PREVENTION. CARE. RECOVERY.

Te Kaporeihana Āwhina Hunga Whara

Guidelines for neuromodulation treatment with Spinal Cord Stimulators for pain management

Abbreviations used in this document:

ARTP – Assessment Report and Treatment Plan

CRPS – complex regional pain syndrome

ePPOC – electronic Persistent Pain Outcomes Collaboration

FBSS – failed back surgery syndrome

IDA – interdisciplinary assessment

IDSR – interdisciplinary summary report

IRP – individual rehabilitation plan

SCS – spinal cord stimulators

Contents

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1. Introduction

In 2012 the Accident Compensation Corporation (ACC) published the guidelines for neuromodulation treatment with spinal cord stimulators (SCS) for pain management. The guidelines were based on research evidence and consensus with the service providers. This document is an update of the 2012 guidelines.[1]

1.1 Purpose of the guidelines

The purpose of the guidelines update is to work in partnership with the service providers on reducing clinical practice variations between the services and to optimise the client's rehabilitation.

These guidelines:

- outline how to get ACC approval to implant an SCS, or revise implants, in patients who have persistent and disabling limb pain or complex regional pain syndrome (CRPS) and similar conditions as a result of an ACC-covered injury
- describe conditions that need to be met before approval is given
- ensure that clinical decision-making is well integrated with all aspects of the client's long-term management, and incorporates a well-planned approach to their rehabilitation
- help providers deliver high-quality care to clients
- help ACC determine whether providing a procedure is necessary and appropriate for a client and is likely to contribute to their recovery or rehabilitation.

1.2 ACC's responsibilities for treatment of injuries

ACC is a Crown entity that administers New Zealand's accident compensation scheme. The scheme provides 24-hour, no-fault cover for all New Zealand citizens, residents and temporary visitors who suffer personal injury in New Zealand. The service scope of ACC includes injury prevention, case management, medical and other care, and rehabilitation.

1. While the focus of these guidelines is on neuromodulation treatment with spinal cord stimulators, the same principles and processes apply when treatment with peripheral nerve stimulation is being considered or applied.

Under the Accident Compensation Act 2001, ACC is liable to pay the cost of the client's treatment if the treatment is for the purpose of restoring the client's health to the maximum extent practicable, and the treatment (among other things) is necessary, appropriate and of the quality required for that purpose.

The Accident Compensation Act 2001, Schedule 1, cl 22(d) instructs that, in deciding to purchase treatment services, ACC must take into account a range of matters including "the cost in New Zealand of the generally accepted means of treatment and of the other options, compared with the benefit that the claimant is likely to receive from the treatment".

2. Purpose and use of spinal cord stimulators

Implanting an SCS is a carefully chosen intervention for a person and should be part of a comprehensive pain management strategy. The selection process, implantation, and regular follow-up reviews of a person with an SCS needs an interdisciplinary approach and should be sited at centres of expertise.

The neuromodulation technique of an SCS for pain relief involves an operation to insert a lead that has an electrode array[2] into the spinal extradural space so that it overlies an appropriate level of the spinal cord. By stimulating the implantable pulse generator (IPG), the patient's pain can be reduced or even eliminated.

The IPG supplies an electrical current which can be modified in respect of amplitude, frequency and pulse-width to the electrodes. The energy transmits across the dura and cerebrospinal fluid to the underlying spinal cord. The region of the spinal cord influenced by this stimulation is the posterior/dorsal aspect, which gives the patient a tingling sensation over the area of pain. The aim is to position the electrode array so that the tingling sensation is superimposed over the painful area(s). The impulses are thought to activate pain-inhibiting neuronal circuits within the dorsal horns and thereby suppress the transmission of impulses along the pain nerve/pathways.

A typical SCS system has three components.

- **An implantable pulse generator (IPG).**

  This is surgically implanted in a subcutaneous pocket under the skin (often the abdomen) connected by a lead, also hidden under the skin, to an electrode array.

