidance is implemented in an effective and sustainable way:

- Clinical champion: they could be a consultant in pain management or neurosurgeon with an interest in chronic pain management, and should have the relevant knowledge and understanding to be able to drive the project, answer any clinical queries and champion the project at a senior level.
- Project manager: they could be someone in a clinical or managerial role who will be responsible for the day-to-day running of the project, coordinating the project team and ensuring the project is running as planned. This could be a nurse specialist in chronic pain management.

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- Management sponsor: they will be able to help assess the financial viability of the project, ensure the business case is produced and help to show the potential cost savings. This may be the departmental operations manager or someone from the finance team.
- Clinical audit facilitator: they will be able to help set up systems to collect and analyse local data needed to measure the project's performance and carry out audits. NHS contributors said that a dedicated data analyst would be best, but in practice this was commonly done by a nurse specialist.
- Patient representatives: to ensure the service meets the needs of patients.
- Other stakeholders: they will be valuable members of the project team, including representatives from operating theatres (anaesthetist, nurse) and day-surgery unit.

Assessment of readiness

The project team may wish to consider:

- Will a pilot period be helpful?
- How will the project be funded and the devices commissioned for a pilot and in the long term?
- How will project performance measures be identified and implemented at a local level?
- Who will be responsible for collecting clinical data?
- How will the education needed for adoption by healthcare professionals be provided?
- Can lessons be learnt from colleagues in other pain centres?
- Are there any obvious challenges and how can these be overcome?

Pilot study

All NHS contributors reported first adopting Senza as part of a pilot study, or for research purposes. This gave an opportunity to observe the clinical benefits and better inform the case for adoption. The pilot studies included varying numbers of patients, from 5 to 30. They were either identified as patients newly in need of spinal cord stimulation (SCS), or as patients already having SCS who were due for a change in treatment (for example, they

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were awaiting device removal, or battery replacement).

Care pathway mapping

NHS contributors to this resource were already using SCS devices before adopting Senza, so the device fitted into established care pathways. If a trust is not already using SCS, staff would benefit from visiting, engaging and learning from other places already using these devices before adopting Senza. The Specialist Practitioners in Neuromodulation Forum (SPIN, based at Newcastle upon Tyne Hospitals NHS Foundation Trust) and Specialist Neuromodulation Nurses and Associated Professionals (SSNAP) could provide these links.

Multidisciplinary neuromodulation team

All NHS contributors reported that the decision to offer SCS should be made by a multidisciplinary neuromodulation team after a full assessment. These teams comprise a psychologist, a nurse specialist in pain management, and a consultant in pain management or neurosurgeon. They may also include:

- physiotherapist
- pharmacist
- neurologist
- occupational therapist
- orthopaedic and spinal surgeons
- mental health professional.

Patients are commonly referred to a neuromodulation service when conventional management of chronic neuropathic pain has failed. After referral, a consultant in pain management or a neurosurgeon (as well as potentially a nurse specialist) assess the patient to decide whether SCS is suitable. This is followed by a physiotherapy review and, if not already done, a review by a psychologist and nurse specialist. The results of these help inform the decision to use SCS.

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Patient selection

NHS contributors reported that Senza is most beneficial with careful patient selection. Several factors contribute to Senza's suitability for a patient, including:

- Residual chronic neuropathic back or leg pain (at least 50 mm on a 0 mm to 100 mm visual analogue scale) at least 6 months after back surgery, despite conventional medical management.
- Chronic pain of neuropathic origin (measuring at least 50 mm on a 0 mm to 100 mm visual analogue scale) for at least 6 months despite appropriate conventional medical management (see NICE technology appraisal guidance on spinal cord stimulation).
- Successful completion of a trial of stimulation.
- Under the care of a multidisciplinary team.
- Have had a psychological assessment.
- Have completed a pain management programme (or equivalent).
- Physically and cognitively able to manage the technical demands of the device.
- Treatment has aimed to reduce opioid use as much as possible (ideally stop it) before considering SCS.

Contributors report that Senza is 1 of a number of SCS devices available at their trust. Which SCS device is used depends on individual (social and psychological) and clinical factors (function, comorbidity, site and nature of pain). Most contributors use Senza in patients with continued neuropathic back or leg pain despite back surgery, but some use it in patients with other neuropathic pain who may not have had back surgery. One contributor uses Senza in patients with upper limb neuropathic pain, for which paraesthesia is sometimes a particular issue with other SCS devices.

Senza is not suitable for people who may forget to charge the device or those for whom the daily 30- to 45-minute charging is not appropriate. Considerations also need to be made for people who are allergic to any components of Senza.

NHS contributors reported potential contraindications for implanting any SCS device, including Senza:

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- anatomical issues affecting insertion
- comorbidities including infections, postural orthostatic tachycardia syndrome, mental health issues or chronic disease (such as multiple sclerosis and severe respiratory disease)
- very high or very low BMI
- alcohol or drug misuse.

Patient education before implantation

As part of patient selection, people should take part in a programme of education, learning and assessment about chronic pain and SCS. This is commonly later in the care pathway than the pain management group programme and different in content. The name, length and structure of the programme differs, but all are run by members of the multidisciplinary neuromodulation team. The programme aims to:

- support patients to make more informed choices, including informed consent
- inform the selection decision
- help give a better understanding of pain and how to manage it
- provide technical and practical information on using SCS (supported by meeting other people who have had Senza, and their families)
- detail the risks and benefits of SCS
- help develop realistic expectations and goal-setting.

Trial

When trialling Senza, the leads are either inserted permanently (tunnelled) or temporary (percutaneously) by a consultant in pain management or a neurosurgeon. It is a day-case procedure done in the operating theatre under sedation or local anaesthesia. Permanent or temporary lead insertion, as well as which anaesthetic to use, is based on a number of factors including comorbidities, complications and risk of infection.

For temporary lead implantation, the procedure takes around 20 minutes (or 45 minutes including anaesthesia). For permanent lead implantation, the procedure takes between

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40 minutes and 1.5 hours including anaesthesia. An external Senza device is connected to the leads for the trial.

A Senza trial usually lasts for 1 to 2 weeks. People can get support from the neuromodulation team over the phone and may return to clinic if the dressing, leads or device need checking. After the trial, the external device is disconnected and any temporary leads are removed. The programmes are read and pain scores recorded. Permanent leads are left in place ready for implantation of the Senza device unless the trial was not successful, in which case they are removed.

NHS contributors judged a trial's success based on a number of factors, including: very positive patient response; a 50% or more reduction in reported pain on a visual analogue or verbal rating scale; reduced disability; improved sleep; and improved quality of life. The trial is assessed based on discussions with the patients rather than a predetermined scoring system.

Permanent implantation

After a successful trial, Senza is implanted permanently. If permanent leads have been left in place after the trial, a permanent implant should be done as soon as possible. Permanent implantation is done under sedation or general anaesthesia in theatre with use of fluoroscopy, by a consultant in pain management or a neurosurgeon.

NHS contributors provided feedback about the procedure for permanent implantation of Senza:

- If permanent leads are already in place the procedure takes around 45 minutes. If new leads are needed (because temporary leads were used in the trial) the procedure can take between 20 minutes (not including anaesthetic) and 2 hours. Insertion times for Senza are more predictable than for low-frequency SCS devices.
- At 3 of the contributors' trusts, a representative from the manufacturer is in theatre during the procedure to check impedance, lead placement and equipment functioning. This is common for all SCS devices. Contributors try to schedule the same devices in a theatre session to avoid having several representatives from different manufacturers.

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- At 1 contributor's trust, the nurse specialists have extended their role to include in-theatre procedure checks and more complex programming. This negates the need for a representative from the manufacturer to be present. This provides greater flexibility and improved control in managing theatre lists.
- Battery or device position may influence how much pain the patient feels. Clinicians discuss and agree the placement of Senza with the patient before implantation.

Follow-up after implantation

Senza is part of a wider treatment strategy, so postoperative management is holistic rather than focusing on Senza itself.

In some neuromodulation services activating and programming the device (by a manufacturer representative or nurse specialist) is done immediately after surgery. At others, this may be done up to a week after surgery to allow more recovery time.

In general, follow-up after implantation is done in nurse-led clinics. Each service has their own care pathway for reviewing patients, but typically most see patients at around 2 weeks, 6 weeks, 3 months, 6 months and 1 year, and then yearly. At these appointments progress is documented, advice given and reprogramming done as needed. The healthcare professional who implanted Senza commonly only sees the patient if there is a reported problem that may need surgical intervention. Manufacturer representatives can attend if more complicated programming is needed. Some NHS contributors said that follow-up appointments for Senza are quicker and needed less often than those for low-frequency devices, because of differences in programming.

Measuring success

It is important to record a baseline assessment and take measurements during and after implementation to show the cost and clinical benefits of adopting Senza.

NHS contributors to this resource suggested that before implementation, the team should plan who will be responsible for collating and managing these data, and if funding would be available.

The following procedure measures were suggested to help assess impact of adoption:

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- reason for insertion (for example, pain locations)
- device location
- incidences of device failure, wound infection, pocket pain (because of the battery), lead migration and need for battery replacement.

The following service measures were suggested to help assess the impact of adoption:

- time to complete the procedure
- total number of SCS procedures per year, by device.

Patient quality-of-life measures should be taken before, during and regularly after implantation. They could include:

- visual analogue scale for back and leg pain
- pain increase and decrease
- global impression of change
- percentage of improvement overall
- overall pain
- sleep disturbance as measured by the number of awakenings per night
- Oswestry Disability Index
- Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)
- reduction in pain medication
- EQ-5D
- brief pain inventory
- function (sleep, return to work, driving, operating machinery)
- frequency of GP or hospital visits for pain
- assessment against the person's own person goals (rather than standardised measures)

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- qualitative data from informal sources.

Most of these measures would be documented in the patient's records as part of routine follow-up appointments. In practice, contributors mostly used paper records to collect and analyse data. However, they all agreed that collecting and storing the data electronically would be more sustainable.

All contributors were aware that the Neuromodulation Society of the United Kingdom and Ireland (NSUKI) has recently launched a national database to collate data from services offering SCS.

Training

The contributors' trusts were already inserting other SCS devices before adopting Senza, and they did not need any further training specifically for Senza. They reported that the manufacturer provides additional training if needed.

Contributors said that the manufacturer provided training for the nurse specialists in programming the device which involved classroom-based-learning as well as training during clinic appointments. At 1 trust, the nurse specialists had further training from the manufacturer to extend their responsibilities to in-theatre device checks and programming. The team felt this additional knowledge about the device and lead placement made them more skilled in programming.

Cost savings

NICE estimates that, over 15 years, using Senza has similar costs to low-frequency SCS using either a rechargeable or non-rechargeable device.

The case for adopting Senza could be supported by:

- NICE medical technologies guidance on the Senza SCS system for delivering HF10 therapy to treat chronic neuropathic pain.
- NICE technology appraisal guidance on spinal cord stimulation.
- The British Pain Society publication Spinal cord stimulation for the management of pain: recommendations for best practice (2009).

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- A summary of the results of any pilot studies or research done in-house or at other pain centres.

If a new neuromodulation service is being planned, all of the above sources of information would be useful for building a business case.

Service commissioning and procurement

All contributors' trusts are designated specialised pain centres and adhere to the standard of care expected in the NHS England Specialised Pain Clinical Reference Group's service specification. NHS England commissions implanting SCS devices (including Senza) at these designated specialised pain centres.

Historically, if a trust was not a designated specialised pain centre, an individual funding request was needed from the relevant clinical commissioning group (CCG) for each proposed implantation. In February 2018, the NHS Supply Chain produced a provider trust FAQ on the NHS England High-Cost Tariff-Excluded Devices (HCTEDs) programme, which clarified that the contractual and payment responsibility for SCS devices moved to NHS England from 1 April 2017.

At regional CCG-commissioned centres, local policies will still be relevant and the associated procedure will still be paid for by CCGs.

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Consultant in pain medicine and anaesthesia and associate professor of pain, Leeds Teaching Hospital NHS Trust

Carol Bourke
Nurse specialist, Pain Centre, Leeds Teaching Hospital NHS Trust

Mr Alistair Jenkins
Consultant neurosurgeon, Newcastle upon Tyne Hospitals NHS Foundation Trust

Dr Adnan Al Kaisy
Clinical lead consultant in neuromodulation and pain medicine, Guy's and St Thomas' NHS Foundation Trust

Dr Sarah Love-Jones
Consultant in pain medicine and anaesthesia, North Bristol NHS Trust

Rose Marriott
Clinical nurse specialist/sister, North Bristol NHS Trust

Karen Sanderson
Nurse practitioner in neuromodulation and chronic pain management, Guy's and St Thomas' NHS Foundation Trust

Miriam Walker
Nurse specialist in chronic pain and neuromodulation, Newcastle upon Tyne Hospitals NHS Foundation Trust

Heather Williams
Nurse consultant in chronic pain and neuromodulation and honorary lecturer in pain management, Newcastle upon Tyne Hospitals NHS Foundation Trust

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7 About this resource

This resource accompanies NICE medical technologies guidance on the Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain. It was developed using NICE's process guide for adoption support resources for health technologies. It is an implementation tool that summarises the experiences reported by NHS clinicians who have adopted this technology and shared the learning that took place.

It is the responsibility of local commissioners and providers to implement the guidance at a local level, being mindful of their duty to advance equality of opportunity and foster good relations. Nothing in this document should be interpreted in a way that would be inconsistent with this.

More information about the adoption team.

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