Private Healthcare Australia
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Spinal cord stimulator post listing review impact assessment

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have more than 20 registered health funds throughout Australia as members and collectively represent 99% of people covered by private health insurance. PHA member funds provide healthcare benefits for more than 15 million Australians.

Introduction

Private Healthcare Australia welcomes the recommendation to reduce benefits for spinal cord stimulators, but this measure does not go far enough. There is no evidence these devices work better than a placebo, therefore, they should not be funded for the treatment of chronic pain.

Multiple high-quality studies have cast doubt on whether spinal cord stimulation successfully treats back, neck and nerve and/or complex regional pain syndrome and there is evidence it can cause patients significant harm.

Independent research published in the Medical Journal of Australia examined data from five health insurers covering thousands of patients between 2011 and 2022 and found around 35 per cent required unplanned revision surgery due to complications. The median cost to insurers for a permanent device was nearly $56,000, with some patients' treatment costs exceeding $500,000.[1]

Leading Australian clinicians have also called for these devices to only be used within properly conducted randomised controlled trials that have strict oversight and mandatory reporting of outcomes. That advice should be heeded.

If spinal cord stimulators were a new technology seeking public funding today, they would struggle to meet contemporary standards for safety, clinical effectiveness and value for money. They should be reviewed by the Medical Services Advisory Committee (MSAC) and removed from the Medicare Benefits Schedule (MBS) and the Prescribed List (PL) if they cannot demonstrate clear patient benefit.

While considering further action is necessary, PHA welcomes the department's proposed actions to reset the benefits for internal pulse generators (IPGs) and leads for spinal cord stimulators for pain management, aligning them with better performing sacral neurostimulators. PHA further supports reducing the prices paid by consumers for leads in line with the evidence for efficacy.

However, the proposal to remove benefits for trial leads is flawed. The conclusion that the lack of use of trial leads in Australia means the category should be removed is based on a false assumption that the category is redundant. These trial leads are available overseas, and it is simply a choice by the suppliers that they are not supplied in Australia which is designed to maximise revenue. The reason trial leads are not used in Australia is that the PL has no conditions on listing. Given the choice of using trial leads or much more expensive permanent leads for trials, the international

[1] Jones et al, *"Spinal cord stimulation patterns of care, re-intervention and cost for private health insurers, Australia, 2011-22; a retrospective observational study"* MJA Volume 223, issue 5, March 2025.

device companies chose to maximise their revenue. This choice to prioritise profits over patients should not be rewarded.

Further, the existence of $152 basic surgical tools for spinal cord stimulators on the PL is ridiculous. These overpriced, basic tools, spun out from the kit to attract additional revenue are another example of the historical flawed PL processes, and the Government should remove these items from the list and the stimulator and its component parts funded as a single entity.

Recommendations

PHA recommends:

- The prices for IPGs be adjusted as recommended
- The prices for leads be adjusted as recommended with conditions placed on their use
- The overpriced accessories be removed from the PL and re-incorporated into the listing for the primary device
- The category of trial leads be maintained with any permanent leads used for trials to be funded at the lower level, and
- The efficacy of spinal cord stimulators be assessed by the MSAC.

Response

The evidence base

The founding principle of a Health Technology Assessment (HTA) review is that if there is no evidence a technology can be shown to be effective, its value to the health system is effectively considered to be zero, or at the very least, no higher than existing alternative treatments.

Spinal cord stimulation has never been tested by MSAC, and after more than half a century of use, the efficacy of these devices remains unproven.

Global commercial supply of spinal cord stimulation has provided sufficient time to validate the clinical effectiveness – or lack of – the technology. Two independent Cochrane Reviews, and a further paper by Hana et al has found these devices are no more effective than a placebo, while also capable of generating new and distinct harms from the surgery itself (including nerve damage from dural tears) and from outputs of the device itself (including excess painful shocks and burns).

