From: s22
To: s22
Cc: s22 ,s47E(d) ; s22
Subject: FW: RE: FOR FEEDBACK: Terms of Reference - Spinal cord stimulators [SEC=OFFICIAL]
Date: Monday, 28 November 2022 1:58:00 PM
Attachments: image002.png
image003.png

Hi s22

Thank you for this. s22 and I have added our comments to the document in TRIM. s22 agrees with our comments and will review a subsequent version.

From our review of the document, it looks as if you have produced a description of services, including broad research questions, to be included in the contract for HereCo. I have included comments on the document as if they are research questions/description for services to be used in the contract (rather than ToRs).

The Terms of Reference are generally broader and meant for publishing on the web/distribution to stakeholders. They are more high level than the research questions and are used to guide and state the aims of the review.

The research questions are between the Department and HereCo, and will generally be more detailed and descriptive that the Terms of Reference. This is where we break down what we want the contractor to do, so research questions necessarily have to include more technical detail than the terms of reference.

Hope this helps.

Kind regards,

s22
Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Australian Government Department of Health and Aged Care
☏ (02) 6289 s22 | s22 @health.gov.au
Location: Level 16, 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

s22

I acknowledge the traditional custodians of the lands and waters where I live and work, and pay my respects to elders past, present and future.

From: s22 @health.gov.au>
Sent: Monday, 28 November 2022 9:10 AM

To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: FOR FEEDBACK: Terms of Reference - Spinal cord stimulators [SEC=OFFICIAL]

Hi s22

The TRIM version is the most updated one - D22-3463390
I've also attached the document here for your review.

Thanks
s22

From: s22 @health.gov.au>
Sent: Monday, 28 November 2022 10:02 AM
To: s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: FOR FEEDBACK: Terms of Reference - Spinal cord stimulators [SEC=OFFICIAL]

s22, can you send the most recent version of the ToRs for us to review?
Thanks
s22

From: s22 @health.gov.au>
Sent: Thursday, 24 November 2022 12:49 PM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: FOR FEEDBACK: Terms of Reference - Spinal cord stimulators

Good Afternoon All

Please find attached the final Terms of reference (D22-3463390) for the post-listing review of spinal cord stimulators.
Let us know if you have any comments/feedback on the ToR before we share it to Hereco next week.
I would appreciate any changes/comments tracked in TRIM document by **COB next Wednesday 30 Nov 2022**.

Background on the Review
The Department has commenced the spinal cord stimulators review and engaged an external consultant, Hereco to undertake the review using a focused Health Technology Assessment (HTA) approach. This review will focus initially on the assessment of comparative clinical effectiveness that will lead to an economic assessment of the comparative cost effectiveness.

Thank you!

Best regards,

s22
Assistant Director – Prostheses List Reform Taskforce
Technology Assessment & Access Division | Health Resourcing Group
Australian Government, Department of Health and Aged Care
T: 02 6289 s22 @health.gov.au
Location: Sirius 9.N.200
PO Box 9848, Canberra ACT 2601, Australia

The Department of Health and Aged Care acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.

From: s22
To: s47F @hereco.com.au"
Cc: s22
Subject: FOR ACTION: Review scope - Spinal cord stimulators review [SEC=OFFICIAL]
Date: Thursday, 1 December 2022 3:27:00 PM
Attachments: Review Scope - Spinal Cord Stimulators Review.DOCX

Hi s47F

Hope you are well.

Following on from our meeting a couple of weeks ago about spinal cord stimulators review, please find attached the review scope which outlines the scope of the review including timelines.

As discussed during the meeting, we are expecting that the review will be undertaken under the existing official order in place with PLRT for focussed HTA services.

I am going to book a meeting next week for us to catch-up again where we can discuss any queries/issues you might have with the review scope.

In the meantime, please let us know if you have any concerns.

Thanks & regards
s22

Australian Government
Department of Health and Aged Care

Prostheses List Reform Taskforce
Technology Assessment and Access Division

Prostheses List Post Listing Review - Spinal cord stimulators

Review scope

Introduction

Spinal cord stimulators are devices implanted under the skin, which treat chronic pain by delivering electrical impulses via leads placed in the epidural space. The following devices are outside scope of this review: peripheral nerve stimulators, sacral nerve stimulators and vagal nerve stimulators.

Concerns have been raised about the long-term safety and effectiveness of spinal cord stimulators. Prostheses List (PL) expenditure on the group 04.05.01 Pulse Generators has been relatively stable since 2016 at around $30 million per year for around 1400-1500 devices. Pulse generators are the major expense item for the subcategory 04.05 Neurostimulation Therapies for Pain Management (total annual expenditure around $55-60 million), which also includes external components, leads, lead extensions, revision kits and accessories.

