

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Medical technology consultation document

### Senza for delivering high frequency spinal cord stimulation to treat chronic neuropathic pain

The National Institute for Health and Care Excellence (NICE) is producing guidance on using Senza for delivering high frequency spinal cord stimulation to treat chronic neuropathic pain in the NHS in England. The medical technologies advisory committee has considered the evidence submitted and the views of expert advisers.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the draft recommendations made by the committee. NICE invites comments from the public. This document should be read along with the evidence base (see Sources of evidence considered by the committee).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical effectiveness and resource savings reasonable interpretations of the evidence?
- Are the provisional recommendations sound, and a suitable basis for guidance to the NHS?
- Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?

**Note that this document is not NICE's final guidance on Senza for treating chronic neuropathic pain. The recommendations in section 1 may change after consultation.** After consultation the committee will meet again to consider the evidence, this document and comments from public consultation. After considering these comments, the committee will prepare its final recommendations which will be the basis for NICE's guidance on the use of the technology in the NHS in England.

For further details, see the [Medical Technologies Evaluation Programme process guide](#) and [Medical Technologies Evaluation Programme methods guide](#).

Key dates:

- Closing time and date for comments: 17:00 04 December 2017
- Second medical technologies advisory committee meeting: 8 December 2017

NICE medical technologies guidance addresses specific technologies notified to NICE by sponsors. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence

Page 1 of 12

NICE medical technology consultation document: Senza for delivering high frequency spinal cord stimulation to treat chronic neuropathic pain

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submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.

## 1 Draft recommendations

- 1.1 The case for adopting Senza for delivering high frequency spinal cord stimulation to treat chronic neuropathic back and leg pain is supported by the evidence. It is associated with better pain control than low frequency spinal cord stimulation. It also improves quality of life, reduces functional disability and avoids the tingling sensation (paresthesia) patients can experience with low frequency spinal cord stimulation.
- 1.2 Senza should therefore be considered for patients who are eligible for spinal cord stimulation as described in NICE technology appraisal guidance on [spinal cord stimulation](#).
- 1.3 Assuming that the device costs £16,648, using Senza to deliver HF10 therapy may save up to £7,755 over a 15 year period (equivalent to £517 per year) compared with low frequency spinal cord stimulation. These savings are mainly from Senza's longer lifespan and fewer associated complications.

## 2 The technology

### *Description of the technology*

- 2.1 The Senza spinal cord stimulation (SCS) system (Nevro) is a neuromodulation device that delivers electrical impulses to the spinal nerve root. Senza can be used to deliver low frequency SCS (2 to 1,200 Hz), but it is also able to provide a novel high frequency treatment called HF10 therapy. HF10 therapy consists of an algorithm of high frequency (10 kHz), low amplitude electrical pulses designed to relieve

pain and not be felt by the patient. The treatment is provided by small electrodes, which are surgically placed in the spinal epidural space and are connected to a small, battery-powered pulse generator that is implanted under the skin. The strength, duration and frequency of the electrical pulses can be controlled remotely. The focus of this evaluation is Senza SCS delivering high-frequency spinal cord stimulation therapy and this is referred to as Senza throughout the remainder of this document.

2.2 Senza was CE marked as a class III device in May 2010. It should only be used for patients who have had effective pain relief in a trial of stimulation. Patients who have Senza implanted should not receive shortwave, microwave or therapeutic ultrasound diathermy because of a risk of severe injury or death. They should only be exposed to MRI using special procedures outlined in the instructions for use.

2.3 The cost of Senza as stated in the company's submission is £16,648 (excluding VAT). This includes electrodes, leads, an implantable pulse generator (with rechargeable battery), a remote control and a battery charger.

2.4 The claimed benefits of Senza in the case for adoption presented by the company are that, compared with low frequency SCS, there is:

- clinically superior pain relief for most people with back or leg pain. It is also associated with more successful clinical outcomes (greater than or equal to a 50% reduction in pain) and better functional outcomes.
- no paresthesia so treatment can be continued during sleep and while driving or operating machinery.
- sustained and long-term improvement in pain relief and function, which may reduce the need for pain medication and follow-up attendance at pain clinics.
- no need for paresthesia mapping during implantation, which allows shorter and more predictable procedure times.

## ***Current management***

- 2.5 NICE technology appraisal guidance on [spinal cord stimulation](#) recommends SCS as a treatment option for adults with chronic neuropathic pain of neuropathic origin chronic pain that continues for at least 6 months despite conventional medical management (including pharmacological treatment, physiotherapy and psychological support) who have had a successful trial of stimulation as part of a wider assessment by a multidisciplinary team. SCS is not recommended for adults with chronic pain of ischaemic origin, except in the context of research. Available devices considered in the guidance deliver low frequency SCS and have either a rechargeable or non-rechargeable battery. The guidance was reviewed in 2013 at which time evidence on other devices such as Senza was identified. The review concluded that evidence available since the original guidance would be unlikely to change the recommendations and the guidance was placed on the static list.
- 2.6 NICE has also produced related guidance on [neuropathic pain in adults in non-specialist settings](#) and on [low back pain and sciatica in over 16s](#).