O'Connell et al[2] noted:

> *'There is low to very low-certainty evidence that implanted spinal cord stimulation (SCS) devices provide clinically important benefits for pain intensity or benefits on health-related quality of life (HRQoL) when added to conventional medical management or physical therapy. However, we also found very low-certainty evidence that SCS may not provide clinically important benefits on pain intensity or HRQoL when compared with placebo (sham) stimulation. These findings raise questions about how much of the observed benefits of SCS*

[2] O'Connell et al, 'Implanted Spinal neuromodulation interventions for chronic pain in adults', *Cochrane Database Syst Rev* 2021 Dec 2; doi: 10.1002/14651858.CD013756.pub2.

may result from the stimulation itself and how much may be the result contextual effects of receiving this complex, expensive and invasive intervention.'

In addition, Traeger et al[3] noted:

'Moderate-certainty evidence suggests there is probably no benefit of SCS over placebo on pain, function, or health-related quality of life in the medium term… our findings suggest SCS probably has little to no sustained benefit over placebo for people with low back pain.'

Hana et al[4] also noted:

"Among patients with chronic radicular pain after lumbar spine surgery, spinal cord burst stimulation, compared with placebo stimulation, after placement of a spinal cord stimulator, resulted in no significant difference in the change from baseline in self-reported back pain-related disability".

Contrary to when the consultant review was published in early 2023, compelling evidence now shows that outcomes for SCS do not support the efficacy of these devices.

There is, however, evidence of substantial harm. Over 1,500 individual Database of Adverse Events Notification reports have been lodged with the Therapeutic Goods Administration about SCS. Articular Surface Replacement hip systems and pelvic floor mesh devices were removed from sale with significantly lower adverse events reported. There is also a very high reintervention rate for SCS. In 2025, Jones et al[5] reported on 5,839 patients over a 10-year period in the Australian private health insurance setting. Their review, published in the Medical Journal of Australia, found:

"The cumulative probability of requiring surgical reintervention at 36 months was 0.35…. In the absence of convincing evidence for their efficacy for reducing chronic pain, their use should be reconsidered."

The Department has repeatedly received advice to reconsider guidelines on how these devices are used. The report highlights an overall lack of evidence, concerns over lack of robust scientific evidence (demonstrating that trial procedures are more effective than proceeding directly to permanent implantation), and concerns about patient selection. From the peer-reviewed literature, the Cochrane Reviews, and the expert opinion sought by the Department, there are significant concerns about the safety, efficacy and cost-effectiveness of these devices, in addition to questions raised about patient selection. While noting the current process is an impact assessment for adjusting benefits, the Department should act on the warnings provided by clinicians, academics and others.

PHA recommends the devices be referred to MSAC for their efficacy to be tested. This would examine the suitability of SCS for the Medicare Benefits Schedule (MBS) and the Prescribed List (PL) and provide much needed advice on under what circumstances, if any, these devices should be used. Our reading of the peer-reviewed evidence is that the devices would struggle to demonstrate safety

[3] Traegar et al, 'Spinal Cord Stimulation for low back pain,' Cochrane Database https://doi.org/10.1002/14651858.CD014789.pub2
[4] Hara et al, 'Effect of spinal cord burst stimulation vs placebo stimulation on disability in patients with chronic radicular pain after lumbar spine surgery: a randomized clinical trial', *JAMA*. 2022;328(15):1506-1514. doi:10.1001/jama.2022.18231
[5] Jones et al 2025.

and efficacy through the current processes. In the meantime, PHA supports the reduction of benefits payable by consumers for IPGs and leads.

Internal Pulse Generators

There is no justification for the price of IPGs for SCS to be higher than similar IPGs for vagal neurostimulation (VNS), sacral neurostimulation (SNS) and deep brain stimulators (DBS). DBS, SNS and VNS have all undergone MSAC assessment and have a rigorous basis for the benefits paid. Higher rebates for SCS simply provide supernormal profits at the expense of Australian consumers.