The Department of Health and Aged Care (DOHAC) has commenced this post-listing review in accordance with the post-listing review framework. An external reviewer (Contractor) has been engaged by the Department to undertake the assessment while consultation and liaison with sponsors and other stakeholders will be undertaken by the Department.

The Contractor will assess the comparative clinical effectiveness and cost effectiveness of spinal cord stimulators currently listed on the Prostheses List (PL), in accordance with the *PL Guide to listing and setting benefits for prostheses* and advise the department on appropriate actions and/or policy considerations (if any).

Services to be provided:

Q 1. Determine which types of devices are in scope by reviewing the devices listed in the PL subcategory - *04.05 Neurostimulation therapies for pain management* to identify those that are used or can be used for spinal cord stimulation.

Q 2. Review the following key documents provided by DOHAC to the extent that the materials inform the assessment i.e. comparative clinical effectiveness and cost effectiveness:

- Information and submissions from sponsors
- Information and submissions from stakeholders (including relevant clinical guidelines)
- The TGA literature review that forms part of the TGA's post market review of spinal cord stimulators (which incorporates key literature including the 2021 Cochrane review: *Implanted spinal neuromodulation interventions for chronic pain in adults*) and further TGA updates as available.
- The 2019 Deloitte report 'Cost effectiveness of pain devices' written for the 'Neuromodulation Society of Australia and New Zealand' and a complete budget impact model provided by Nevro Medical with consent to share.
- The PLRT *Utilisation Review of Spinal Cord Stimulators* (incorporates Case Mix and MBS data) and accompanying agenda item provided to May 2022 PLAC and a copy of the PLAC advice.
- The 2022 Cochrane review: *Spinal cord stimulation for low back pain* will be incorporated into the review if/when it becomes available.

Q 3. Summarise the knowledge/evidence base regarding comparative clinical effectiveness of the in-scope spinal cord stimulators (the appropriate comparator may be standard care, or alternative therapeutic approaches).

Q 4. Conduct a targeted, systematic literature review of the evidence regarding cost effectiveness of spinal cord stimulators.

Q 5. Based on the information and evidence in Q1-4, and guided by the PL Post Listing Review Framework, compile information to support the Department to assess what actions or policy initiatives should be considered with regards to devices used for spinal cord stimulation for chronic pain.

The Contractor may also consider and provide advice or comment on other related matters identified during the review.

The Contractor will provide the following deliverables:

1. Complex Focused HTA Report

   The Contractor will collate the review findings and discussion into a written report*. This will include:

   - method for determining the type of devices that are in-scope
   - method for document analysis
   - systematic review protocol including: methodology, inclusion/exclusion criteria, outcomes of interest, quality assessment of included studies
   - a glossary with definitions for key clinical terms
   - an executive summary
   - technical written report of the literature review
   - methodology used for the document review, stakeholder and sponsor submissions, literature review and guidelines
   - quality assessment of the evidence used in the report
   - conclusions in relation to each of the research questions
   - further research policy considerations as appropriate

2. An initial draft report will be provided to the Department for consultation with stakeholders and sponsors.
3. A final report that incorporates feedback provided by the Department, sponsors and other stakeholders.

The final report is to be accepted by the Department prior to the completion of the review. This report should include identification of Commercial in Confidence (CIC) information for redaction as well as other safeguards that are included in the Official Order.

*The Department will provide an example of a report template to the Contractor to use as a guide, noting that the final report will be the Contractors' product and isn't required to be on the Departments' report template.

Further assistance to help guide the design of the final report:

- report is to be provided in .doc or .docx format
- use default styles and structural headings
- use true numbered and bulleted lists by using the formatting tool
- use tables rather than tab stops or carriage returns
- provide alternative text for images and graphics
- link all hyperlinks and provide meaningful hyperlink text
- include an automatically generated table of contents

- not use colour as the only way to convey meaning
- comply with the Level AA accessibility requirements in the Web Content Accessibility Guidelines 2.0 (available at Web Content Accessibility Guidelines)
- Comply with World Wide Web Access: Disability Discrimination Act Advisory Notes, version 4.0 (2010), released by the Australian Human Rights Commission (available at Human Rights Commission website).