- **A lead: an extradural electrode array.**

  The array may be narrow and small, with four or eight electrodes spaced along a 2cm to 4cm length so it can be inserted through a 14g needle by percutaneous insertion. Or it may be a plate electrode with between four and twenty electrodes requiring insertion by a laminotomy.

- **A patient programmer/remote controller.**

  The patient uses this to control the IPG. They can turn the IPG on/off by either a magnet or the patient programmer. The programmer can also be used to activate different programs in the IPG. A variety of stimulation effects are available for the patient to use, eg to allow for postural changes, different activities.

2. An electrode array is a configuration of electrodes used for measuring either an electric current or voltage. Some electrode arrays can operate in bidirectional fashion, and can also be used to provide a stimulating pattern of electric current or voltage.

2.1 Evidence for continuing to purchase SCS

According to the available evidence, SCS may be effective in carefully selected patients (1). The evidence review in 2009 concluded on balance that SCS will provide greater than 50% pain relief in more patients than would be obtained with continued standard treatment for carefully selected:

- patients with persistent and disabling radicular pain following failed back surgery (FBSS) who have not responded to conventional medical management, eg medication, physical therapy, and surgery, after at least six months
- patients with CRPS who have not responded to conventional medical management, including physical therapy, after at least six months.

The evidence suggests that this balance in favourable outcomes is only assured over intermediate timeframes (three years) and in the case of CRPS may not apply at five years. A reasonable conclusion is that ACC should continue to purchase SCS on a case-by-case basis for treating neuropathic pain related to FBSS and CRPS.

Monitoring outcomes to establish evidence of effectiveness in the New Zealand setting is important. This information will be captured within the electronic Persistent Pain Outcomes Collaboration (ePPOC) as is required of all services under the Pain Contract.

ACC has made a decision to purchase SCS services from only two centres of excellence – at Auckland District Health Board and Canterbury District Health Board.

2.2 SCS potential benefits and indications

2.2.1. Potential benefits

The potential benefits of SCS treatment for neuropathic pain include improved:

- levels of pain
- quality of life
- ability to participate in daily living activities including work
- psychological well-being.

While the neuromodulation technique of SCS involves surgery and relatively expensive upfront costs, the potential benefits to the patient can be immense for both long-term pain relief, with a reduction or cessation of analgesic medications, and improved quality of life. Some patients are able to resume normal, or near normal, activities.

2.2.2. Indications

The indications for using SCS neuromodulation should include the following:

- The area of pain (typically limb pain) can be covered with stimulation by one or more of the varieties of electrodes inserted into the spinal extradural space at an appropriate level.

- There is no underlying cause of pain which could be plausibly expected to benefit from additional surgery or other treatment.
- The pain is functionally disabling and inadequately controlled by conventional pain treatments such as medications and active participation in interdisciplinary pain management programmes and approaches.
- The patient is psychologically, physically and cognitively able to understand and use the technology involved in SCS.
- The patient understands this is a long-term commitment.

2.2.3. SCS risks and issues

Adverse consequences associated with use of SCS include technical complications related to the device, and biological complications associated with patient's response to an SCS insertion.

- Technical and hardware complications include lead migration, breakage or fracture, hardware malfunction, loose lead connections, and battery depletion or recharging problems. The majority of technical complications involve issues with leads and this may result in changes in stimulation, unpleasant paraesthesia and subsequent reduction in pain relief (2).
- Biological complications include dural puncture, cerebrospinal fluid leak, epidural haemorrhage, epidural infection, disturbance of spinal cord function, and pain at the incision, electrode or IPG site. Although very unlikely, the procedure could cause paralysis or aggravation of pain through damage to the spinal cord or nerve roots, and there is a risk of epidural haematoma (2, 3).
- Diathermy used in subsequent surgery must not be monopolar, and MRIs are usually not compatible with the device.
- Patients should also be aware that batteries need to be surgically replaced periodically, and that airport and other security systems are activated by the device.

2.3 *SCS costs*

SCS is an expensive procedure. The minimum cost of the clinical services including equipment costs, interdisciplinary assessment (IDA), implantation procedure, device, and follow-up services will exceed $45,000 during the first year of the implant alone.

