Australian Government
Department of Health, Disability and Ageing

Spinal cord stimulator post-listing review

DRAFT Department report – February 2026

Purpose

The purpose of the spinal cord stimulator (SCS) post-listing review was to determine if the benefits for devices in the subcategory *04.05 - Neurostimulation therapies for pain management* represent comparative clinical and cost effectiveness.

The purpose of the draft department report is to summarise the review process to date and outline the proposed recommendations. The report is provided as a draft for stakeholder feedback on the proposed recommendations. The department will consider all stakeholder feedback before finalising the recommendations for delegate decision.

Background

In the 2021-22 Federal Budget, the Australian Government announced an investment of $22 million over four years to improve the Prescribed List (PL) and its arrangements. A process for formalised post-listing reviews was introduced as part of the reforms. Post-listing reviews of devices on the PL help ensure that Australians, with relevant health insurance cover, continue to have access to appropriate, clinically effective devices that meet their healthcare needs.

The post listing review framework was first published online in June 2022. The framework promotes a consistent approach to each review while providing flexibility to accommodate different review requirements. SCS were identified as 1 of the 4 topics suitable to pilot a draft post-listing review framework. Reasons included:

- a review by Jones et al in 2022[1] raised concerns about the long-term benefit and safety profile of SCS
- prior to being listed on the PL, SCS were not assessed by the Medical Services Advisory Committee (MSAC) or the Prostheses List Advisory Committee (PLAC) (now the Medical Devices and Human Tissue Advisory Committee (MDHTAC)).

Scope

Devices in the subcategory *04.05 - Neurostimulation therapies for pain management,* excluding peripheral nerve stimulators.

TGA review

The Therapeutic Goods Administration (TGA) completed a post market review of SCS in 2024. The TGA review only focused on safety and performance of SCS devices. The TGA review resulted in cancellation of some SCS devices from the Australian Register of Therapeutic Goods (ARTG) and imposed conditions on the inclusion of the remaining SCS

[1] Jones CMP, Shaheed CA, Ferreira G, Mannix L, Harris IA, Buchbinder R, Maher CG. Spinal Cord Stimulators: An Analysis of the Adverse Events Reported to the Australian Therapeutic Goods Administration. J Patient Saf. 2022 Aug 1;18(5):507-511. doi: 10.1097/PTS.0000000000000971. Epub 2022 Jan 24. PMID: 35067619; PMCID: PMC9329040.

devices in the ARTG. The TGA required changes to labelling to improve information about the risks associated with SCS and to clarify the indications and contraindications for use. There were also requirements for providing further information about the lifespan and performance of the devices. More information can be found here.

Process

This review was conducted in 3 stages. Each stage involved different research questions, based on findings from the previous stage and MDHTAC advice.

Sources of evidence

Multiple sources of evidence were considered as part of the review. A description of each source is in the table below.

Source	Description
External health technology assessment (HTA) consultant report: Stage 1 evidence review	Analysis and evaluation of comparative clinical and cost effectiveness evidence
Pain Australia consumer experience report (December 2023)	Report on consumer experience from pain advocacy group
Outcomes from the TGA post market review (December 2024)	Advice about changes to ARTG listing of devices including cancellations
Expert HTA advice: benefit setting	Expert HTA advice comparing different types of neurostimulator implantable pulse generators (IPG) and leads on the PL
Internal data – Hospital Casemix Protocol (HCP)1	Review of HCP1 data on use of PL SCS devices
Stakeholder input (throughout the review)	• written submissions • stakeholder meetings including sponsors and clinical associations to understand device use • feedback on Stage 1 report
External HTA advice: benefit setting	Expert HTA advice comparing the benefits of SCS IPG and deep brain stimulation (DBS) IPG
External HTA advice: benefit setting	Expert HTA advice to assess the use of leads in SCS trial procedures and review the benefits payable for SCS leads
Best Practice Guidelines for Neuromodulation in Pain Management: Insight from the Neuromodulation Society of Australia and New Zealand (May 2025)	Australian evidence-based best practice guidelines for SCS in chronic pain management
MDHTAC and SNECAG advice	Expert advice on direction of the review and outcome options for the department to consider