Timeframe

The Contractor is required to provide the Services in accordance with the timeframes specified in the table below *(reference is the service designation - Complex Focused HTA Report that is costed on the basis of 30 days in the Official Order).*

Deliverable	Date Due	Fees (excl GST)
Commence	9 January 2023	s47G
Draft report	20 February 2023	
Final report	27 March 2023	

SCHEDULE 6
OFFICIAL ORDER

Australian Government

Department of Health and Aged Care

Official Order under Deed of Standing Offer (Head Agreement for Services) Deed of Standing Offer number – 3599169 – 04

Customer details	**Contractor details**
Technology Assessment and Access Division Office of Health Technology Assessment Branch Prostheses List Administration ABN: 83 605 426 759 MDP 959 GPO Box 9848 Canberra ACT 2601	Closed Loop Design Pty Ltd ABN: 59 142 272 464 Director Operations PO Box 308 Westgate NSW 2048
Customer Contract Liaison Officer: Contracts Officer, s22 Telephone: 02 6289 s22 Email: s47E(d) @health.gov.au	**Contractor Contract Liaison Officer:** s47F Telephone: s47F Email: s47F @hereco.com.au

This Official Order is placed pursuant to and subject to the terms and conditions of the Deed of Standing Offer (Head Agreement for Services) between the **Department of Health and Aged Care** and **Closed Loop Design Pty Ltd** dated **17 June 2019.**

Note to Contractor: If you wish to provide the Services to the Customer, please sign this Official Order and send it to the Customer. If the Customer wishes to accept your offer to provide the Services, it will execute the Official Order and return a copy of the executed Official Order to you. You must not supply the Services until after you have received the copy of the executed Official Order from the Customer.

Service	**Detail**
Service Description	The Contractor will provide up to 20 Focused Commentaries or other HTA reports to inform considerations on the Prostheses List (PL)
Cost	s47G
Date services to commence on	On signing by the Department
Date services to be completed by	As per Item 2 of the Official Order
Contract End Date	30 June 2023

Service	Detail
Extension Option	Extension option is available for this Official Order depending on funds availability

Invoices are to be issued to s47E(d) [redacted] @concursolutions.com **with attention to the Customer Contract Liaison Officer named above.**

Internal codes for Customer Purposes Only

Internal Code	Insert code number
Cost Centre	s47E(d) [redacted]
Charge Code	
SAP Contract #	
SAP PO#	

For fees and rates, see Item 3.

1. The Services and subcontractors

Department is seeking services to provide up to 20 Focused Commentaries or other HTA reports to inform considerations for listing or assessing products on the Prostheses List (PL).

The Contractor agreed that these services are categorised as follows:

i. **Standard Focused Commentary** on a sponsor's application for listing a prosthesis on the PL. This would typically be for one simple PL application. The services would include one or more of the following: a literature scan for evidence that may have been omitted from the application; repackaging of clinical data in a format that is more informative for committee deliberations; a detailed comparison of device characteristics; no or limited economic analysis; a Rejoinder to the sponsor's Response to the Focused Commentary.
The fees proposed in Section 5 allow for ten (10) Standard Focused Commentaries.

ii. **Complex Focused Commentary** on a sponsor's application(s) for listing one or more prostheses on the PL. This would typically be for multiple related PL applications or a complex single application. The services would include one or more of the following: a literature scan for evidence that may have been omitted from the application; re-extraction and analysis of clinical data; a detailed comparison of device characteristics; economic analysis (excluding cost-utility analysis, which requires consideration via the MSAC pathway); a Rejoinder to the sponsor's Response to the Focused Commentary.
The fees proposed in Section 5 allow for eight (8) Complex Focused Commentaries.

iii. **Other HTA reports**, as required.
This includes development of HTA approaches for addressing specific clinical or economic issues related to the assessment of prostheses.
The fees proposed in Section 5 allow for two (2) of these reports.

The Contractor proposes that the designation of each service (as either a Standard Focused Commentary, a Complex Focused Commentary or Other HTA report) is agreed in writing at the commencement of each project. However, once a service commences there may a requirement to change the designation (i.e. from a Standard to a Complex Focussed Commentary, or vice versa). Any requests to change the designation would be made as soon as practicable and would contain clear justification for the requested change.

The Contractor understands that milestones, deliverables and requirements may change at the request of the Department, particularly for Other HTA reports.

Performance Management Framework

If marked 'yes' below, the Contractor is required to undertake a self-assessment against the Performance Management Framework to assess its performance of the Services provided under this Official Order.

x Yes ☐ No	If yes, (mark one or more below for frequency) x Upon request of the Customer. ☐ Every 12 months during the term of the Official Order. ☐ End of the term of this Deed.

2. Time frame

The Contractor is required to provide the Services in accordance with the timeframes for draft and final versions of deliverables as agreed by the Department in writing at the commencement of each project. The Contractor may supply the deliverable earlier than the previous negotiated timeframe. The final document for any deliverable must be of a standard acceptable to the Department.

Timeframes will take into account the relevant circumstances, which may include the timing of Clinical Advisory Group (CAG) and Prostheses List Advisory Committee (PLAC) meetings, the need for consultation with third parties (including the Medical Services Advisory Committee [MSAC]), and whether the sponsor will be given an opportunity to respond to the Focused Commentary or report.