Note: Accommodation, travel, and management of complications are additional costs.

3. Clinical service requirements

When individuals undergo an SCS implantation procedure, they are committing to a long-term treatment extending for many years or perhaps even for their lifetime. Therefore, the person must be motivated to participate actively in follow-up treatment.

Because SCS involves multiple outcome goals and long-term care, it is imperative that the SCS procedure is integrated with the individual rehabilitation plan (IRP) developed between the patient/client and their ACC case manager.

The goals of SCS must include decreased pain and improved quality of life. In addition, people with persisting pain severe enough for SCS to be considered are usually significantly disabled, including often occupationally. Hence goals should also normally include improved function.

3.1 SCS quality requirements and credentialling

ACC only approves implantation of SCS devices by named providers at:

- Canterbury District Health Board and
- Auckland District Health Board facilities.

Any additional sites and medical providers must be credentialled and approved by ACC.

SCS service suppliers must:

- provide comprehensive assessments by an inter-disciplinary team, and a plan for optimising the patient's functional activity
- select candidates based on inclusion and exclusion criteria
- demonstrate integration with the patient's/client's IRP, and include the case manager
- provide treatment goals that show how the patient can improve function and activity levels, and reduce reliance on healthcare and ACC
- provide long-term maintenance of equipment
- be committed to long-term management and follow-up of patients
- measure the outcomes of implantation and post-insertion at specified intervals (see Reporting outcome measures)
- integrate their service into the pain management services of the facility.

3.1.1. Credentialling SCS units

To meet criteria for credentialling, a unit must:

- be DHB based
- have a holistic team approach to considering SCS that includes physical, psychological, biomedical and social functions
- demonstrate planning for long-term service
- demonstrate a commitment to excellence in assessment, communication and management of the SCS device
- have a team committed to a collaborative relationship with ACC – communication with ACC's Clinical Services is expected
- demonstrate high-quality, functional relationships with pain management services
- be committed to approaching SCS within a shared guideline
- have the capacity to provide long-term follow-up, and a commitment to supporting patients with SCS.

3.1.2. Staffing requirements

The Neuromodulation Clinic will ensure that each member of the team is suitably qualified, is experienced in the particular part of the assessment and procedure they undertake, and practises within their scope of practice and competency.

4. Patient selection for SCS

The patient selection must be determined by an IDA team including a psychologist/psychiatrist, pain management specialist, and occupational therapist/physiotherapist working as a team. It should be evident that the findings from all disciplines have been integrated into a final recommendation.

When considering SCS for persisting pain, the focus must be on the level of function or disability, not just the report of pain, and take account of the specific and general inclusion and exclusion criteria set out below.

Patients presenting for SCS consideration must have had a comprehensive pain assessment which considers patient needs holistically and identifies pertinent pain management strategies within the previous two years. Evidence must show that the client has made reasonable attempts to optimise the recommended medications and self-management strategies.

The proceduralist must be part of the team making the recommendation for implantation and will carry final responsibility for the procedure.

4.1 Inclusion and exclusion criteria

4.1.1. General inclusion criteria

- The patient has severe and disabling pain suitable for treatment with SCS, with a clear diagnosis and the absence of reversible organic pathology.
- The patient has participated in rehabilitation programmes as required, and medication, psychological and behavioural strategies have been integrated and optimised.
- Psychological screening has not elicited any contraindications.
- The patient has a full understanding of the assessment, implantation, follow-up processes, and risk of complications.
- The patient has understood the above and has expressed their willingness to participate with all these processes, including full participation in post-implant management and other appropriate rehabilitation activities, such as physical reactivation, in order to augment the SCS benefits.
- The patient has realistic expectations of the procedure and likely outcome.

- The patient has expressed a desire to improve their function and reduce their disability.
- There is evidence that the patient's General Practitioner (GP) has been informed throughout the process.

4.1.2. Relative general exclusion criteria

- The presence of another clinically significant or disabling persisting pain condition.
- A coagulation disorder, immunosuppression, or other conditions associated with an unacceptable surgical risk.
- An expected inability to receive or operate the SCS system.
- A life expectancy of less than one year.
- An expected or planned pregnancy.
- Expected or planned surgery.
- Lack of adherence to, integration with and optimisation of recommended pain management.
- Lack of evidence that the patient has optimised the integrated medication, psychological and behavioural rehabilitation strategies (inclusion criteria).
- Lack of evidence of ongoing commitment to engage in rehabilitation that would increase function across life domains and reduce disability.

4.1.3. Psychological consideration factors

A systematic review carried out by the ACC Research Team on the role of psychological factors in patient selection for SCS suggested there may be an association between high levels of depression, poor coping strategies, such as low self-efficacy and a tendency to catastrophise when experiencing or thinking about one's pain, and poorer outcomes from SCS (4). These factors may not necessarily exclude people from eligibility for SCS, but the evidence suggests they should be part of the psychological assessment to identify candidates at risk of poorer outcomes and that targeting these factors may enable patients to actively manage their pain and optimise outcomes from SCS.

Psychological factors that may impact on the likelihood of SCS success need to be identified, considered and actively managed. If any, or a combination, of the factors below are present, access to SCS can be deferred while treatment is implemented to try and address the factors. If there is a positive response to treatment, access to SCS can be considered.

The factors include:

- a history of escalating medication reliance
- poorly controlled psychosis
- significant impulsivity and poor mood regulation, major uncontrolled depression

- active suicidal behaviour, untreated self-harm behaviour
- untreated alcohol or drug dependence or abuse
- major cognitive deficits.

Whether these constitute exclusion factors for a particular client needs to be carefully considered. The reason/s why they are considered exclusion factors should be outlined as pertinent to the individual client in question.

4.1.4. Other relative contraindications

- Abnormal or inconsistent pain ratings.
- Inconsistency among the history, pain description, physical examination, and diagnostic studies.
- Occupational driving (private and occupational driving needs to be assessed by a qualified occupational therapist).
- Local or systemic infection.
- The presence of a pacemaker or implanted defibrillator. Seek advice from pacemaker company representative prior to trial/implant. A company representative may need to attend the case (trial and permanent implantation) to check the pacemaker device.
- A foreseeable need for an MRI.
- Anticoagulant or antiplatelet therapy at the time of implantation.

Referrals for SCS will be received by either the Auckland or Canterbury specialist services and must originate from specialists in secondary or tertiary care centres. In every case the service should acknowledge the referral.

The SCS service will contact the patient's:

- GP to obtain any other supportive information, inform them of the process and gain their support
- case manager to discuss the potential place of SCS in wider rehabilitation goals, and collect all necessary information held on the client's/patient's file.

Information obtained from GPs and ACC may include, but is not limited to:

- pain management reports
- neurophysiological reports
- psychological/psychiatric reports
- medical specialist reports, eg neurologist, internal medicine specialist, radiologist
- outpatient reports.

A nominated medical specialist in the team will review the background information and undertake an initial triage to determine if the patient is likely to be a good SCS candidate. If appropriate, the specialist will complete an Assessment Report and

Treatment Plan (ARTP) requesting funding for a full IDA. The ARTP should comment on the suitability of the patient regarding the SCS absolute and relative inclusion and exclusion criteria.

The ARTP is sent to ACC and forwarded to an appropriate case manager, who ensures there is integration with the individual rehabilitation plan.

The case manager will assess the application and, if complete, refer the request to the ACC Clinical Services for consideration.

When considering SCS IDA approval, ACC Clinical Services will refer to the SCS Guidelines 2018. Approval will be considered in two phases:

1. Interdisciplinary assessment phase.
2. Implantation phase.

5. Interdisciplinary SCS screening assessments and reports

The interdisciplinary assessment includes three standalone assessments from medical, psychological and functional perspectives. Each assessment provides an integrated recommendations report and must use mutually agreed measurement tools.

5.1 Assessment measurement tools

5.1.1. Pre-'temporary lead' trial baseline function instruments

The ePPOC stipulates the use of certain assessment measurement tools at defined timeframes. These tools represent the required minimum, though services can choose other tools in addition to these if they wish.