## **3 Evidence**

### ***Summary of clinical evidence***

- 3.1 The evidence for Senza assessed by the external assessment centre (EAC) comprises 6 studies in adults with chronic neuropathic pain. These comprised:
- 1 randomised controlled trial comparing Senza SCS with low frequency SCS (Senza-RCT; Kapural et al. 2015 and 2016)
  - 1 before-and-after study (Tiede et al. 2013)
  - 4 single-arm observational studies (Al-Kaisey et al. 2014 and Van Buyten et al. 2013, Russo et al. 2016, Rapcan et al. 2015, Al-Kaisey et al. 2017).

For full details of the clinical evidence see section 3 of the assessment report.

### ***Main points from the EAC's analysis of the clinical evidence***

- 3.2 The EAC considered Senza-RCT to be the most relevant study providing the best quality evidence. Although it identified the potential for performance, detection and reporting bias, the EAC was satisfied that the trial's limitations did not affect the overall direction of the results.
- 3.3 The other 5 studies were single-arm observational studies the results of which were generally supported and corroborated the results of Senza-RCT. The highest quality of these was Al-Kaisey et al. 2014, which reported results up to 2 years.
- 3.4 The EAC concluded that there is strong evidence to support the claimed benefits presented by the company in the case for adoption. However, it noted gaps in the evidence base, particularly the lack of long-term studies.

### ***Summary of economic evidence***

- 3.5 The company's economic model was based on a published cost-effectiveness study (Annemans et al. 2014) comparing Senza SCS separately with conventional medical management, reoperation and low frequency SCS devices (both rechargeable and non-rechargeable). The model, which was also used to inform NICE technology appraisal guidance on [spinal cord stimulation](#) (Simpson et al., 2008), was a 2-stage decision analytic model that used a decision tree for the first 6 months, followed by a Markov state transition model with a 15-year time horizon. The EAC was satisfied that the model's structure, assumptions and parameters were robust and accurately reflected the important considerations. For full details of the economic evidence see section 4 of the assessment report.

## ***EAC's analysis of the economic evidence***

- 3.6 The EAC considered the Annemans et al. (2014) study to be of high quality. The results showed that Senza was the most cost-effective treatment, dominating both rechargeable and non-rechargeable low frequency SCS devices (that is, Senza works better and costs less).
- 3.7 The company's base-case results showed that, over 15 years, Senza could lead to cost savings of £4,795 compared with rechargeable low frequency SCS devices and £7,755 compared with non-rechargeable low frequency SCS devices. The EAC considered the company's cost model to be of good methodological quality and was satisfied with the reported results and sensitivity analyses.
- 3.8 Many of the costs in the model, including purchase prices for Senza and its comparators, were adjusted for inflation from the original values in the Annemans et al. study. The EAC considered it inappropriate to inflate drug prices to 2016 prices because they are subject to a wide range of non-inflationary factors. The EAC explored this further with 4 hypothetical scenarios to assess how different drug costs affect the cost-saving potential of Senza. In all scenarios Senza remained cost saving, with patient savings over 15 years of £3,816 to £10,576 compared with non-rechargeable low frequency SCS devices and £856 to £7,616 compared with rechargeable low frequency SCS devices.
- 3.9 The main drivers of cost savings were device longevity particularly for non-rechargeable SCS devices which must be replaced every 4 years and complication rates. Some of the complication rate results were highlighted as academic in confidence by the company, but the full data were available to the External Assessment Centre and committee.

## 4 Committee discussion

### *Clinical effectiveness*

- 4.1 The committee considered that the evidence supporting the clinical benefits of Senza compared with low frequency SCS was robust and adequate for decision-making. It acknowledged the lack of an effective sham-controlled study, in the evidence base, but noted that the consistency of the study results available, mainly those of a randomised controlled trial, were sufficiently convincing to conclude that the evidence supported the claimed patient benefits. In particular, the committee noted the improvements in pain control, functional disability, patient satisfaction and quality of life scores measured in Senza-RCT, and acknowledged that the single-arm studies reported similar findings. The clinical experts explained that the low frequency SCS device used in the Senza-RCT is typical of those used in standard clinical practice in the NHS and that the available low frequency SCS devices do not differ significantly in terms of their performance.
- 4.2 The committee noted that the published evidence for clinical outcomes following Senza SCS implantation is limited to 2 years' follow-up and it would encourage the future publication of longer term outcomes in due course. The committee was informed by a clinical expert that 3-year outcome data with Senza will soon be available, and the intention is to collect 5-year data in due course. Having acknowledged the 10-year lifespan of Senza's battery, the committee concluded that long-term data would reduce uncertainty in the long-term effectiveness of its use.