In situations where timelines are particularly short or multiple deliverables have competing delivery dates, the Contractor will discuss existing commitments and deadlines for the Contract with the Department so that priorities are agreed and resources allocated accordingly.

On signing the Official Order the Contractor has agreed to meet all timeframes/deliverables listed above. If for any reason the Contractor cannot fulfil their contractual obligation then they must, as soon as possible:

a. Advise the Department in writing their non-compliance of the agreed deliverables in the Official Order;
b. Identify the reason for not meeting the agreed deliverables;
c. Identify the component/s that cannot be delivered within the required timeframes; and
d. Advise the HTA Contracts Team in writing identifying the risk and seek a resolution agreeable to both the Department and Contractor.

3 Fees, allowances and costs

The maximum Contract Price inclusive of GST and all taxes and charges will not exceed s47G (GST incl.) as set out below.

As per the Deed, the fee for Service Category 2 (Research Support and other services) is s47G (excluding GST) per day (7 hours) per staff member.

The table below shows the fee for each of the services proposed in Section 4, based on the average estimated number of days' work per Service designation.

Service Designation	Number of days	Fee per service (excl GST)
Base Focused Commentary	5	s47G
Complex Focused Commentary	10	

Service Designation	Number of days	Fee per service (excl GST)
Base Focused HTA Report	20	s47G
Medium Focused HTA Report	25	
Complex Focused HTA Report	30	
Other HTA Reports	To be agreed (TBA) on a case-by-case basis	To be agreed, based on daily rates in the current Deed

The total fee for services is based on the relative mix of 20 Deliverables as indicated in the table below. However, the Contractor is willing to accept an alternative mix of Deliverables based on the Fee per Deliverable defined in the table above and recognises that the actual mix of Deliverables in practice is difficult to predict.

Although 'Other HTA Reports' have not been individually costed, it is assumed they would be included within the overall maximum amount agreed for the contract.

Service Designation	Number of services	Total fee per service type (excl GST)
Base Focused Commentary	12	s47G
Complex Focused Commentary	4	
Base Focused HTA Report	2	
Medium Focused HTA Report	1	
Complex Focused HTA Report	1	
Other HTA Reports	TBA	not costed separately
Total number of services	20	
Total fee excl GST		s47G
GST amount		
Total fee incl GST		s47G

The Contractor understands that travel, accommodation or other expenses associated with the delivery of these services cannot be claimed, unless agreed and approved by the Customer's representative prior to booking.

The due date for payment is 21 days after delivery of a correctly rendered invoice to the Department.

4. Specified Personnel

The Specified Personnel for this project will be s47F.

5. Customer Material to be provided by Customer

The Customer may be provided with meeting papers or documents that are commercial-in-confidence or committee-in-confidence to assist with the development of the Contract Material. These are to be kept secure and at the end of the Contract Period, or as otherwise requested by the Customer, securely destroyed.

The Customer may provide the Contractor with documents throughout the life of the Contract which are to be considered Customer Material.

6. Existing Material

Prostheses List application being assessed under the Official Order.

7. Contract Material

The Contractor must provide the following Contract Material:

- Draft focused commentary; and
- Final focused commentary in accordance with the guidelines provided by the Department;
- Any written questions and answers that may arise during development of the focused commentary

The Contractor must ensure that any Contract Material which is to be placed on a Departmental website or the intranet complies with the:

Level AA accessibility requirements in the Web Content Accessibility Guidelines 2.0 (available at Web Content Accessibility Guidelines); and

World Wide Web Access: Disability Discrimination Act Advisory Notes, version 4.0 (2010), released by the Australian Human Rights Commission (available at Human Rights Commission website).

8. Confidential Information

The Contractor confirms that all Contract Materials provided by the Department shall be regarded as confidential Information.

9. Customer facilities and assistance

No Customer facilities or assistance is required.

10. Invoice procedures

The Contractor must forward correctly addressed invoices that are in the form of a tax invoice and include the following:

- the title of the Services or other identification of this Contract;
- the name of the Customer Contract Liaison Officer;
- the fees, allowances and costs due; and
- a written statement signed by the Contractor, or where the Contractor is a body corporate, by a representative of the Contractor authorised to sign on behalf of the body corporate, verifying that no wages are due and owing by the Contractor in respect of the performance of the Services at the time the claim for payment is made.

10A Use of Material – Service Category 1 – Health Technology Assessment Services

The Contractor agrees and confirms the requirements under 10A of Schedule 2 in regard to the use of any material provided to the Contractor by the Customer or third party.

11. Use of Material – Service Category 1 – Health Technology Assessment Services

The Contractor agrees and confirms the requirement under clause 16A of Schedule 2 in regards to undertaking any new work in respect of any application for service category 1.