Findings of the review

Stage 1

The department engaged an external HTA consultant (consultant) to assess the comparative clinical and cost effectiveness of SCS. The consultant found that, overall, the evidence for clinical effectiveness of SCS was uncertain. The consultant sought stakeholder feedback on the draft report and finalised it in September 2023 (available on our website). The report recommended SCS devices continue to be listed on the PL and advised that a cost effectiveness analysis to establish a suitable benefit was unlikely to be informative. The MDHTAC discussed the consultant report at its December 2023 meeting. MDHTAC advised the department to consider reviewing the benefits payable for SCS. This initiated Stage 2 of the post-listing review.

Please note. Some recommendations in the consultant's report, such as develop high-quality clinical guidelines were outside the Technology Assessment and Access Division (TAAD) remit. These recommendations were not considered as part of the review.

Stakeholder input into Stage 1 also identified that permanent leads are used in SCS trial procedures, and this issue was referred to Stage 2.

Stage 2

The department considered options to review the benefits payable for SCS devices (including the implantable pulse generator and leads). Expert advice noted that SCS devices attract a substantially higher benefit than other neurostimulation devices on the PL, with no clear reason for the discrepancy. The department engaged the consultant to provide advice on the potential to benchmark benefits payable for SCS devices against the following neurostimulation devices on the PL:

- vagal neurostimulation (VNS)
- sacral neurostimulation (SNS)
- deep brain stimulators (DBS).

PL listing of SCS predates the MSAC assessment process, but DBS, SNS and VNS have all undergone MSAC assessment. The consultant summarised the MSAC assessments and their outcomes and evaluated current PL benefits for SCS devices compared to other neurostimulators.

Consultant findings:

- permanent leads have comparable PL benefits across SCS, VNS, SNS and DBS
- SCS IPGs have a higher benefit compared to IPGs for other neurostimulators, without a clear justification.

Consultant recommendations:

- non-rechargeable IPG:

    - reduce the PL benefits by 43% in line with non-rechargeable VNS (mid-point of the 3 comparators).
- rechargeable IPG:
    - reduce the PL benefits by 43% as per non-rechargeable devices (there are no rechargeable VNS on the PL), or
    - assess the likely cost savings associated with rechargeable devices to determine a suitable benefit.

MDHTAC discussed the consultant findings and recommendations at the September 2024 meeting. The MDHTAC noted that DBS have demonstrated clinical and cost-effectiveness. The MDHTAC advised the department to consider benchmarking the SCS IPG benefits to the DBS IPG benefits. This initiated Stage 3 of the post-listing review.

Leads

Stakeholder input into Stage 1 identified that leads in subgroup *04.04.03.01 - Permanent Lead* are used in SCS trial procedures. This is despite a dedicated PL subgroup for trial leads *04.05.03.02 - Trial Lead*, which has a significantly lower benefit. The department spoke with clinical stakeholders and sponsors in December 2024 to understand more about the type of leads claimed in a SCS trial procedure. The stakeholder consultation identified:

- the funding source for devices used in a trial varies between sponsors: some sponsors provide some components at no charge; some components are reused between patients; and some components are reimbursed through the PL
- leads in subgroup *04.05.03.02 - Trial Lead* are not currently being supplied in Australia
- leads in subgroup *04.04.03.01 - Permanent Lead* are used in both trial and permanent SCS implants
- in most cases, leads used in a SCS trial are removed after the trial is complete
- new leads are implanted if a patient goes onto have a permanent SCS after a successful trial
- sponsor technicians provide varying levels of support to surgeons, such as device programming during and/or after the procedure and patient monitoring.

After reviewing these findings, the department obtained expert advice on the types of leads and the benefits payable as part of stage 3.

Stage 3

Implantable pulse generators

As per MDHTAC advice in Stage 2, the consultant was asked to provide revised benchmarking of SCS IPG (in grouping 04.05.01 - Pulse Generators) compared to DBS IPG.