5.2 Medical assessment and recommendations

5.2.1. Assessment

The medical assessment must include a:

- history of general health, other medical/surgical conditions
- history of the pain condition
- review of reports, tests and documents
- response to previous medical approaches and pain management interventions
- detailed physical examination of the affected region and a general physical examination of other systems.

5.2.2. Recommendations

The medical assessment must provide a diagnostic summary of the pain condition and other conditions, and make recommendations that:

identify and give the rationale for further investigations and treatments

identify factors that should be addressed to maximise current pain modulation/ perception.

5.3 Psychological assessment and recommendations

Psychological testing does not predict outcome; however, assessment by a psychologist is required to assess the patient's beliefs about, and expectations and understanding of, the treatment in relation to the condition. The assessment is also an important opportunity to discuss pain management strategies both before and after the procedure (5).

5.3.1. Assessment

The purpose of the psychological assessment is to identify psychological factors that may influence the success of SCS implantation.

Psychometric tests must have well-recognised reliability and validity, and be suitable for repeated measurements, including symptom reporting. At a minimum, this should include the ePPOC questionnaire.

5.3.2. Recommendations

The psychological assessment must provide a diagnostic summary and make recommendations that address:

- factors to maximise current pain modulation/perception
- a summary of the psychological factors present and their summative effect on the patient's functioning and suitability for an SCS trial
- the patient's ability to participate in further rehabilitation
- interventions for identified issues to be aware of when implementing an SCS trial.

Examples: an escalating analgesic dose, unresolved compensation status, unrealistic expectations, inadequate support from spouse, family or others, a history of compliance problems, or a history of substance abuse.

5.4 Functional assessment and recommendations

5.4.1. Assessment

The functional assessment must clinically address the patient's:

- general health history from a functional perspective
- abilities in areas of activity including:
  - ➠ mobility ➠ strength ➠ endurance ➠ flexibility ➠ balance
- functioning at home and in the community, and work or social participation
- specific barriers to activity, including personal, behavioural, physical and support factors.

Objective functional tests must have well-recognised reliability and validity, and be suitable for repeated measurements.

5.4.2. Recommendations

The functional assessment must provide a diagnostic summary of:

- all factors contributing to reduced activity and participation
- areas where functional activity and participation have not been maximised.

It must include recommendations that address:

- factors to maximise current pain management and function
- interventions or activities that will help increase the patient's participation in daily living.

5.5 Interdisciplinary summary report

The interdisciplinary summary report (IDSR) should be a succinct document with copies of the medical, psychological and functional reports attached. The summary report should include:

- evidence of discussion between the three assessors of their experience with the patient and their clinical findings
- evidence of consultation with, and inclusion of, the patient's ACC case manager
- comment on any discrepancies in the patient's presentation as identified by the assessors
- specific comment on the inclusion/exclusion criteria
- integrated diagnoses and a summary of the important pain and rehabilitation issues
- integrated recommendations to maximise function and optimise pain modulation, pain perception, and pain behaviours, including post-implantation recommendations
- a surgical ARTP completed by the proceduralist – if SCS is recommended
- a clear statement that the patient holds realistic expectations of the SCS procedure and provides informed consent.

5.6 Actions after the IDSR

If the IDSR recommends…	then…
an SCS implant trial	the interdisciplinary summary and surgical non-core ARTP, including estimated costs, should be forwarded to ACC.
other interventions and reconsideration of a trial at a later date	refer back to the case manager to initiate the other interventions.
no SCS trial	refer back to the case manager and recommend further pain management.

6. Implantation procedure

6.1 Pre-trial patient education and consent

To familiarise the patient with the practical aspects of the trial implantation so they can give informed consent for the 'temporary lead' trial, providers must give them:

- a clear understanding of the procedure, the risks and benefits, possible complications, and treatment alternatives
- educational information such as pamphlets, videos/internet links, and demonstrations of the implantable hardware
- clear, written instructions about self-care and the patient's responsibility to report various functions and experiences over the trial period
- descriptions of reasonable restrictions and what to expect over the trial period, including appropriate use of medications, and the importance of slowly building activity tolerance.