The Contractor agrees and confirms the warranties provided under clauses 23 (m) and (n) of schedule 2 are correct and up to date.

This Contract/Official Order is **SIGNED** as a Contract.

SIGNED for and on behalf of the **COMMONWEALTH OF AUSTRALIA** as represented by the **Department of Health and Aged Care**, ABN **83 605 426 759** on:

12 September 2022
.....
Date

by:

s22

.....
Printed name of signatory

s22

.....
Signature

Director, Prostheses List Administration
.....
Position of signatory

in the presence of:

s22

.....
Printed name of witness

s22

Signature

SIGNED for and on behalf of **Closed Loop Design Pty Ltd**, ABN **59 142 272 464** on:

8 Sep 2022
.....
Date

by:

s47F

.....
Printed name of Director

s47F

.....
Signature of Director

and:

s47F

.....
Printed name of Director/Secretary

s47F

.....
Signature of Director/Secretary

Prostheses List Advisory Committee

Meeting #32

Thursday 12 May 2022

Videoconference

Attendees

Chair

Emeritus Professor Terry Campbell AM

s47F

Department of Health

Ms Adriana Platona, First Assistant Secretary, Technology Assessment and Access Division

Ms Tracey Duffy, First Assistant Secretary, Medical Devices and Product Quality Division, Therapeutic Goods Administration

Ms Elizabeth Flynn, Assistant Secretary, Prostheses List Reform Taskforce

s22 , Director, Prostheses List Administration

Dr Megan Keaney, Senior Medical Adviser, Technology Assessment and Access Division

Dr Jeff Brownscombe, Senior Medical Adviser, Prostheses List Reform Taskforce

Department of Veterans' Affairs

s47F

Apologies

s47F

Departmental support

Prostheses List Administration Section, Prostheses List Reform Taskforce; and HTA Support Unit, Office of Health Technology Assessment

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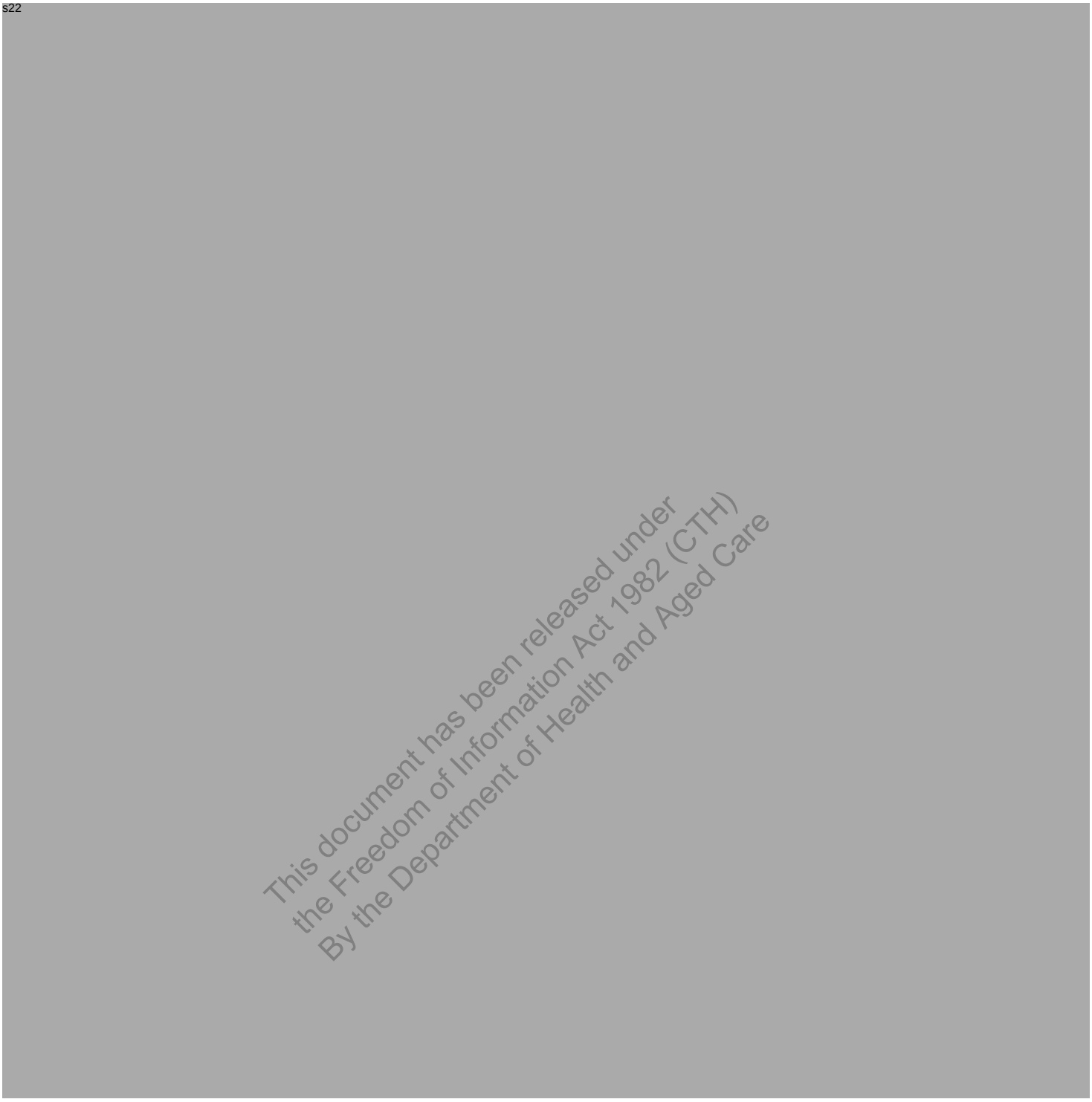

8.1 Proposed Reviews

8.1.1 Review of spinal neurostimulators

Private Healthcare Australia (PHA) wrote to the Department regarding a journal article raising concerns about the long term safety and performance of spinal cord stimulators used for pain management that triggered consideration of these issues.

The Department advised that these devices became available on the market before the advent of the Medical Services Advisory Committee (MSAC), and that they have never undergone health technology assessment for comparative clinical effectiveness and cost effectiveness. Spinal neurostimulators are high-cost devices and the PL benefit expenditure has increased significantly since the devices initially were listed on the Prostheses List, although it has been stable over the past few years.

It was also noted that as advised under the agenda item 3, the TGA has commenced a post market review of spinal cord stimulators and the review is in progress.

The Department proposed that undertaking the review of the spinal neurostimulators listed on the PL would be a good case study for developing protocols and framework for the PL post-listing reviews. The PL post-listing review would examine comparative clinical effectiveness as a possible precursor to an economic analysis and could run in parallel with the TGA review.

Some participants asked if it is better to conduct the PL review after the TGA completes its post-market review. If the TGA review results in cancellation of the ARTG entries, the relevant billing codes on the PL would also be deleted so a post-listing review would be redundant. It was however noted that the TGA's review will not necessarily result in suspension or cancellation of ARTG entries but will more likely it will include clarification of indications and patient selection [e.g. by amending Instructions For Use (IFU)], and therefore the two reviews are not contingent on each other and could be run in parallel.

Participants noted that the article has flaws and should not be strictly taken as the evidence that the spinal neurostimulators have serious safety problems. Specifically, the adverse events referred to in the article are more accurately described as 'incident reports' and that causation is not been established between these and the neurostimulation devices.

Further there are publications and clinical evidence available that suggest spinal neurostimulation can provide effective pain management in some patients and for this reason, it has become a very popular treatment option, although there are some patients for whom spinal neurostimulation delivers little or no benefit. Despite this, it was agreed that the spinal neurostimulation is an expensive treatment, and it requires assessment of its cost-effectiveness in context of more effective patient selection.

It was also suggested that State and Territory workers' compensation bodies and Comcare should be consulted as they have already undertaken some work and reviews on the spinal neurostimulators.

PLAC supported the Department progressing a post-listing review of spinal neurostimulators as outlined in the agenda paper.

Actions

32.03 Department to progress the review of spinal neurostimulators as outlined in the PLAC agenda papers.

s22

[redacted]

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ISSUES

There has been increased focus on the optimal role of spinal cord stimulators in the treatment of chronic pain, following a recent peer reviewed article (Jones et al)[1] and media report.[2] The Jones et al article queries the long-term safety and effectiveness of these devices (refer Attachment 8.1.1.B).

The Therapeutic Goods Administration (TGA) is also currently undertaking a post market review (PMR) of spinal cord stimulators.

BACKGROUND

The annual Prostheses List expenditure on the group 04.05.01 – Neurosurgical - Neurostimulation Therapies for Pain Management - Pulse Generators () is around $30 million – the major component of the $55-60 million spent on the subcategory Neurostimulation Therapies for Pain Management, which also includes external components, leads, lead extensions, revision kits and accessories. This has increased significantly from the baseline a decade ago, though has been stable over the past few years.

The Department developed a discussion paper (refer Attachment 8.1.1.A) regarding this issue proposing the following:

- Post Listing Review (PLR) will be undertaken focussing on a clinical effectiveness review as a possible precursor to an economic analysis (noting cost effectiveness analysis may be challenging given the likely shortage of comparative effectiveness data and lack of a robust comparator).
- Use of this PLR as a test case for formalising PLR processes as planned under the Prostheses List reforms, informing legislative and policy developments.
- Further discussions to take place regarding MBS data and MBS Items.
- Ongoing liaison with TGA to ensure that the reviews are complementary.