The consultant compared suffixes[2] and features across SCS and DBS IPG and examined the MSAC assessment of DBS to understand cost-effectiveness and clinical justification.

Consultant findings:

- suffixes associated with advanced features in SCS are no longer relevant and do not justify higher benefits
- non-rechargeable SCS IPG are suitable to be benchmarked against dual channel DBS IPG
- rechargeable SCS IPG are suitable to be benchmarked against rechargeable dual channel DBS IPG.

The consultant recommended the following adjustment to the benefits for SCS IPG:

Device type in 04.05.01 - Pulse Generators	SCS IPG current benefits	DBS IPG benefits	Proposed SCS IPG benefit	Difference (%)	Billing codes impacted
Non-rechargeable	$21,660	$13,592 (dual channel)	$13,592	-37.3%	SJ379, SJ389, SJ432, BS383
Rechargeable	$23,465	$17,283 (dual channel)	$17,283	-26.3%	UY003, BS389, QQ660, SJ374, BS330, WW003, WW021

MDHTAC discussed the consultant findings and recommendations at their May 2025 meeting. The MDHTAC agreed with the proposed benefits and advised the department to consider reducing the benefits as per the recommendation.

Leads

The consultant was asked to provide expert HTA advice on:

- the characteristics and differences in technology between leads with different benefit settings
- the composition, structure and function of trial leads (on the ARTG or internationally) compared to permanent leads
- the practice of using leads in a trial procedure
- options to determine the appropriate benefit for leads when used in a SCS trial procedure.

[2] Suffixes are part of the Prescribed List grouping scheme. There are 13 categories of devices on the PL. The categories have subcategories, groups, and subgroups that are identified numerically; and in some instances, they have suffixes, which are identified alphabetically. The final benefit point is the 'grouping'. The grouping schemes determines the benefits payable for a device. Each grouping has an individual benefit amount assigned.

The consultant used PL and MBS claims data, publicly available product information, and conducted a desktop review of comparative clinical and cost-effective evidence.

Consultant findings:

- leads, in trial procedures can be used according to 2 different approaches: 'temporary' where the lead/s are removed after the trial or 'permanent' where the lead/s are retained and used with the IPG after successful trial. No evidence was identified to support one approach over the other and there is international variation
- no evidence was identified to suggest leads used in temporary trial procedures differ in composition or structure compared to leads used in permanent procedures
- leads listed in subgroup *04.04.03.01 - Permanent Lead* are used for both trial and definitive procedures. No strong evidence was identified to justify higher benefits for:
    - paddle leads (However, paddle leads have low usage and tend to only be used for a select group of patients)
    - leads with higher numbers of electrodes

Consultant recommendations:

- consider removing subgroup *04.05.03.02 - Trial Lead* from the PL due to redundancy
- consider removing external pulse generators (EPGs) from the PL
- consider removing accessory devices that are known to be packaged in kits with leads (e.g. lead anchors, epidural needles, tunnelling tool) from the PL
- for leads listed in subgroup *04.04.03.01 - Permanent Lead:*
    - consider separating surgical and percutaneous leads
    - for paddle leads, consider a benefit that is 1.5 times that of percutaneous leads (Option 1 in table below)
    - consider reducing or removing the benefit premium for 8 electrodes or more (Option 2 in table below)

Device type in 04.05.03.01 - Permanent Lead	Suffix	Current Benefit	OPTION 1 proposed Benefit	Difference (%)	OPTION 2 proposed Benefit	Difference (%)
Percutaneous lead	4 electrodes	$3,041	$3,041 (all billing codes)	-	$3,041	-
	8 electrodes	$3,817		-20.3%	$3,817	-
	>8 electrodes	$6,895		-55.9%	$4,593	-33.4%
	>8 electrodes bifurcated proximal tail	$8,123		-62.5%	$5,821	-28%
Epidural paddle lead	greater than 8 and less than 32 electrodes	$6,895	$4,561.50 (all billing codes)	-33.8%	$5,725.50	-29.5%
	greater than 8 and less than 32 electrodes, bifurcated proximal tail	$8,123		-43.8%	$6,953.50	-14.4%
	≥32 electrodes	$11,011		-58.6%	$6,501.50	-40.9%