Prior to the recommended assessment by MSAC, PHA supported the findings of the consultant, the clinical advisory group and the Department to adjust the benefits payable for SCS devices in 04.05.01 – Pulse Generators by benchmarking against DBS devices in 04.04.01 – Implantable Pulse Generators.

Trial leads

There is no evidence that suggests trial procedures are effective. Despite the lack of evidence, the proposal would require consumers to pay in excess of $6,000 for the device component alone, for a procedure that has no evidence base. Noting the review has highlighted the need to re-examine guidelines, typically, funding is not available for procedures unless there is a demonstrated benefit to patients. While the draft report highlights "any HTA review of devices used in trials would be limited by the availability of high-quality evidence", this alone is a strong argument to remove funding support.

One of the fundamental weaknesses of the Prescribed List (PL) is that once a device is listed, it may be used for any procedure, regardless of quality, efficacy, value or even safety. This enables low value care to be funded, which is the case for trial leads.

Trial leads are available in several other countries,[6] [7] [8] [9] with one site listing prices starting at US$234.50. The draft department report notes that leads in subgroup 04.05.03.02 - Trial Leads are not currently available in Australia. This is because the suppliers are choosing not to offer the devices here. Instead, they have chosen to use permanent leads as trial leads, to increase their revenue. There is no additional benefit to the patient from this practice, simply a desire to maximise profits.

The consultant has concluded the trial leads are a redundant category, but the Department's draft report does not go into the reasoning behind this.

PHA notes that suppliers could easily stock trial leads here that are available overseas and should be required to do so at the cheaper price. Alternatively, a reduced benefit level should be applied regardless of the leads used, given there appears to be little difference.

[6] Spinal Cord Stimulation (SCS) 2022 Outpatient Hospital Reimbursement & Coding Reference Guide NEVRO link here.
[7] Neuromodulation – HCPCS Device Category C-Codes Coding Guide ABBOTT link here.
[8] Spinal Cord Stimulation – System Surgical Equipment Crosswalk to HCPS codes. Boston Scientific link here.
[9] Evoke SCS System Surgical Guide (P49) Saluda Medical link here.

There is no HTA justification for choosing devices that cost more than $6,000 – that are only used for a week or two – when there is no evidence the procedure makes a difference to the patient. This is wasteful spending that should not be supported by the Government.

PHA does recommend, however, that subgroup 04.05.03.02 - Trial Lead is retained. Given moves towards a Private National Efficient Price, the Department may consider using a bundled procedure approach with trial leads not listed individually, but with a code that suppliers can use for any trial lead or leads, at a cost of $876. An alphanumeric code could be added to the PL for the use of one or more trial leads for SCS (where MBS item 39134 is not billed), which any supplier could bill. Medical practitioners would still need to record the devices used as part of the medical record.

This will reduce administrative complexity for the Department and allow providers the opportunity to use any type of lead that meets relevant TGA guidelines.

Leads

PHA supports the findings of the consultant, the clinical advisory group and the Department in recommending reduced benefits for leads.

PHA further recommends that conditions be placed on the use of these devices, and that they should only be remunerated at the recommended rate where an IPG is placed (MBS item 39134). Where the same devices are used for trial procedures, they should be remunerated at the existing rate for subgroup 04.05.03.02 - Trial Lead ($438), possibly using a bundled approach as outlined above.

A key principle of HTA is that devices should be priced on function not the characteristics of the device. The trial for effectiveness is the same no matter what device is used and, as such, the trial cost should be the same irrespective of the lead used.

Accessories

PHA recommends that each of the accessories in the SCS category be removed, with the surgical tools being remunerated as part of the kit.

While the draft Department report does not specifically discuss accessories, the consultant's findings that PL suffices are not justified provides a precedent for removing the accessories from the PL. Further, the Department's abandoned regrouping review report from 2022 recommended removing these items from the PL.

Surgical tools for implanting SCS such as wrenches, tunnelling tools, insertion needles and lead anchors are each priced at $152 on the PL. The total cost to the consumer in 2022-23 for these devices was more than $600,000.