Action

☐ PLAC to note the advice provided regarding the review of spinal cord stimulators.

☐ PLAC to provide any advice or comments that may assist with this review.

☐ The Department to progress the review as outlined.

Attachments:

8.1.1.A TAAD discussion paper – spinal cord stimulators

8.1.1.B Jones et al article

[1] Jones CM, 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. *Journal of Patient Safety*. 2022 Jan 21.

[2] Liam Mannix, 'To hell and back: Devices meant to ease pain are causing trauma', The Age 5 February 2022.

Attachment 8.1.1.A

Discussion paper – spinal cord stimulators

Background

In a letter to the PLAC and MSAC chairs dated 09/02/ 2022, Private Healthcare Australia (PHA) have expressed concern about the rising costs of spinal cord stimulators, considering uncertainties around their long-term safety and effectiveness, and suggesting a health technology assessment. This paper provides preliminary advice on the nature and merits of the expressed concerns and advises on Departmental action taken to date, and the merits of undertaking more formal Post Listing Review.

Spinal cord stimulators are contained in Prostheses List (PL) Group 04.05.01 (Pulse Generators). These subcutaneously implanted medical devices treat chronic pain by delivering electrical impulses (which modulate nociceptive pain signals) through electrodes in the epidural space. They typically treat back pain, but other indications include complex regional pain syndrome, angina, ischemic leg pain, and peripheral neuropathy. A recent article by Jones et al questions the long-term safety and effectiveness of these devices, based on analysis of Therapeutic Goods Administration (TGA) adverse events (AE) data and citing recent literature, and notes significant growth in device usage.

There has been no Health Technology Assessment (HTA) conducted on spinal cord stimulators, with listing of MBS items regarding leads (insertion, repositioning, removal) and neurostimulators (placement and removal) occurring prior to the inception of MSAC (ie Item 39134 for neurostimulator placement was listed in 1993). These items, and the Prostheses List (PL) listings, cover both peripheral nerve stimulation (via peripheral nerve lead placement, Item 39138) and spinal cord stimulation (via epidural lead placement, Item 39139).

Note: There are different PL devices for vagal nerve stimulation (for epilepsy management) and sacral nerve stimulation (for faecal and urinary incontinence), with complementary MBS items which have been listed more recently and following MSAC assessment. These devices are outside the scope of this paper.

Usage patterns and data analysis

Prostheses List (PL) expenditure on the group 04.05.01 Pulse Generators has been relatively stable since 2016 and is currently estimated at around $30 million per year for around 1400-1500 devices. See Appendix 1 data. This represents around half of all such device insertions in Australia.

Pulse generators are the major expense item for the subcategory 04.05 Neurostimulation Therapies for Pain Management (total expenditure around $55-60 million), which also includes external components, leads, lead extensions, revision kits and accessories. The average PL benefit for a neurostimulator is around s47D, though the average PL benefits paid per insertion will be significantly higher considering these additional devices (the PHA letter provides a figure of s47G though the method of calculation is not described). Expenditure on the subcategory Neurostimulation Therapies for Pain Management was substantially lower prior to 2012.

Total numbers of insertions and removals across all hospitalisations, irrespective of funding source, is calculated by Jones et al using Admitted Patient Care National Minimum Dataset data. From 2012-2019 in Australia there were 26,786 pulse generators inserted, based on Item 39134 for device placement (average around 3350 per year); there were 10,702 removed, based on Item 39135 for device removal (averaging around 1340 per year). No yearly trend is provided.

Internal Department of Health Casemix data (HCP1, Hospital Casemix Protocol 1) calculates that the numbers of devices funded by the Prostheses List (limited to procedures performed in private hospitals and for private patients in public hospitals) remained relatively stable from 2016-2017 to 2020-21 at around 1200 – 1400 per year. Expenditure peaked around $33.5 million in 2017-18, fell prior to COVID before bottoming out at $27.6 million in 2019-20, then rose again in 2020-21 to $28.5 million (final figures still pending). This is based on data capture around 90% compared to Australian Prudential Regulation Authority (APRA) data (which provides no breakdown by subcategory or group), hence actual expenditure could be around 10% above these values. Casemix (HCP 1) data is discussed in greater detail in Appendix 1.