The MDHTAC discussed the consultant findings and recommendations at their May 2025 meeting. The MDHTAC agreed with the proposed benefits in Option 1 and advised the department to consider reducing the benefits as per Option 1. The MDHTAC agreed with the proposed removal of subgroup *04.05.03.02 – Trial Lead* from the PL due to redundancy. The MDHTAC advised the department to consider reviewing the benefits payable for leads when used in a SCS trial procedure.

Benefits payable for leads used in trial procedures

As per MDHTAC advice the department considered reviewing the benefits payable for leads when used in a SCS trial procedure. The department reviewed:

- HCP1 data on claims for leads used in spinal cord stimulator trial procedures
- Best Practice Guidelines for Neuromodulation in Pain Management: Insight from the Neuromodulation Society of Australia and New Zealand 2025

The Spinal and Neurosurgical Expert Advisory Committee (SNECAG) discussed leads used in trial procedures at the October 2025 meeting. The department requested SNEGAC advice on:

- current clinical practice and the impact of the recently published guidelines
- assessing cost effectiveness of the devices used in trial procedures
- the direction of the review for the department to consider.

The SNECAG noted:

- spinal cord stimulation (SCS) is a complicated matter and different clinicians (e.g. pain care physicians, and spinal and neurosurgical surgeons) often have different opinions regarding SCS trial procedures
- concerns over lack of robust scientific evidence demonstrating that trial procedures are more effective than proceeding directly to permanent implantation of SCS IPG and leads. Prior to trial procedures, patients need to undergo a comprehensive clinical assessment to determine suitability, and obtaining the second opinion is considered best practice given the likely unintended consequences
- patients selected for SCS trials often belong to vulnerable cohorts with significant comorbidities.

The SNECAG advised the department to:

- review all available guidelines relating to trial SCS procedures to ensure information is objective and comprehensive and includes inputs from all states and territories, and different perspectives of both pain management physicians as well as spinal and neurosurgical surgeons.
- expressed support to assess both the clinical and cost-effectiveness of trial procedures.

The department discussed SNECAG's advice at the December 2025 MDHTAC meeting. It was noted that there are no further actions for the PL as the advice relates to an overall procedure perspective which is out of scope. The department noted that the review found the comparative clinical effectiveness of SCS versus standard care remains uncertain. Consequently, any HTA review of devices used in trials would be limited by the availability of high-quality evidence. However, this situation may change if further evidence on clinical and cost-effectiveness is published. SNECAG's advice has been passed onto the relevant areas of the department

Proposed outcomes

The proposed outcomes have been developed based on MDHTACs advice on the findings of the review. The proposed outcomes are outlined for stakeholders to provide feedback to the department before the review is finalised and the proposed outcomes presented to the Delegate for decision.

IPG outcomes

- **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*.**

The proposed benefit amounts are below:

Device type in 04.05.01 - Pulse Generators	SCS IPG current benefits	Proposed SCS IPG benefit
Non-rechargeable	$21,660	$13,592
Rechargeable	$23,465	$17,283

Lead related outcomes

- **Remove subgroup 04.05.03.02 – Trial Lead.**
- **Remove suffices for SCS devices in *04.05.03 – Leads***
- **Adjust the benefits for paddle and percutaneous leads.**

The proposed benefit amounts are below:

Device type in 04.05.03.01 - Permanent Lead	Number of electrodes	Current benefit	Proposed benefit	Other changes
Percutaneous lead	4 electrodes	$3,041	$3,041	Suffices removed
	8 electrodes	$3,817		
	>8 electrodes	$6,895		
	>8 electrodes, bifurcated proximal tail	$6,895 - $8,123		
Epidural paddle lead	>8 and <32	$6,895 - $8,123[a]	$4,561.50	Suffices removed
	>32	$11,011		