Since at least 2019, PHA has been asking the Department to remove these items from the PL. They are surgical tools not implanted in the patient. They have been placed on the PL as they were deemed to be specific and essential to implanting SCS. However, as surgical tools, they should not be eligible for reimbursement, let alone at such ridiculously high prices.

The $152 torque wrenches are simple tools to tighten screws. The $152 insertion needles and $152 tunnelling tools are simple pieces of shaped metal used in the surgeries. The $152 lead anchors are simple devices used to hold the leads in place.

None of these tools are complex and none deserve to be funded on top of the generous allowances for SCS generators and leads. Some providers do not even have these tools on the PL, yet all manage to implant the device at the base cost as part of the kit.

Specific Department questions

What impacts, if any, do you anticipate these changes will have on patients who are considering or receiving SCS therapy?

Consumers considering this therapy are unlikely to be affected. Medical devices on the PL do not attract a patient co-payment, so reducing the rebate should not affect supply. The equivalent devices for DBS, SNS and VNS are all able to be supplied at the price recommended for SCS.

What outcomes, if any, do you anticipate as a result of the proposed benefit adjustment?

PHA does not expect a change in the benefit level to change practice. It will simply reduce supernormal profits for international device companies, reducing profits to a level where the same companies are quite happy to provide equivalent IPGs for DBS, SNS and VNS.

Removing the lower benefits for trial leads will cause an increase in cost for consumers for trials involving any currently supplied genuine trial leads. It will also endorse the actions taken by sponsors that have chosen not to supply trial leads in Australia, increasing costs for consumers and promoting low value care. This proposal will validate one of the chronic flaws in the PL where suppliers can determine what items they offer in the market to maximise their revenue.

While unlikely, benefit changes may theoretically trigger an increase in the number of trials performed to offset lower benefits. This is not expected, as it would require medical practitioners to increase the number of trials undertaken. Medical practitioners are bound by professional ethics and law to act in the best interests of their patients (as they see it).

Reducing the benefits may also affect the funding available for sponsorships or other financial support from suppliers to clinicians and hospitals, which may influence health care decisions or policy outcomes.[10]

PHA hopes benefit reductions will provide opportunities for providers to reflect on the poor evidence base for this type of therapy.

[10] For example, industry funding provided for the Deloitte paper and PainAustralia paper cited in the draft report.

How do you expect the proposed benefit reduction to impact your coverage of SCS procedures? Will it change which levels of cover include SCS?

No. Overwhelmingly, health funds see SCS as an unproven therapy. It remains a technology that has been identified in Cochrane reviews as performing no more effectively than a placebo.

PHA acknowledges that for some people, an unproven therapy may be the best option where other treatment options have failed. We expect health funds will continue to consider ex-gratia requests for these patients.

Do you anticipate these changes could impact out-of-pocket costs for your members, if so, how?

The proposed changes should not increase out-of-pocket costs for consumers. Contracts between health funds and hospitals generally prohibit out-of-pocket costs for devices on the PL, and there is no justification for increased out-of-pocket costs for hospital costs or medical services – these mechanisms remain unchanged.

Statement of interests

PHA has not received any financial support or other consideration from suppliers or providers of SCS or related entities.

Conclusion

For people considering a spinal cord stimulator, it is important to ask clear questions: What is the evidence this device will improve my pain and function? What are the risks of complications or revision surgery? What are the total costs, including potential follow-up procedures? Are there non-surgical or multidisciplinary pain management options available? Patients should feel empowered to seek a second opinion before proceeding.

Australians should be confident they are receiving a safe, evidence-based medical treatment that represents value for money. Continuing to fund devices that may cause harm, at enormous cost to patients, taxpayers and health fund members, undermines that confidence.

While reducing benefits is welcomed, it is insufficient to provide Australians with confidence that SCS are safe, effective and value for money. Across the three stages of the review, multiple experts have called for a reconsideration of how these devices are used. Referring these devices to the MSAC will ensure that SCS are assessed by modern standards.