Preliminary Medicare Benefits Schedule (MBS) data is consistent with the HCP1 data. MBS data covers a similar population subset. It shows around 1300-1500 annual insertions (Item 39134) and 400-500 removals (Item 39135) during the same time period, with similar year-to-year fluctuations. Further MBS data is pending, aimed at better understanding usage patterns, including demographics, relationships between insertions and removals and previous spinal surgery, item combinations, and out-of-pocket expenses. MBS item 39134 commenced in 1993 and includes the condition of 'management of chronic neuropathic pain or pain from refractory angina pectoris' (the latter appears rarely used); it also includes significant Explanatory Notes around best practice (see below). MBS matters are discussed further in Appendix 2.

Notably, the above figures relate to devices that may be connected to epidural or peripheral leads, hence the figures for spinal cord stimulators may be a subset of this data, which also includes peripheral nerve stimulators. The available data do not distinguish the two.

The Jones at al paper

The 2022 *Journal of Patient Safety* article 'Spinal Cord Stimulators: An Analysis of the Adverse Events Reported to the Australian Therapeutic Goods Administration' by Jones et al is cited in the PHA letter. Clinical evidence for the effectiveness of spinal cord stimulators is limited to short (< 3 week) trial periods, with modest treatment effects observed from pooled data. Evidence for long term safety is lacking. Some clinical guidelines endorse their use whilst others don't.

The total device usage calculated from the AIHW's National Hospital Morbidity database (based on the Admitted Patient Care National Minimum Dataset) covers a wide range of settings and would be expected to give a fairly complete picture of device usage nationally (see above - 26,786 pulse generators inserted and 10,702 removed from 2012-19).

The analysis of TGA Adverse Events (AE) data by Jones et al reports 520 adverse events (AE rate 1.94%), of which 93% were serious adverse events. The authors discuss the limitations of this data. TGA has provided additional cautions around interpretation of this data (see below). The issue of what proportion of this data relates to peripheral nerve stimulation is not addressed.

Jones et al questions the effectiveness, safety and durability of spinal cord stimulators, and calls for more high-quality research, and a national registry to track long-term safety. This was reported in an article in The Age To hell and back: Devices meant to ease pain are causing trauma.

Discussions with Therapeutic Goods Administration (TGA)

TGA is currently undertaking a post market review (PMR) of spinal cord stimulators (a 2010/11 PMR is considered of minimal relevance), triggered by the Jones et al article. Responses to requests for post market data (ie sales, complaints, AEs) and risk management documentation, but not clinical evidence, was due 25 March, though some extensions have been granted. Some preliminary findings are expected by May 2022, though the completed PMR is likely to take significantly longer. The PMR may result in amendments to Instructions for Use (IFUs – clinical indications, warnings etc) and risk management documentation.

TGA cautions that the TGA data cited is more accurately characterised as incident report data, rather than adverse events data. The number of events, and predominance of those classified as serious adverse events, are partially explained by reporting patterns related to regulatory obligations. This dataset is not comparable to the type of adverse events data obtained through a clinical trial or registry. Further discussion around TGA liaison is provided in Appendix 3.

MBS changes following 2019 Pain Management review

Amendments were made to MBS items 39131, 39134, 39135, 39136, 39137 and 39139 (associated with spinal cord stimulators) following the 2019 *Medicare Benefits Schedule Review Taskforce - Final Report on the Review of Pain Management MBS Items.* These amendments focused on effective use of the health system. There were also additional Explanatory Notes added for neurostimulator items as follows:

> *As with all interventions, implant procedures should be performed in the context of clinical best practice. This is of particular importance given the high cost of the devices. Current clinical best practice for use of these item numbers includes:*
>
> *- All procedures being performed in the context of a comprehensive pain management approach with a multidisciplinary team.*
>
> *- Patients should be appropriately selected for the procedure, including, but not limited to assessment of physical and psychological function prior to implantation with findings documented in the medical record.*
>
> *- Outcome evaluation pre and post implantation.*
>
> *- Appropriate follow up and ongoing management of implanted medical devices should be ensured.*
>
> *Implantable devices require ongoing monitoring and management. If the person providing the implantation service is not the ongoing physician manager of the device, they are responsible for ensuring that appropriate ongoing management has been arranged.*

Observations

- Jones et al argues there is minimal clinical evidence supporting long term safety and performance of spinal cord stimulators.
- Spinal cord stimulators have not undergone HTA.

- At around $55-60 million, the subcategory is a significant PL expense item, relatively stable since 2016 but with significant growth in preceding years.

Preliminary actions

- Department to undertake a Post Listing Review (PLR) focussing on a clinical effectiveness review as a possible precursor to an economic analysis, noting that a cost effectiveness analysis may be challenging given the likely shortage of comparative effectiveness data and lack of a robust comparator.
- This PLR is being used as a test case for formalising a PLR processes as planned under the Prostheses List reforms, informing legislative and policy developments.
- Further discussions to take place regarding MBS data and MBS Item, with further data to follow.
- Ongoing liaison with TGA to ensure that the reviews are complementary.

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