The proceduralist must confirm that the patient is a suitable candidate for SCS, has willingly agreed to the long-term therapeutic relationship with the SCS team, and has a commitment to undertaking the rehabilitation necessary to maximise function with the SCS device.

Setting goals is important for getting better results. Re-setting goals and further monitoring the patient's expectations should be considered. Issues that were submerged by severe persisting pain may surface. These may involve adaptation to life with less pain, including the impact on families and relationships.

6.2 The 'temporary lead' trial for an SCS

The trial consists of inserting trial leads in the epidural space to cover the spinal cord area matching the distribution of pain. The trial should be performed over approximately seven days, during which time different levels of stimulation, including no stimulation, are compared with the level of pain reduction achieved (6).

Functional assessment is difficult because: a) one week post-op is a very short period of time to measure functional improvements; b) if a patient has had a laminotomy this is too early to measure functional outcomes.

Patient's reporting is a good measure of the effectiveness of the trial. If the patient reports substantial and unequivocal improvement in pain relief, this is indicative of the success of the trial. Experience shows that if the temporary lead doesn't provide pain relief, patients wouldn't want to proceed to a permanent implant.

The implantation team reviews the results to determine the success or otherwise of the trial. The clinical leader then decides whether to complete the required procedures for a permanent SCS placement.

6.3 Proceeding to permanent lead and battery insertion

The SCS proceduralist makes the final decision to proceed to permanent lead and battery insertion. ACC relies on the SCS team to determine the success or failure of the trial and the appropriateness of final insertion of the device. No further approval for the implant surgical procedure is required from ACC at this stage since the approval covers the trial and insertion.

7. Discharge and follow-up

7.1 Providing an integrated care plan and applying for follow-up sessions

The SCS team must provide ACC with:

- a surgical operation record
- a detailed follow-up plan
- an application for follow-up clinical costs.

7.2 For the client and GP

The SCS team must provide clear, written documentation about the implant for patients to take with them to any future consultation with a health professional. This should include explicit details about investigations or procedures that are contraindicated, such as ultrasound or MRI scans.

Patients need to be made aware that:

- exposure to external defibrillators, certain types of diathermy, electrocautery, and radiation therapy may be contraindicated
- the SCS system may be affected by magnets from a wide range of sources: theft detectors (as found in libraries, airports etc), store and airport security devices, aircraft communications systems, large stereo speakers with magnets, power lines, electric substations and power generators. Electric arc welding equipment should be used with caution.

Patients should read the information in the booklets provided at the time of implantation. A card is provided by the SCS distributor to alert health care professionals and security personnel that a patient has an implanted neurostimulation device. Patients are advised to keep these cards on them at all times. This card should include details of the device, contact details of the implanting clinician and a contact phone number for post-implantation care.

7.3 Follow-up progress reviews

The implantation team should conduct regular reviews of progress at a minimum two weeks, six weeks, three months, six months and annually following implantation. The reviews should consider a wide range of outcomes, which must be recorded. Suitable outcome measures for persisting pain problems are:

- reported pain
- use of analgesics, or other medications
- activities of daily living and social participation
- return to productive activity (full- or part-time paid work, study or training,
- voluntary work or work trial)
- sleep
- neuromodulation effect/issues.

7.4 Assessment measurement tools

The ePPOC stipulates the use of certain assessment measurement tools at defined timeframes. These tools represent the required minimum, though services can choose other tools in addition to those if they wish.

8. Reporting outcome measures

To ensure appropriate outcomes are achieved, it is important that clinicians report on the clinical outcomes from SCS through ePPOC tool.

ACC will require outcome measures and written progress reports to be completed at six months (corresponding with the six-month follow-up), and at the annual follow-up relative to the pre-implantation baseline. The information will cover the patient's clinical progress, functionality, self-care, use of medication, participation, activities of daily living, and return to work (as listed above in the follow-up sessions), and any complications, including revisions.

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