### **Avoiding paresthesia**

- 4.3 The clinical experts explained that paresthesia mapping is routinely done when implanting low frequency SCS devices, and that this increases procedural time and complexity. They explained that paresthesia mapping does not need to be done when implanting Senza, because it does not cause paresthesia. The clinical experts stated that paresthesia mapping

may be distressing and disorientating for the patient. Furthermore, the experts advised that paresthesia awareness continues throughout the use of low frequency SCS devices, which may negatively affect day-to-day living. However, the committee heard that some patients (usually those who have had SCS for a long time) find the paresthesia reassuring and a means of confirming for themselves that the device is still working. In general, however, patients would welcome not having paresthesia. The committee also noted significant potential quality of life benefits, such as patients being able to drive and use machinery while using Senza.

### **Patient selection**

- 4.4 The committee noted that most of the evidence for Senza was in people with failed back surgery syndrome and predominantly either chronic back or leg pain. The clinical experts agreed that this is the largest patient group who may benefit from the use of Senza, but explained that there are other patients who may particularly benefit (for example, people for whom surgery is unlikely to be helpful and people with complex regional pain syndrome). The committee acknowledged that there is currently limited evidence available for these patient groups, but would welcome further evidence about the potential role of Senza in these clinical circumstances.
- 4.5 The committee considered the risk of Senza being used in more patients than those for whom low frequency SCS is recommended (in NICE technology appraisal guidance on [spinal cord stimulation](#)). The clinical experts advised that this is unlikely, because patient selection should be done by a multidisciplinary team and would only be considered after conventional medical management (including surgery and drug treatment). The committee concluded that Senza should be considered for the same patients for whom SCS is recommended in NICE technology appraisal guidance on [spinal cord stimulation](#) (see section 2.5).

## **Mode of action**

- 4.6 The clinical experts advised that HF10 therapy delivered by Senza uses different physiological mechanisms to low frequency SCS. The committee concluded that Senza has a plausible scientific basis and is innovative.

## ***NHS considerations***

- 4.7 The clinical experts explained that the implantation procedure is the same for Senza and low frequency SCS devices. However, because paresthesia mapping is not needed with Senza, procedure times are shorter and more predictable compared with those for low frequency SCS devices. The committee concluded that, even though this has had not been quantified in the cost-consequence modelling (see section 4.16), using Senza was likely to allow for better planning of procedures and potentially more procedures per day.
- 4.8 The clinical experts explained that when first adopting Senza in their services, the company provided trained experts to attend procedures and support clinicians until competence has been achieved. This was confirmed by the company representatives who attended the meeting.
- 4.9 The clinical experts also explained that there may be further time savings at follow-up appointments, because programming SCS with Senza is easier and less time-consuming than programming low frequency SCS devices.

## **Charging the device**

- 4.10 Based on expert advice, the committee considered that the low frequency non-rechargeable SCS devices are the most relevant comparator for use in the NHS. The clinical experts explained that patients prefer non-rechargeable SCS devices because of the inconvenience of regular charging, which can be time-consuming. However, the clinical experts noted that this advantage is offset by the shorter lifespan of non-

rechargeable devices. The clinical experts confirmed that Senza needs charging for 30 to 45 minutes every day.

### **Cost savings**

- 4.11 The committee considered that the cost-saving case with Senza was persuasive. In particular, it noted that the company's model replicated the cost model used to inform NICE technology appraisal guidance on [spinal cord stimulation](#), and that the model had been peer reviewed and published in a number of publications. The model also used clinical data from Senza-RCT. Based on this, the committee concluded that the use of Senza is likely to be associated with overall cost savings.
- 4.12 The committee noted that the model assumed a time horizon of 15 years but that evidence is currently available for only up to 2 years. Nonetheless, the clinical experts explained that SCS devices appear to work for many years and there is no reason to believe that their clinical effectiveness diminishes over time.
- 4.13 The committee noted the uncertainties in the model associated with using drug costs adjusted for inflation. The EAC explained that accurately estimating the cost of drug management in the relevant patient cohorts would be difficult. The EAC reported that, in further scenario analyses assessing different drug costs, Senza had remained cost saving (see section 3.8). The committee concluded that it is unlikely that Senza would become cost-incurring in any realistic scenario.
- 4.14 The committee acknowledged that the device costs of Senza and the comparators were an important component of the cost modelling, and noted that these had also been adjusted for inflation from the cost model used to inform NICE technology appraisal guidance on [spinal cord stimulation](#). The cost of Senza SCS was assumed to be £16,648, with a lifespan of 10 years. The cost of a non-rechargeable low frequency SCS

device was assumed to be £11,281, with a lifespan of 4 years. The EAC confirmed that these costs are typical of current device prices.

- 4.15 The EAC explained that the cost model did not include all the pathway consequences that could develop from using Senza, which are a reduction in procedure and follow up times. In addition the EAC stated the cost model assumed the same drug costs for Senza and low frequency SCS. The committee concluded, therefore, that the estimated cost savings may be conservative.

Peter Groves  
Chair, medical technologies advisory committee  
November 2017

## **5 Committee members and NICE project team**

### ***Committee members***

This topic was considered by the [medical technology advisory committee](#) which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The [minutes](#) of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

### **NICE project team**

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the topic) and a technical adviser or senior technical analyst.

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ISBN: