s22

From: s22
Sent: Wednesday, 7 September 2022 3:28 PM
To: s 47F ; s47F
Cc: ; s22 ; s22 ; s22 ; s22
Subject: FW: Documents for AHA [SEC=OFFICIAL]
Attachments: The Saturday Paper - Greg Hunts $400 million secret deal.docx; D22-1164408 Prostheses List Post-listing Review Framework.docx; SURGICAL GUIDES AND BIOMODELS BILLING CODES AND PRODUCT NAMES AS PER PL JULY 2022.pdf; FW: FOR INFORMATION: PROSTHESES LIST POST-LISTING REVIEW OF SURGICAL GUIDES AND BIOMODELS - UPDATE [SEC=OFFICIAL]; accurate and cost-effective mandibular biomodels Zeller et al 2021.pdf; prostheses-list-guide.pdf; PLAC 32 Surgical guides and biomodels.pdf; 20220606 - Surgical guides and bio models - Final Tables.XLSX; Stakeholder List Review of Surgical Guides and Biomodels.xlsx

Hi s 47 (and s47F

Please see attached initial background information from the Department. Please treat all information provided by the Department (that is not already publicly available) as confidential information.

- Prostheses List Post listing Review Framework
- List of billing codes and product names.
- Most recent correspondence with sponsors (email)
- Sponsor and stakeholder list
- Utilisation review (title: PLAC 32 Surgical Guides and Biomodels) and background tables
- Prosthesis list guide
- link to reforms webpage The Prostheses List reforms | Australian Government Department of Health and Aged Care.
- Published articles/papers for some background

List of clinical experts (this may be added to):

s47F

In our meeting yesterday, I also indicated we would be able to share some sponsor applications but unfortunately we cannot do so. If you think this information is necessary to inform the review, perhaps this can be requested this from sponsors when they submit evidence.

I hope you are feeling better soon s47F

Kind regards,
s22

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
☎ s22 | s22 @health.gov.au
Location: s22 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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.

ScienceDirect

Journal of Stomatology, Oral and Maxillofacial Surgery

Volume 122, Issue 4, September 2021, Pages 355-360

Original Article

Accurate and cost-effective mandibular biomodels: a standardized evaluation of 3D-Printing via fused layer deposition modeling on soluble support structures

Alexander-N. Zeller [a], Michael-Tobias Neuhaus [a], Sina Fresenborg [a], Rüdiger M Zimmerer [a], Philipp Jehn [a], Simon Spalthoff [a], Nils-Claudius Gellrich [a], Jan Alfred Dittmann [a, b]

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https://doi.org/10.1016/j.jormas.2020.09.018

Abstract

Introduction

Medical biomodels can be used for illustration of medical conditions, preoperative planning or to facilitate pre-bending of osteosynthesis material. They have been shown to be an effective and efficient method to reduce operating time, blood loss and wound stress in cranio-maxillo-facial surgery. Lately, new time and cost-efficient 3D-printing methods have been introduced into the mass-market. The aim of this study was to establish a standardized method of evaluation and consequently evaluate Fused Layer Deposition Modeling in combination with soluble support structures for fabrication of medical biomodels regarding precision and cost-effectiveness.

Materials & Methods

Twenty-one biomodels of human mandibles equipped with measuring appliances were printed on a FLDM 3D-printers (Ultimaker 3 Extended) using a polyactate filament and a water-soluble Polyvinyl alcohol-based support structures. Precision of these models was compared to commercial, polyamide sintered models and the planning data. Production costs, printing times and post processing procedures were evaluated.

Results

Duration of printing of mandibular biomodels was between 6 h 5 min - 15 h 9 min (mean 9 h 12 min, ±2 h 25 min). The average cost of materials was €5.90 (± €1.28) per model. With an average aberrance of 0.29 mm, FLDM printing delivered a high level of accuracy. It was significantly superior to the polyamide reference models in the area of the semilunar incision, yet inferior at the coronoid process.

Conclusion

FLDM printers are able to provide very precise biomodels at very low costs. The use of using soluble support structures reduces time, costs and equipment needed for post processing procedures close to zero.

Introduction

Biomodels are a product of three-dimensional, tomographic data offering numerous advantages and applications [1], [2], [3], [4]. They can be utilized to illustrate anatomical and medical conditions, to facilitate preoperative planning or to practice surgical techniques. They have been shown to be an effective and efficient method to help reducing operating time, blood loss and wound stress in cranio-maxillo-facial surgery [5], [6], [7].

In contrast to tomographic data and 3D renderings of it, biomodels can provide a haptic way to get to know a surgical site before the procedure. They enable the surgeon to visualize individual challenges of pre-operative situations and can also be used to simulate possible post-operative outcomes. Thus, surgical strategies can be evaluated preoperatively. Furthermore, biomodels can be used for pre-bending of osteosynthesis plates [5]. This is especially feasible for mandibular reconstruction plates [8], as reciprocal bending actions causing material instabilities can hereby be avoided. Besides all their advantages, printing biomodels does account for additional costs, which have to be taken into account in modern health care systems [9].

To manufacture biomodels, a variety of additive and subtractive processes exist. Originally, subtractive procedures such as Computerized Numerical Control (CNC) milling were predominant [1], [10]. As biomodels are not optimal to be produced by subtractive procedures [11], additive manufacturing has almost fully displaced it. Initially, these methods were accompanied by significant fix and variable costs. Due to an increasing variety of free and low-cost software suitable for segmentation and object manipulation, technical hurdles for surgical planning have been drastically lowered [12], [13]. With 3D-printing establishing itself in a mass market, a variety of low-cost 3D-printers for personal or semi-professional use have been released lately. This group mainly consists of printers using photoreactive resins (stereolithography, SLA) and those extruding filaments layer by layer (fused layer deposition modelling, FLDM). Both offer several materials with different properties with and without medical approval. On the one hand, SLA printing certainly offers a larger range of medically

approved materials. On the other hand, FLDM printing can be considered to be more attractive in terms of production costs per piece. Due to the necessary support structures printed from the same material as the model itself, post-processing of FLDM-printed models is time-consuming. Removing support structures by breaking or milling poses a threat to their shape accuracy and general stability.

Recently, water soluble support structures have been introduced to reduce the amount of post processing in FLDM printing to near zero. The aim of this study was to evaluate the feasibility of FLDM printing of mandibular biomodels using water-soluble support structures for pre-operative planning procedures and plate pre-bending in cranio-maxillo-facial surgery. To achieve this, a novel standard anatomical model for accurate and reproducible printer evaluation was developed.

Section snippets

Preliminary studies

To guarantee constant printing results, several series of calibration cubes of $30 \times 30 \times 30 mm^3$ were printed and measured prior to this study. Printer settings were adjusted to guarantee comparable results in all areas of the build plate....

Digital model generation

Models used for this study were generated from pre-operative computer-tomographic (CT) or cone-beam-tomographic (CBCT) data from patients undergoing ablative surgical procedures of the mandible. Criteria for inclusion were complete depiction of the mandible,...

Results

A total of 21 reference models was obtained from industrial suppliers. STL files of these 21 models were equipped with additional measuring aids as described before and consequently printed with FLDM technology using water-dissolvable PLA support structures. One model (4.8%) had to be re-printed due to a printer failure....

Discussion

Later generations of FLDM 3D-printers are supposed to achieve levels of accuracy suggesting its usability for regular biomodel printing [15], [16]. Documented uses of biomodels in cranio-maxillo-facial surgery are mostly for preoperative planning, pre-bending of osteosynthesis plates and construction of individual drilling guides [8]. Uses for documentation and

education of patients and healthcare-professionals have also been described [17]. Most importantly, biomodels have been proven to...

Conclusion

FLDM printers are able to provide precise biomodels at low costs. Recent developments have significantly improved their clinical usability, as biocompatible, even thermosterilizable materials have become available. The combined use of these materials with dissolvable support structures can effectively cater for the needs of clinical use. Reducing time, costs and equipment needed for post processing procedures makes this technology valuable to clinicians. Especially in times of cost-driven...

Authors contributions

ANZ: Conception and design, collection and assembly of data, data analysis and interpretation, manuscript writing and final approval of manuscript.

MTN: Data analysis and interpretation, manuscript writing and final approval of manuscript.

SF: Collection and assembly of data, data analysis and interpretation and final approval of manuscript.

RMZ: Data analysis and interpretation and final approval of manuscript.

SS: Data analysis and interpretation and final approval of manuscript.

PJ: Data analysis ...

Funding

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CONFLICTS OF INTEREST

All authors have no conflicts of interest....

Acknowledgements

We would like to thank our dental technician Stephan Oelker for his valuable assistance....

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2021, Journal of Stomatology, Oral and Maxillofacial Surgery

Show abstract

3D printing in oral and maxillofacial surgery: a nationwide survey among university and non-university hospitals and private practices in Germany

2022, Clinical Oral Investigations

Recommended articles (6)

Research article

Do patient-reported outcome measures correlate with clinical follow-up after arthroscopic treatment of internal derangement of the temporomandibular joint?

Journal of Stomatology, Oral and Maxillofacial Surgery, Volume 122, Issue 4, 2021, pp. e21-e26

Show abstract

Research article

Digital navigation and 3D model technology in mandibular reconstruction with fibular free flap: A comparative study

Journal of Stomatology, Oral and Maxillofacial Surgery, Volume 122, Issue 4, 2021, pp. e59-e64

Show abstract

Research article

DIVA, a 3D virtual reality platform, improves undergraduate craniofacial trauma education

Journal of Stomatology, Oral and Maxillofacial Surgery, Volume 122, Issue 4, 2021, pp. 367-371

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Research article

Surgical Training 2.0: A systematic approach reviewing the literature focusing on oral maxillofacial surgery – Part II

Journal of Stomatology, Oral and Maxillofacial Surgery, Volume 122, Issue 4, 2021, pp. 423-433

Show abstract

Research article

A comparative evaluation of parasymphyseal fracture fixation in edentulous patients performed using dynamic navigation systems and Herbert screws with the conventional two-plate method: A study on models

Journal of Stomatology, Oral and Maxillofacial Surgery, Volume 122, Issue 4, 2021, pp. e39-e44

Show abstract

Research article

Evaluation of the CBCT imaging accuracy in the volumetric assessment of unilateral alveolar cleft

Journal of Stomatology, Oral and Maxillofacial Surgery, Volume 122, Issue 4, 2021, pp. e1-e5

Show abstract

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SURGICAL GUIDES AND BIOMODELS – BILLING CODES AND PRODUCT NAMES AS PER PL JULY 2022

Billing Code	Product Group	Product Sub Group	Suffix	Benefit	Sponsor	Product Name
AT081	07.02.02 - Cranium	07.02.02.04 - Surgical Guide	Biomodelled	$1,950	Anatomics Pty Ltd	Anatomics Surgical Guide
SY777			Biomodelled	$1,950	Johnson & Johnson Medical Pty Ltd	ProPlan
SY825			Biomodelled	$1,950	Johnson & Johnson Medical Pty Ltd	Surgical Guide for OBL PSI System - Cranium
AT085	07.02.05 - Mandible, Maxilla and Temperomandibular Joint (TMJ)	07.02.05.07 - Surgical Guide	Biomodelled	$2,011	Anatomics Pty Ltd	Anatomics Patient Specifc Surgical Guide
HI001			Biomodelled	$1,163	DIGITAL DENTAL NETWORK PTY LTD	DDN Guide
HW650			Biomodelled	$2,011	Stryker Australia Pty Ltd	VSP Orthognathics Bundle (Surgical Guide and Implants)
HW653			Biomodelled	$2,011	Stryker Australia Pty Ltd	VSP Reconstruction Mandibular/Maxillary Case Bundle
KT005			Biomodelled	$2,011	KLS Martin Australia Pty Limited	UNIQOS Patient Specific Surgical guides
MV007			Biomodelled	$2,011	More Group Pty Ltd	MGuide
OG001			Biomodelled	$2,011	Maxoniq	OMX Solutions patient Optimized Guide system
SY778			Biomodelled	$2,011	Johnson & Johnson Medical Pty Ltd	ProPlan
SY827			Biomodelled	$2,011	Johnson & Johnson Medical Pty Ltd	SynpliciTi System – Surgical Guides
SY829			Biomodelled	$2,011	Johnson & Johnson Medical Pty Ltd	Custom made plates (including Megaplates) – Surgical Guides
SY835			Biomodelled	$2,011	Johnson & Johnson Medical Pty Ltd	Surgical Guide for OBL PorousiTi® PSI System – Mandible & Maxilla
UI001			Biomodelled	$2,011	SPECIFICA PTY LTD	OsGuide
UI003			Biomodelled	$2,011	SPECIFICA PTY LTD	DGUIDE
ZZ047			Biomodelled	$2,011	AA-Med Pty Ltd	OrthoTin Surgical Guide

Billing Code	Product Group	Product Sub Group	Suffix	Benefit	Sponsor	Product Name
ZZ049			Biomodelled	$2,011	AA-Med Pty Ltd	Lyka Smith Patient Specific Guides
AT076	07.02.09 - Anatomical Biomodel			$1,829	Anatomics Pty Ltd	Anatomics Biomodel
HI002				$1,829	DIGITAL DENTAL NETWORK PTY LTD	DDN Biomodel
HW544				$1,829	Stryker Australia Pty Ltd	Stryker Anatomical Biomodel for Mandible
HW546				$1,829	Stryker Australia Pty Ltd	Stryker Anatomical Biomodel for PEEK
HW651				$1,829	Stryker Australia Pty Ltd	VSP Orthognathics Bundle (Custom Biomodel and Implants)
HW652				$1,829	Stryker Australia Pty Ltd	VSP Reconstruction Maxillofacial Case Bundle
KT004				$1,829	KLS Martin Australia Pty Limited	UNIQOS Patient Specific Anatomical Biomodel
OG004				$1,829	Maxoniq	The OMX Solutions Biomodel
SY775				$1,829	Johnson & Johnson Medical Pty Ltd	PSI
SY779				$1,829	Johnson & Johnson Medical Pty Ltd	ProPlan
UI002				$1,829	SPECIFICA PTY LTD	BIOMODEL
UI004				$1,829	SPECIFICA PTY LTD	OMF Model
ZZ046				$1,829	AA-Med Pty Ltd	OrthoTin Anatomic Biomodel
ZZ050				$1,829	AA-Med Pty Ltd	Lyka-Smith Anatomical Biomodel

Australian Government

Department of Health

Prostheses List

Guide to listing and setting benefits for prostheses

February 2017

Version Number:	**February 2017, Revision 3**
Date:	19 February 2020

Prostheses List – guide to listing and benefits for prostheses

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For further information about this guide, the Prostheses List or lodging an application, contact:

Prostheses Section
Office of Health Technology Assessment
Department of Health
GPO Box 9848
Canberra ACT 2601

Email: prostheses@health.gov.au

Web: The Department of Health Prostheses List page

Contents

About this guide

What is the Prostheses List Guide?

The *Prostheses List: guide to listing and setting benefits for prostheses* (the Guide) has been developed to provide guidance on how to submit an application to include a surgically implanted prosthesis and other products on the Prostheses List. The Prostheses List specifies the benefits that private health insurers are required to pay for the listed prostheses to appropriately insured persons.

The information in this document is provided as a guide only. Applicants are encouraged to contact the relevant Prostheses secretariat for assistance and to discuss the information that should be included with an application.

The Guide also provides information for other stakeholders and decision makers about the prostheses listing arrangements.

Additional information about the Prostheses List and prostheses listing arrangements

The Australian Government Department of Health will publish information about the Prostheses List and the prostheses listing arrangements from time to time on its website. Information is published in a Private Health Insurance Circular.

The information included in these publications includes:

- critical dates in the Prostheses List process (e.g. publication and commencement of the Prostheses List);
- meeting dates for the Prostheses List Advisory Committee and its subcommittees; and
- clarification on matters of policy or process.

What is a Prostheses List application?

Sponsors or suppliers of medical devices can make applications to list prostheses on the Prostheses List. In this document, references to sponsors will also apply to suppliers. The Prostheses List Advisory Committee considers these applications, and applications to make changes to existing listings, and makes recommendations to the Australian Government Minister for Health for products to be listed on the Prostheses List.

How is the Guide structured?

The Guide is divided into four parts:

- **Part I (Prostheses listing arrangements)** describes the legal arrangements for managing the Prostheses List.
- **Part II (Supporting evidence)** describes the rationale for the evidence requirements for new applications and provides a framework to assist sponsors to select the most appropriate clinical evidence to support their applications.
- **Part III (Step-by-step guide to completing an application to list a new prosthesis)** provides instructions for completing each section of the application form (particularly for new users of the application process).
- **Part IV (Changing an existing listing)** provides details about how to make changes to a current listing.

A copy of the Guide is available on the Australian Government Department of Health website.[1] Frequent users of this guide should ensure that they have the latest version.

This version of the guide supersedes *Guide to listing and setting benefits for prostheses*, dated December 2015 and provides updates to the February 2017 version.

Relevant legislation

Legislation relating to the Prostheses List includes the following:

- *Private Health Insurance Act 2007*
- *Private Health Insurance (Prostheses) Rules*, as made from time to time
- *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*
- *Private Health Insurance (Prostheses Application and Listing Fees) Rules*, as made from time to time
- *Private Health Insurance (National Joint Replacement Register Levy) Act 2009*
- *Private Health Insurance (National Joint Replacement Register Levy) Rules*, as made from time to time
- *Private Health Insurance (Complying Products) Rules*, as made from time to time.

How will this guide be updated?

The Department will update the Guide, as required, to ensure its currency and accuracy. When significant amendments have been made, advice will be distributed through the PHI Circulars.

Please refer to the online version of the Guide located on the Department's website (http://www.health.gov.au/internet/main/publishing.nsf/Content/health-PLAC-subcommittees).

[1] Prostheses List - Applications and Requests

Ongoing updates

The Department has commenced a review of the Guide, which includes consideration of the assessment process for Part B (Human Tissue). Minor updates may be published from time-to-time.

A version control table outlining changes made can be found in Appendix A.

Part I — Prostheses listing arrangements

1 Overview

Definitions

Medical device

The Therapeutic Goods Administration (TGA) defines a medical device as an instrument, apparatus, appliance, material or other article intended to be used for human beings for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

Medical devices include a wide range of products, from those used externally (such as surgical gloves, bandages and condoms) to internal devices (such as pacemakers and dialysis equipment). Prostheses are a subset of medical devices. Safety, quality and performance of medical devices are assessed by the Therapeutic Goods Administration, and products must be entered on the Australian Register of Therapeutic Goods before they can be provided in Australia.

Medical service

Medical services include therapeutic, investigative and consultative procedures. When a surgically implantable prosthesis is provided to a patient, it is linked to a medical service. The evidence supporting the safety, effectiveness and cost effectiveness of the medical service is assessed by the Medical Services Advisory Committee; the evidence supporting the clinical effectiveness and cost effectiveness of the prosthesis is assessed by the Prostheses List Advisory Committee. Medical services that are subsidised by the government are listed on the Medicare Benefits Schedule.

Prosthesis

The types of prostheses covered by the Prostheses List are those that meet the criteria shown in Section 2, Table 2.1 of this guide. Essentially, this is only those devices that are surgically implanted; or are essential to, and specifically designed as an integral single-use aid for, implanting such a product; or are critically important to the ongoing function of a surgically implanted product. Human tissue items such as corneas, bones and heart valves are also covered by the Prostheses List, as are insulin infusion pumps, cardiac loop recorders and cardiac home/remote monitoring systems. External prostheses, such as external legs, external breast prostheses, wigs and other such devices are not included on the Prostheses List, and are not the subject of the arrangements covered by this guide.

1.1 Health technology assessment in Australia

Health technology assessment uses scientific evidence to evaluate the quality, safety, efficacy, effectiveness and cost-effectiveness of health services and health technology. In Australia, several advisory and regulatory bodies provide health technology assessment:

- The Therapeutic Goods Administration (TGA) assesses the safety, quality and performance of medicines and medical devices, and enters them on the Australian Register of Therapeutic Goods (ARTG). This allows the product to be sold in Australia. The TGA also monitors safety and performance of products in use.
- The Medical Services Advisory Committee (MSAC) assesses the safety, effectiveness and cost-effectiveness of medical technologies and procedures to inform decisions about public funding.
- The Pharmaceutical Benefits Advisory Committee (PBAC) assesses the effectiveness and cost-effectiveness of medicines and vaccines to inform decisions about public funding.

- The Prostheses List Advisory Committee (PLAC) assesses the comparative clinical effectiveness of prostheses and the proposed benefits to inform decisions about reimbursement by private health insurers.

1.2 What is the Prostheses List?

The purpose of the Prostheses List is to ensure that privately insured Australians have access to clinically effective prostheses that meet their health care needs.

Under the *Private Health Insurance Act 2007* (the PHI Act), private health insurers are required to pay benefits for prostheses that are included on the Prostheses List:

- for which an insured person has appropriate cover
- that are provided as part of an episode of hospital treatment or hospital-substitute treatment
- for which a Medicare benefit is payable for the professional service associated with the provision of the prosthesis.

The arrangements for including products on the Prostheses List help to ensure that benefits paid by insurers are relative to clinical effectiveness. The purpose of clinical assessment for the Prostheses List is reimbursement, not regulation.

Benefit

In the context of the Prostheses List, the term 'benefit' means the reimbursement to health consumers when they receive treatment.

The Medicare benefit is the amount payable by Medicare for the professional service associated with the provision of the prosthesis.

The benefit shown on the Prostheses List is the amount payable by private insurers for the prosthesis.

The Prostheses List arrangements are set out in Division 72 of the PHI Act and the *Private Health Insurance (Prostheses) Rules* (the Prostheses Rules). The Minister will make the rules under the authority of ss. 72-1, 72-10 and 333-20 of the PHI Act.

The Prostheses List is the schedule to the Prostheses Rules and is in three parts:

- Part A—prostheses that satisfy the criteria for listing agreed by PLAC and approved by the Minister.
- Part B—human tissue (includes products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply [however described, including trade, sell, give or gift] is governed by state or territory law). Unless explicitly identified, human tissue products are not addressed in this guide.
- Part C—prostheses that satisfy the criteria for listing on Part C. These criteria specify that a prosthesis will be listed in Part C if it is
  i. insulin infusion pump;
  ii. implantable cardiac event recorder; cardiac home/remote monitoring system
  iii. a cardiac ablation catheter;
  iv. a mapping catheter for cardiac ablation; or
  v. a patch for cardiac ablation.

The Prostheses List is updated three times per year (1st March, 1st July and 1st November). The applications deadlines are presented in the table below:

Application submission closes	**For the xx Prostheses List update**
Midnight[2] of the 2nd Sunday in January	July
Midnight of the 2nd Sunday in May	November
Midnight of the 2nd Sunday in September	March (the following calendar year)

A prosthesis will be incorporated in the next released Prostheses List if the Minister has granted the application and the applicant has paid the initial listing fee.

See Section 2 for further details about the Prostheses List.

1.3 Assessment of products

The PLAC is a non-statutory committee. Members of the PLAC are appointed by the Australian Government Minister for Health. PLAC makes recommendations to the Minister about which products should be included on the Prostheses List, and the appropriate benefits for these products. In making its recommendations, the PLAC considers the comparative clinical effectiveness of the product and the cost effectiveness.

In deciding to list a product and the benefit payable, the Minister may have regard to the recommendations of the PLAC. For the purposes of this guide, all further references to the Minister in the context of decisions to list on the Prostheses List also include the Minister's delegate.

Section 3 contains further details about the PLAC and its subcommittees.

The legislation requires an application to list a prosthesis to be made on an approved form.

The *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007* and the Private Health Insurance (Prostheses Application and Listing Fee) Rules set out the mandatory cost-recovery arrangements, including fees for:

- making an application to list a prosthesis
- initially listing a prosthesis where the Minister has granted an application
- maintaining an ongoing listing of a prosthesis

Section 4 contains further details about the application process.

[2] For the avoidance of doubt, this is to be read as the midnight between the Sunday and Monday.

2 The Prostheses List

2.1 Criteria for listing

The legislation underpinning the prostheses arrangements does not define 'prosthesis'. Instead, criteria for listing products on the Prostheses List are applied by the PLAC to each product assessed for listing. This helps to ensure that every product is considered in the same way, and that the PLAC's recommendations for listing are consistent, fair and equitable.

Criteria for listing on Part A

The PHI Act provides that benefits from hospital treatment cover will be paid in respect of a kind of prosthesis listed in the Prostheses Rules.

The criteria for listing a kind of prosthesis on Part A of the Prostheses List are as follows:

1) The product must be entered and current on the Australian Register of Therapeutic Goods
2) The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment
3) A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)
4) A prosthesis should:
   (a) be surgically implanted in the patient and be purposely designed in order to
      (i) replace an anatomical body part; or
      (ii) combat a pathological process; or
      (iii) modulate a physiological process;

   or

   (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted

   or

   (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and
5) The product has been compared to alternative products on the Prostheses List or alternative treatments and
      (i) assessed as being, at least, of similar clinical effectiveness; and
      (ii) the cost of the product is relative to its clinical effectiveness.

Table 2.1 shows the criteria for listing on Part A and the rationale for each criterion. Criteria 1–3 are based on Commonwealth legislation; criteria 4 and 5 are not mandated by legislation, but PLAC has agreed that these criteria should be satisfied to list a product on the Prostheses List.

Table 2.1 Criteria for listing a product on the Prostheses List—Part A

Criterion	Rationale
Legislatively based criteria	
1 The product must be entered and current on the Australian Register of Therapeutic Goods	All therapeutic products must be included on the Australian Register of Therapeutic Goods before they can be lawfully supplied in Australia
2 The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment	This is a requirement of item 4 of the table in subsection 72-1(2) of the *Private Health Insurance Act 2007*
3 A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)	This is a requirement of item 4 of the table in subsection 72-1(2) of the *Private Health Insurance Act 2007*. An exception to this rule is where the provision of the prosthesis is associated with podiatric treatment by an accredited podiatrist. It is intended that a Medicare benefit should be payable under an item that is specific to the procedure in which the product is 'delivered'
Other criteria	
4 The product should: (a) be surgically implanted in the patient and be purposely designed in order to (i) replace an anatomical body part; or (ii) combat a pathological process; or (iii) modulate a physiological process;	The word 'surgically' has been chosen to convey the intention that the product be provided through an interventional process, and 'implanted' has been chosen to convey that the interventional process breaches the interface (or integument) between the body and the outside world (i.e. the skin or other epithelial surfaces, such as the rectal mucosa). This is to distinguish Prostheses List products from those that are externally attached to the body, such as artificial limbs (which meet the ordinary dictionary meaning of prosthesis but are not items that are considered in the context of the Prostheses List). The term 'surgically' is not intended to limit the performance of the intervention to surgeons, but is meant in the broader sense of performance of an interventional procedure by a suitably qualified medical, dental or podiatrist practitioner. Based on the ordinary dictionary meaning of implant, 'implanted' includes the implantation of tissues into the body, or an organ of the body, by grafting. Examples of tissues are harvested bone, heart valves and corneas. A product that is implanted for the purpose of replacing an anatomical body part is considered to be a prosthesis. This includes products such as knee and hip replacements. If an implanted product does not replace an anatomical body part, its principal function should be to either combat a pathological process or modulate a physiological process. 'Combating a pathological process' may include averting, repairing or correcting a pathological process; examples include cardiac and vascular stents, and cardiac defibrillators.

Criterion	Rationale
	'Modulating a physiological process' can mean either blocking or facilitating a process. Examples are pacemakers (to regulate heartbeat) and nerve stimulators for pain management (modulates a physiological process and prevents a pathological process)
or (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted	This criterion is for associated products that are essential and manufactured specifically to enable the delivery of a product that meets the criteria above. Associated products (as opposed to equipment) are only for use once in a patient, have a unique and direct connection to the product and are integral to implanting the product into the patient. This does not include products whose use is of a more general nature (e.g. sutures, scalpels, trocars). 'Only for use once' means that, once used, the associated product is of no further use. That is, it is incapable of further use, and may only be discarded. It does not have a general-purpose use. An example is a preloaded coronary stent that is supplied fixed on a balloon catheter that is needed for positioning and implanting the stent. Without the balloon catheter, the stent is unable to be satisfactorily implanted. The catheter is specific and integral to the particular stent. Neither the packaging of the associated product with the subject product nor its labelling as 'single use only' will be sufficient to determine compliance with this criterion. That is, even if the product has a manufacturer's stamp of 'single use only', if the product can be reused for a practical purpose or has a purpose that is not specific to the implanted product (e.g. a screwdriver is of a general nature and not specific, even where a screw is to be implanted), then the criterion is not met
or (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and	This criterion is for associated products that can only be used by the patient for whom they are provided because of their connection to the product that has been implanted in the patient. These products are critical to the continuing function of the implanted prosthesis and remain with the patient, as part of the prosthesis, after the episode of hospital treatment or hospital-substitute treatment. On their own, these products would not otherwise meet the criteria for listing on the Prostheses List. Examples are processors that are a critical element of the functioning of the implanted product, such as cochlear speech processors and patient-controlled products for pacemakers. Under this criterion, the associated product must have an ongoing role in the function of the implanted product and not be a generic disposable or consumable item. Batteries, catheters, cannulas and similar accessories whose association with the implanted product is not ongoing are considered to be disposable products under this criterion.

Criterion		Rationale
		The product's use is also restricted to an individual patient; the product cannot be one that may be used by more than one patient. For example, office-based equipment to read and download information from implanted ECG loop recorders, which is used in multiple patients, would not meet this criterion
5	The product has been compared to alternative products on the Prostheses List or alternative treatments and (i) assessed as being, at least, non-inferior in terms of clinical effectiveness; and (ii) the cost of the product is relative to its clinical effectiveness.	This criterion is included with the intention that clinical effectiveness and relative cost be considered. The term 'alternative treatments' is included to allow for entirely new products or technology to be compared with current treatments for the same clinical condition, as it is anticipated that not all products to be considered will have an existing counterpart on the Prostheses List. For example, when cochlear implants were first introduced, the comparator would have been a conventional hearing aid or no hearing assistance at all; when pins and plates were introduced to treat fractured femurs, the comparator would have been use of an external splint and bed rest for 10 weeks. The word 'similar' is used because it is impossible to state that one product is exactly 'equal' to another product when considering clinical effectiveness. The assessment procedure for consideration of products for inclusion on the Prostheses List does not involve analysis of cost-effectiveness; therefore, the term 'cost-effective' is not used. However, a product's cost should be considered relative to alternative products or treatments, and relative to its clinical effectiveness compared with those alternative products or treatments

Criteria for listing on Part C

The criteria for listing on Part C are contained in the Prostheses Rules. Currently, a prosthesis will be listed on Part C if it is an:

i. insulin infusion pump;
ii. implantable cardiac event recorder; cardiac home/remote monitoring system
iii. a cardiac ablation catheter;
iv. a mapping catheter for cardiac ablation;a patch for cardiac ablation
v. a monopolar device for surgical cardiac ablation;
vi. a bipolar device for surgical cardiac ablation;
vii. a system for surgical cardiac ablation; or
viii. a probe for surgical cardiac ablation.

2.2 Product categories and groupings

The PLAC considers information on Prostheses List product grouping as an indicator of comparative clinical effectiveness in determining the most appropriate benefit for each product recommended for listing.

Categories

The Prostheses List is divided into several categories of prostheses:

- cardiac
- cardiothoracic
- hip
- knee
- ophthalmic
- specialist orthopaedic
- spinal
- urogenital
- vascular
- ear, nose and throat
- neurosurgical
- plastic and reconstructive
- general/miscellaneous products (prostheses not included in other categories)

Groupings and benefits

Within categories, products are grouped according to similar clinical effectiveness. For simplicity, product categories, subcategories, groups and subgroups are identified numerically; some also have alphabetical suffixes or descriptive text to designate additional features and reflect different benefits.

Each grouping of products on the Prostheses List has a single group benefit. Groups and subgroups of products may be differentiated at the suffix level (i.e. the addition of a suffix may result in a different benefit). Sponsors can accept the group benefit, choose to list at a lower benefit or choose not to list the product.

For products implanted into privately insured patients in public hospitals, insurers are required to pay the group benefit or the patient's liability to the hospital for the prosthesis, whichever is the lesser amount.

2.3 Billing code and catalogue number

The billing code is a reference code allocated to a listed prosthesis. The billing code facilitates hospital invoicing procedures and the payment of benefits by insurers. A billing code may be allocated to:

- a single piece product;
- a 'set' comprising two or more non-identical components;
- a pack containing different sizes of otherwise identical items; or
- a 'kit' or 'set' consisting of implantable components and other non-implantable components that are agreed to be integral to the delivery or ongoing functioning of the implantable components

The billing code is specific to the sponsor of the product. If a billing code has been deleted, the same billing code will not be reused in future Prostheses Lists. New billing codes are created for products on the Prostheses List that are duplicated, expanded, compressed or transferred to another sponsor.

Sponsors are asked to provide a catalogue number (a unique identifier) for each component of a billing code. This assists in identifying the products that are included under the billing code.

2.4 Release dates

The Prostheses List is updated 1st March, 1st July and 1st November each year, and is available on the Department's website.

A Prostheses List is published approximately 10 business days before it becomes effective. This allows insurers to update their payment systems and hospitals to update their invoicing systems before the new Prostheses List commences. Critical dates for new Prostheses Lists, along with publication and commencement dates are advised via Private Health Insurance Circulars.

3 The Prostheses List Advisory Committee

Rule 9 of the Private Health Insurance (Prostheses) Rules provides that the Minister may have regard to recommendations from the PLAC in making decisions on granting applications to list prostheses on the Prostheses List.

The PLAC advises the Minister for Health on appropriate listing and benefits of prostheses on the Prostheses List. In making recommendations, the PLAC considers advice provided by its subcommittees.

The PLAC will consider and recommend the listing of products. The PLAC may also report on any other issues it may wish to draw to the attention of the Minister.

The PLAC's terms of reference can be found on the Department's website.

3.1 PLAC membership

The Prostheses List Advisory Committee (PLAC) has an independent Chair and is made up of individuals with expertise in:

- health technology assessment
- specialist surgery/interventional work
- epidemiology
- clinical medicine
- health economics, and
- consumer issues.

The PLAC also includes representatives of the private health insurance industry, the medical device industry, and the TGA.

The Minister for Health appoints the Chair and Members to the PLAC.

3.2 Support for PLAC

The PLAC is supported by the Clinical Advisory Groups (CAGs), Panel of Clinical Experts (Panel), and the Department's Prostheses Sections. The PLAC may seek advice on matters of probity or process from the Department and other experts, as required. Where specialist expertise on a particular matter is required and is not held by the membership of the PLAC, CAGs, Panel or relevant external expert advice may be sought, as required.

Clinical Advisory Groups and Panel of Clinical Experts

The CAGs and Panel advise on the assessment of products against the criteria for listing and appropriate grouping on the Prostheses List. They advise PLAC on the clinical effectiveness of each product proposed for listing compared with products used for the same or similar purposes that are listed as prostheses on the Prostheses List, or current treatments for the indications that the products are designed to treat.

Clinical Advisory Groups

CAGs have been established for the following product categories:

- cardiac
- cardiothoracic
- knee
- hip
- ophthalmic
- spinal
- specialist orthopaedic
- vascular

Members of the CAGs include expert practising clinicians, and a consumer representative nominated by the Consumers Health Forum.

Advisers to the CAGs usually include a non-affiliated adviser from the medical technology industry, nominated by the Medical Technology Association of Australia. If specialised knowledge or experience is required that is not available within the membership, CAGs may co-opt an independent clinician or clinicians, as required.

CAG's terms of reference can be found on the Department's website.

Panel of Clinical Experts

Panel assesses applications to list products that do not fit into the clinical categories of prostheses for which CAGs have been established.

Panel comprises specialist clinicians with a wide range of clinical expertise that include the following specialties:

- otolaryngology
- head and neck surgery
- plastic and reconstructive surgery
- neurosurgery
- interventional radiology
- general surgery

The Panel's terms of reference can be found on the Department's website.

Australian Government Department of Health

The arrangements for the Prostheses List are administered by the Prostheses Section, in the Office of Health Technology Assessment, of the Australian Government Department of Health. The functions of the Prostheses Section include:

- providing secretariat support to the PLAC
- providing secretariat support to the CAGs and Panel
- undertaking (or commissioning) Health Technology Assessment
- contributing to the development of policy on private health insurance funding of prostheses

- providing advice about legislation, regulation and other government programs, such as the Medicare Benefits Schedule (MBS) that affect the use and funding of prostheses
- maintaining and publishing the Prostheses List
- managing sponsors' applications to list products and amend existing listings, including providing advice to sponsors about applications and amendments
- coordinating internal reviews of the PLAC's recommendations
- providing advice to sponsors and other stakeholders about the prostheses arrangements
- facilitating communication and discussion between individuals and external stakeholders

3.3 PLAC processes

Meetings

The PLAC meets regularly to consider Prostheses List applications, and to discuss other matters relating to the prostheses listing arrangements. PLAC takes a consensus approach to making recommendations about listing products on the Prostheses List. Where a recommendation or decision cannot be reached by consensus, it is determined by vote of a majority of members.

The PLAC may discuss and resolve matters out of session on occasion.

The PLAC deliberations and recommendations are recorded in the record of meeting. The PLAC record of meeting is not published, but is subject to the provisions of the *Freedom of Information Act 1982*.

A PLAC Communique will be published on the Department's website after each meeting.

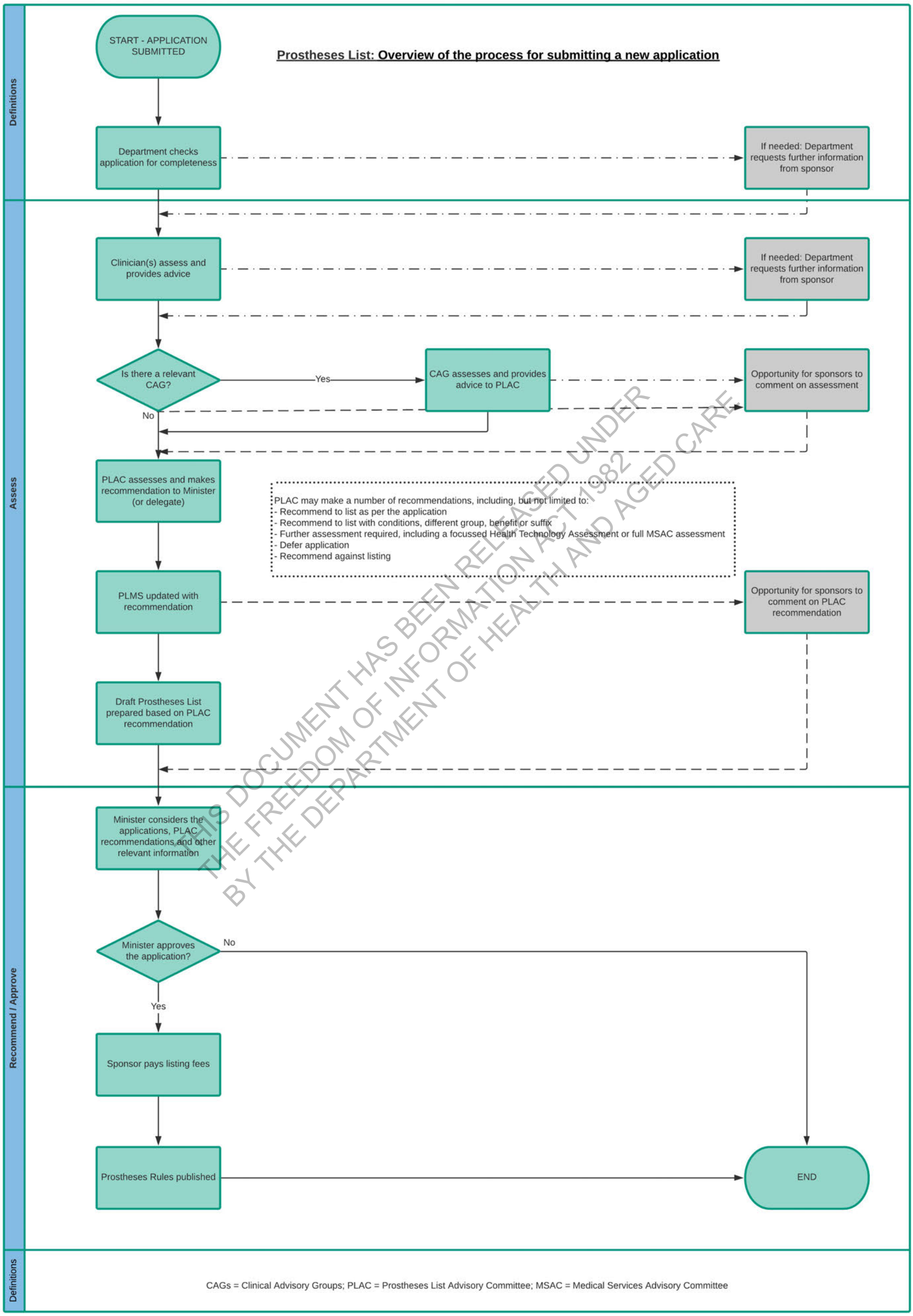
Confidentiality and conflict of interest

Much of the information considered by PLAC and its subcommittees is commercial-in-confidence. All members sign a deed of confidentiality and disclose any conflict of interest.

PLAC and its subcommittees have adopted the *Department of Health advisory committee guidelines for members and nominees: declarations of interests, managing conflicts of interests and confidentiality obligations*. At the time of writing—the guideline is being formally reviewed.

4 Application Process

This section provides an overview of the application process (Figure 4.1).



The Department is the primary contact for any queries that sponsors may have about the application process, and liaises with sponsors as required. Contact details are on the Department's website.

All communication must be via the Department—sponsors or stakeholders must not directly contact CAG, Panel or PLAC members, particularly to query their recommendations. Members of the committees will not engage with stakeholders who are seeking information on committee recommendations.

4.1 Types of applications

Applicants can apply to:

- list a new prosthesis
- expand a current billing code
- compress current billing codes
- change details of a current listing
- transfer or duplicate a current listing
- delete a current billing code

The Department accepts all types of applications on a continuous basis.

New application

New applications are submitted for prostheses that are not already on the Prostheses List. A range of supporting evidence is required to demonstrate comparative clinical effectiveness, depending on the similarity of the product to other products on the Prostheses List. All new applications are subject to clinical assessment and are considered by PLAC. If successful, new products will be listed on the next Prostheses List.

Application to expand or compress billing codes, or change listing details

If a single billing code covers a number of products (e.g. for a range of sizes or different models of a product), it can be expanded into a number of new billing codes. This should be done if some products covered by the current billing code should be listed in other groupings.

Sponsors may apply to compress multiple current billing codes into a single billing code. This may be appropriate where related products, previously listed separately, can be grouped together (share the same grouping and benefit). This may occur for a range of sizes of the same product, or a product with multiple components that is only available as a system.

Sponsors may apply to make the following amendments to their existing listing:

- change the
  - name of a prosthesis (e.g. where there has been a change to branding)
  - catalogue numbers
  - description
  - size
  - grouping of the product
  - ARTG details
- reduce the benefit

If an application could result in changes to grouping or benefit (such as changes to the product name, size or description), the application will be subject to clinical assessment. If an application could result in listing in a new grouping that is not included on the Prostheses List, the application will also be subject to assessment of the proposed benefit.

PLAC considers all applications to expand or compress existing billing codes, or to change the current listing details of a billing code.

Successful applications to expand or compress billing codes will result in the removal of the original billing code(s) and creation of new billing codes.

> **Please note that changes to existing listings resulting from a successful application to change details or to expand a billing code or to compress billing codes will be reflected in the Prostheses List the next time the Minister makes the Prostheses List Rules, and the changed listings will take effect from the commencement of the Prostheses List Rules.**

An application to expand a billing code or compress billing codes, or change the listing details of a current billing code cannot be used to list a new prosthesis that has not previously been listed.

Application to transfer, duplicate or delete a current listing

Sponsors can transfer billing codes if their product is transferred from another sponsor. The receiving sponsor is responsible for submitting the application to transfer a billing code. As part of the application to transfer, the receiving sponsor must supply a letter of authority from the original sponsor providing approval for the transfer.

A sponsor can apply to duplicate an existing listing held by another sponsor if they are also marketing the product (as happens with parallel importing). The product will not need to be assessed against the criteria for listing. The original billing code will remain on the Prostheses List, and a new billing code will be created for the new sponsor.

Sponsors can request that a billing code be deleted if they are no longer selling the prosthesis, and sponsorship of the prosthesis is not being taken over by another sponsor. The billing code will be deleted the next time the Prostheses List is made.

4.2 Applications

An application to list a new prosthesis should be made online via the Prostheses List Management System (PLMS).

4.3 Application fees

Application fee

The application fee payable is specified in the *Private Health Insurance (Prostheses Application and Listing Fee) Rules*.

The current fee for a new application is $600.

There is no application fee associated with amendments, deletions of listings, or duplications, expansions, compressions or transfers of existing billing codes.

An application fee is payable for each new prosthesis or component of a prosthesis that a sponsor is applying to have listed on the Prostheses List. For example, for a hip system, an application fee will apply to each component—cemented femoral stem, uncemented femoral stem, femoral head, etc.

Details for payment of application fees are displayed upon successful submission of an application via the PLMS.

4.4 Application number

Each application is assigned an identifying number. This application number will be used to refer to the application throughout the process. If the application is granted, the new product will be allocated a billing code.

4.5 Clinical assessment

The CAGs and Panel assess the comparative clinical effectiveness of products, based on the evidence submitted by sponsors. The CAGs and Panel advise PLAC on whether a product satisfies the criteria for listing and the grouping in which the product should be listed.

If the CAG or Panel finds that the product does not satisfy the criteria for listing or disagrees with the grouping proposed by the sponsor, it will explain the reasons for the finding.

Clinicians are asked to advise of any potential conflicts of interest that may arise in their assessment of the applications allocated to them. Should a clinician have a conflict of interest, they are asked to return the application to the Department, and it is then forwarded to another clinician for assessment.

Assessment by CAG clinicians

Products that fit into the clinical categories for CAGs are initially assessed by two clinician members of the relevant advisory group. The clinicians' assessments for each application are considered by a meeting of members of the relevant CAG. The CAG will then provide its advice to PLAC on whether or not the product is suitable to be listed and, if so, in which grouping. If the assessing clinicians consider the application not suitable for listing as per the application, sponsors will have an opportunity to provide further information to support their application.

Sponsors have five working days in which to respond in writing.

If there is no response within the five days, the clinicians' assessment will be presented at the CAG and the CAG assessment will be provided to PLAC.

Responses may include additional information (including clinical data) to support the application and will be referred back to the CAG or Panel for reconsideration.

If there is a response within 5 days, the CAG may:

- revise their advice based upon additional information provided; or
- affirm their original advice.

After reassessment, the sponsor will be informed of the outcome and the advice of the CAG or Panel will be provided to PLAC, unless the sponsor advises it does not want the application to proceed.

If the sponsor is seeking to list the product in a new grouping, or the CAG considers that the product should be listed in a new grouping, the CAG will comment on the clinical performance of the product against the comparator(s).

The CAG may identify a different Prostheses List product grouping if it decides that the comparator(s) and/or product grouping proposed by the sponsor are inappropriate. If the CAG has identified a different product grouping, or disagrees with a sponsor's claim that a product is clinically superior to other products in the grouping, the Department will notify the sponsor of the grouping proposed by the CAG and the associated group benefit. The sponsor is given an opportunity to respond to the CAG's recommended grouping.

Sponsors have five working days in which to respond in writing.

If there is no response within the five days, the CAGs assessment will be presented at the CAG will be provided to the PLAC.

Responses may not include any additional evidence or supporting information (as this information needs to be considered by the CAG prior to the PLAC making a recommendation).

If there is a response within five days, the PLAC will consider this in making its recommendation.

Assessment by Panel clinicians

Applications to list products that are not assessed by members of CAGs are assessed by two members of Panel with relevant clinical expertise. The two clinicians' assessments are considered by the PLAC.

If the advice and assessments for an application differ between the two clinicians, the clinicians are asked to confer about their assessments. If they are unable to agree on an assessment, the application may be assessed by a third clinician with relevant expertise. The PLAC then considers the application and formulates a recommendation to list based on the three clinicians' assessments and the reasons for their advice.

Panel may identify a different Prostheses List product grouping if it decides that the comparator(s) and/or product grouping proposed by the sponsor are inappropriate. If the Panel clinicians advise a different product grouping, or disagree with a sponsor's claim that a product is clinically superior to other products in the grouping, the Department will notify the sponsor of the grouping proposed by the Panel clinicians and the associated group benefit. The sponsor is given an opportunity to respond to Panel's grouping assessment.

Sponsors have five working days in which to respond in writing.

If there is no response within the five days, the Panel's assessment will be provided to the PLAC.

Responses may not include any additional evidence or supporting information (as this information needs to be considered by the Panel prior to the PLAC making a recommendation).

If there is a response within five days, the PLAC will consider this in making its recommendation.

CAG and Panel advice to PLAC

If a CAG or Panel conclude that its advice to PLAC is that a product should be listed, then the Department will advise the sponsor of the outcome and provide the advice to PLAC.

If a CAG or Panel conclude that its advice to PLAC is that a product should not be listed, then the Department will advise the sponsor of the CAG or Panel assessment and the reasons for it in writing.

4.6 Assessment of requests for increased benefit or a new group, subgroup, suffix

Applications requesting an increased benefit or the creation of a new group, subgroup or suffix will require assessment of the clinical evidence to demonstrate claimed superiority over an existing prosthesis listed on the PL and an economic evaluation. Applicants should provide sufficient data to enable proper clinical and economic evaluation. The Department may contract a HTA group to perform this assessment which will provide its advice to PLAC.

It is likely that a first in class/breakthrough technology or new technology that is likely to have significant financial impact on the health system will be referred to the Medical Services Advisory Committee (MSAC) for health technology assessment. MSAC will provide its advice to PLAC.

Further details about revised application pathways will be developed in consultation with the sector through 2019-2020. This Guide will be updated to reflect these refinements.

4.7 PLAC consideration and recommendations

In making recommendations on listing and benefits for prostheses, PLAC will consider advice from clinicians, the CAGs and Panel on the assessment of the product against the criteria for listing and the appropriate grouping, and on the appropriate group benefit for a new grouping.

Recommendation to list

PLAC may recommend products for listing that satisfy the criteria for listing.

If the product is not yet included or registered on the ARTG, PLAC may make a provisional recommendation of suitable for listing, pending ARTG. In these circumstances, an application recommended suitable, but "pending ARTG", will be held for up to 18 months from the date of application submission. The PLAC will recommend the product after the

sponsor has advised that the product has been included on the ARTG and a valid ARTG certificate has been supplied.

PLAC may recommend a product for listing pending receipt of advice that there is an appropriate MBS item for the professional service during which the product is intended to be implanted or applied. The sponsor will be asked to ensure that an application is made for the professional service to be assessed by the Medical Services Advisory Committee for public funding (if such an application has not already been made).

When advice is received that there is an appropriate MBS item, the application assessment recommendation will be referred to the Minister for consideration. If the Minister grants the application, the product will be listed on the next Prostheses List.

Recommendation not to list

PLAC may recommend that a product not be listed if one or more of the listing criteria have not been met.

If PLAC recommends that a product not be listed, the Department advises the sponsor of the recommendation and the reasons for it in writing.

Decline of components of a system

If clinical assessment of components of a system recommends that one or more of the crucial components of the system be declined for listing, PLAC will usually recommend that all components of the system not be listed. This is because the clinical data for all components of a system are common—if one crucial component of the system is called into question, then all components of the system will not be recommended for listing.

Group benefit

Where PLAC recommends listing a product on the Prostheses List, it will also recommend the appropriate grouping for the product.

The sponsor may list the product at the group benefit or at a benefit that is lower than the group benefit. If the sponsor does not accept the group benefit, they can choose not to list the product.

Parallel Processing - ARTG number

To support parallel processing with relevant Australian health technology assessment bodies, sponsors can apply to list a product on the Prostheses List if they are able to provide an ARTG inclusion application number issued by the Australian Government Department of Health, Therapeutic Goods Administration.

If an ARTG inclusion application number is provided, sponsors can apply to list a product on the Prostheses List without providing an ARTG certificate for the device. The application will be processed; however, the product will not be listed on the Prostheses List (if recommended) until a valid ARTG certificate has been provided.

PLACs consideration of application assessments without an ARTG certificate number will be deferred for a maximum of 18 months since the date the application was submitted. After which time the application will be deemed to be non-compliant and the sponsor will need to submit a new application to list a product on the Prostheses List.

4.8 Ministerial decision on applications

When PLAC has considered applications to list products and the benefits for the products it recommends for listing, its recommendations are forwarded to the Minister. The Minister decides whether to grant, or not to grant, each application.

Decision not to grant an application to list

If the decision is not to grant an application to list a product, the Department will inform the sponsor of the reasons for the decision in writing. The letter will include information on how to seek an internal review of the process followed by PLAC that led to its recommendation to the Minister (see Section 4.10).

Decision to grant an application to list

Where the Minister decides to grant an application to list a product, the Department will inform the sponsor of the Minister's decision in writing, and advise that an initial listing fee is payable for each product to be listed. The sponsor will be advised of:

- the initial listing fee payable
- the prosthesis for which the initial listing fee is payable
- the date by which the initial listing fee must be paid
- how the initial listing fee can be paid

Initial listing fee

The initial listing fee is specified in the *Private Health Insurance (Prostheses Application and Listing Fees) Act 2007*. The current initial listing fees are:

- nil for human tissue prostheses
- nil for products that were listed as a result of duplicating, expanding, transferring or compressing existing billing codes
- $200 for all other prostheses

4.9 Minister makes the Prostheses List

Products are listed on the Prostheses List by their inclusion in the Prostheses Rules. Three times a year the Minister endorses new Prostheses Rules. The Prostheses Rules are then registered on the Federal Register of Legislation and are tabled in both Houses of Parliament. Following tabling, either House of Parliament may disallow the instrument within 15 sitting days.

4.10 Removal of a prosthesis from the Prostheses List

From time to time, PLAC will consider if a prosthesis should be removed from the Prostheses List, usually because the product does not satisfy the criteria for listing.

If PLAC is considering this action, the Prostheses List secretariat will write to the sponsor informing them of the consideration and offering them the opportunity for comment.

If the sponsor provides further information or evidence to support continued listing, the matter will be referred to a CAG or Panel to provide advice to PLAC.

If the sponsor agrees that the product should be removed, or PLAC affirms the recommendation to remove the product, the matter will be referred to the Minister. If the Minister agrees with PLAC's recommendation, the Minister may remove the product from the Prostheses List the next time it is made or amended.

Australian Register of Therapeutic Goods

In instances where a prostheses on the Prostheses List is no longer registered on the Australian Register of Therapeutic Goods (ARTG), that prosthesis will no longer be eligible for listing on the Prostheses List and will be removed from the Prostheses List at the earliest opportunity. Sponsors should inform the Prostheses List secretariat when their prosthesis is removed from the ARTG.

4.11 Ongoing fees

Ongoing listing fee

Ongoing listing fees are payable for each billing code on the Prostheses List on a given imposition day (unless the billing code is new to the Prostheses List because an application to list a new prosthesis has just been granted by the Minister). There are two ongoing listing fee imposition days set out in the *Private Health Insurance (Prostheses Application and Listing Fee) Rules*:

- 15 March
- 15 September

The ongoing listing fee is payable in respect of prostheses listed on the Prostheses List on these days, regardless of whether the sponsor of the prosthesis on the Prostheses List is still selling the prosthesis.

Ongoing listing fee

The ongoing listing fee is specified in the *Private Health Insurance (Prostheses Application and Listing Fee) Rules*. The current ongoing listing fees are:

- nil for human tissue prostheses
- nil for new products that were added to the most recent Prostheses List as a result of an application to list a new prosthesis
- $200 per billing code for all other prostheses

When ongoing listing fees are imposed, the Department will write to sponsors to advise them of:

- the amount of their ongoing listing fees
- the prostheses for which the fees are being charged
- the due date for payment
- how to make a payment

An invoice for the ongoing listing fees will be included. Sponsors will also be advised that the Minister may remove the sponsor's product from the Prostheses List if they fail to pay the ongoing listing fee.

Sponsors should be aware of the products they have on the Prostheses List and apply to delete any unused items from the list if they do not wish to pay ongoing listing fees. Deletion of an item from the Prostheses List will take effect from the date that the next Prostheses List commences.

National Joint Replacement Registry Levy

The National Joint Replacement Registry (NJRR) levy will also apply to joint replacement prostheses that are tracked on the NJRR. The NJRR levy provides sustainable funding for the NJRR to continue its work in collecting information on the performance and safety of joint replacement devices and providing this information to a range of interested stakeholders, including suppliers of joint replacement devices, surgeons, public and private hospitals, the TGA, private health insurers and PLAC.

The *Private Health Insurance (National Joint Replacement Register Levy) Rules* set out the formula for calculating the levy rate, and sets the levy day (the day on which the levy is imposed) and census day. The census occurs on 30 September each year and the respective levy is imposed on 30 November.

4.12 Key events and timeframes

The following key events and timeframes are provided as a guide (Table 4.1). They may vary depending on the circumstances at the time.

Table 4.1 Key events and timeframes

Event	Timing
Applications to list new prostheses, expand current listings, compress current listings, change listing details, transfer, duplicate or delete existing listing	Applications can be submitted at any time. Applications received by midnight of the 2nd Sunday in January will be considered for the July PL. Applications received by midnight of the 2nd Sunday in May will be considered for the November PL. Applications received by midnight of the 2nd Sunday in September will be considered for the March (of the following year) PL. Applications for duplications, deletions or transfers must be submitted at least three weeks in advance of an expected publishing day for it to be considered for inclusion in the PL.
Submission of ARTG certificates of inclusion	Usually 4–5 weeks before the Prostheses List is published – cut-off dates are published on the Department's website via PHI Circulars*.
Publication of Prostheses List	Usually 10 business days before commencement
Commencement of Prostheses List	1st March, 1st July and 1st November
Ongoing listing fee imposition days	15 March 15 September
National Joint Replacement Registry census day	30 September
National Joint Replacement Registry levy day	31 October

*To subscribe to PHI Circulars, please visit the PHI Circulars webpage.

5 Submitting an application

All applications are to be submitted through the Prostheses List Management System (PLMS) online portal.

Access to PLMS includes a mandatory requirement for the applicant to have an active AUSKey or MyGovID. From the end of March 2020, the ATO will replace AUSKey with myGovID and Relationship Authorisation Manager (RAM). This will provide a more flexible and secure way to access PLMS. A dual login screen will be available on PLMS from 19 February 2020. AUSKey will no longer be available from 1 April 2020 onwards. Information about what you need to do to prepare for the transition from AUSKey to myGovID is available at the ATO's AUSKey Replacement Website.

Part II of this guide provides advice on what evidence sponsors should include with an application.

Part III outlines key information required to apply for a new listing.

Part IV provides information on how to complete other application types (those based on an existing listing).

Access to the PLMS is provided on the Department's website.

5.1 General Comments

- Always refer to the relevant section of the Guide when completing every section of the application. Ensure that you have the latest version of the Guide and grouping scheme from the Department's website.
- Understand the structure of the Prostheses List and how prostheses are listed within categories and product groups.
- Clearly identify your product's comparator(s) and the features that enable your product to provide comparable or better outcomes.
- Understand why and how products are clinically assessed, and what information and evidence should be included in the application to demonstrate the comparative clinical effectiveness of your product.
- Critically assess all evidence provided within the application to determine whether it should be included. **Quality is more important than quantity**.

5.2 Sponsor's details

The Department will use the sponsor's details to liaise with the sponsor about the application. The sponsor name should be as shown on the TGA Certificate of Inclusion of a medical device on the ARTG for the product. The sponsor contacts should be people who can discuss the application and provide further information, if necessary.

The application number is the number assigned to an application by the Department; applications are recorded in the Department's applications database when they are received. The application number is used as the reference for an application throughout the application process.

Please ensure you have your application number on hand when contacting the Department about the status of your application.

5.3 Collating the application

In addition to the clinical and economic evidence requirements (as detailed in Part II), all applications should include:

- A copy of the ARTG certificate
- A clear image(s) of the product
- A comparison table of the product and the comparator to clearly demonstrate the comparative assessment (including images, catalogue numbers)
- Catalogue numbers which have been entered in the application must be clearly identified and highlighted in the brochure
- Instructions for Use (published version)
- Surgical Technique (published version)

Part II — Supporting evidence

6 Rationale for supporting evidence

The process to assess applications to list prostheses on the Prostheses List must be consistent. Clinical evidence is required to provide consistent and clear support for expert clinical judgment.

Comparative clinical effectiveness

Comparative clinical effectiveness is a product's clinical effectiveness against a comparator—that is, the product, treatment or therapy that is most likely to be replaced by the introduction of the product for which listing is sought. In most instances, the comparator is a prosthesis that is already listed on the Prostheses List.

All new applications should include evidence of comparative clinical effectiveness. Some applications to amend listing details, or expand or compress billing codes also require evidence of comparative clinical effectiveness if the proposed change would change the listed product's grouping or benefit.

Cost relative to clinical effectiveness

The criteria for listing a product on the Prostheses List also state that the cost of the product should be relative to its clinical effectiveness. This is to ensure that products of similar clinical effectiveness have similar benefits.

If sponsors are claiming a different grouping from the comparator, with a higher benefit, evidence of measurable improvement in patient outcomes must be submitted. Economic data, including utilisation, should also be provided. Sponsors are invited to contract their own HTA that can form part of the submission.

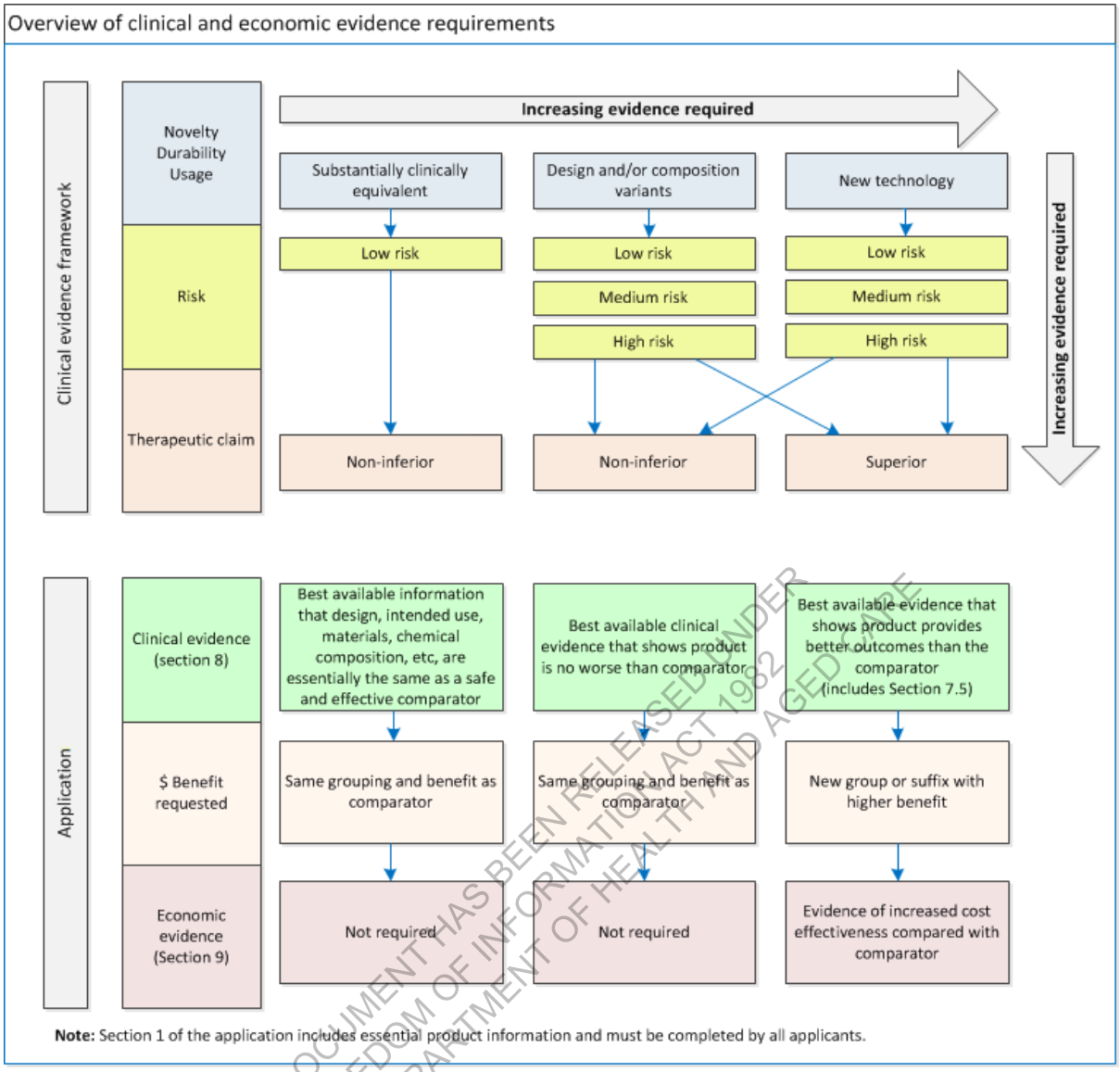
The CAGs and Panel advise their assessment outcomes to the PLAC based on their assessment of information (including clinical evidence) provided by sponsors and their experience and expertise. In assessing a product, clinicians consider how effectively it achieves, or is likely to achieve, the treatment outcome(s) for the clinical indication it is designed to treat.

The clinical and economic evidence required varies according to the type of application (e.g. whether the product is a new technology or a variant of an existing product, the level of risk of the product, therapeutic claims made by the sponsor, and the grouping and benefit requested). In general, the more novel the technology, the higher the risk of the product; and the higher the benefit requested compared with the currently used comparator, the more supporting evidence required.

Sections 7 and 8 of this guide provide a detailed framework for assessing what clinical evidence sponsors need to include in their applications. A step-by-step guide to completing the clinical assessment section of the application form is in Part III, Section 10 of this guide.

A step-by-step guide to filling in the section of the application form to support the proposed benefit and grouping is in Part III, Section 10 of this guide.

An overview is shown in Figure 6.1.



Note: Section A of the application includes essential product information and must be completed by all applicants.

Figure 6.1 Overview of clinical and economic evidence requirements

7 Framework for supporting evidence and clinical assessment

In this section:

- "clinical evidence" generally means peer-reviewed clinical evidence in a published journal (unless stated otherwise)
- "appropriate length of follow-up" means follow-up that reflects factors such as the duration required for the prosthesis to have the intended therapeutic effect
- "representative cohort" generally means a number of patients that reflects the intended uses and likely patient populations for the prosthesis

The best evidence that sponsors can provide to support an application for listing is evidence that relates directly to the prosthesis in the application.

Importantly, there is no "one size fits all" requirement; sponsors should submit the best evidence that fits the design and purpose of their product.

This section describes a framework that helps to refine and clarify the minimum evidence that should be provided to support applications to list a product on the Prostheses List. The amount and type of evidence that sponsors should submit vary according to a range of factors relating to the product. The primary considerations when deciding on the clinical evidence to provide in an application are risk, novelty, durability, usage and the type of claim the sponsor makes.

7.1 Risk

The level of evidence that is appropriate to enable assessment of a prosthesis depends on the risk to the patient if the prosthesis does not perform as intended. The consequences of decisions (the potential benefit or harm from the product) are higher for some devices than others—therefore, the level of evidence required to assess these potential benefits and harms is higher.

PLAC takes a risk-based approach to assessing prostheses, similar to the approach taken by the Therapeutic Goods Administration to assess medical devices for inclusion on the Australian Register of Therapeutic Goods. Table 7.1 shows examples of prostheses in three risk categories: high, medium and low.

Table 7.1 Risk categories for clinical assessment

Level of risk	Examples
High	• Load-bearing prostheses • Finger joints • Electronic prostheses • Prostheses in direct contact with the heart, or central circulatory or nervous system • Prostheses with a biological effect • Prostheses that are wholly or mainly absorbed into the body • Prostheses that undergo chemical changes in the body (but not teeth) • Prostheses that administer a medicine • Active implantable medical devices
Medium	Prostheses that do not meet the definitions of high or low risk, including (but not limited to): • Intraocular lenses • Ureteric stents • Gastric bands
Low	• Clips, staples and screws • Plates • Grommets • Tissue closure prostheses • Haemostatic prostheses

7.2 Novelty

If a product is new or uses novel technology, design or composition, sponsors should include in their application clinical evidence with an appropriate length of follow-up in a representative cohort of patients for the indications the product is designed to treat.

Novel technology is technology that is different from anything seen or known before.

Similarly, if a product is a variant of an existing design or composition, sponsors should include clinical evidence with an appropriate length of follow-up in a representative cohort of patients for the indications the product is designed to treat.

The level and strength of evidence required depend on how novel the proposed product is, or how different it is from the comparator. In all cases, sponsors are encouraged to submit the best evidence available that shows that the new or variant product is comparatively clinically effective.

7.3 Durability/life span

Durability or life span refers to the period of time for which the product remains active or functional in the patient. Clinical effectiveness should be demonstrated over a period of time that is relative to the life span of the product. For example, a product that is designed to remain functional in a patient for 20 years should demonstrate clinical effectiveness over a longer time (i.e. longer follow-up) than a device that is designed to be used for 2 years. However, this does not necessarily mean that evidence should be gathered over the entire life span of the product (although this would be ideal).

Sponsors are encouraged to use data from registries such as Australia's National Joint Replacement Registry (and similar registries in other countries) to support their applications, where appropriate.

7.4 Usage

The level of use of a product can also influence the amount and level of evidence required to support the application. A product that is used less often (e.g. a product designed specifically for revision or oncology surgery) is likely to have a smaller body of evidence that can be used to support an application than a product that is in high use (e.g. a product designed for primary surgery).

7.5 Sponsor's claims

Finally and most importantly, the type of evidence required also depends on the claim that the sponsor makes in relation to the product's effectiveness for the proposed indications.

Sponsors can claim that their product is better than the comparator, which is referred to in this guide as 'superior'. Alternatively, sponsors can claim that their product is equivalent to (i.e. no worse than) the comparator, which is referred to in this guide as 'noninferior'.

Claims of noninferiority

Sponsors can apply to have their product listed in an existing grouping on the Prostheses List based on a claim that, although the product may have some characteristics that are different from comparators in the group, it produces a result that is equivalent to (i.e. not worse than) the appropriate comparator for the indicated uses.

The extent to which a product differs from the comparator may influence the level of evidence required to demonstrate noninferiority, depending on the potential risk of harm from use of the product. A product that is significantly different in design or composition from the comparator may require a higher level of evidence than a product that differs only in aspects that do not affect the product's comparative safety or effectiveness.

Claims that do not need clinical evidence (low-risk products only)

In some cases, a new prosthesis may be so similar in design and function to comparators on the Prostheses List that similar performance and complication rates to the comparator might be assumed in the absence of further clinical information.

Noninferiority claims include claims that the proposed product is substantially clinically equivalent to the comparator. To be substantially clinically equivalent, the product does not need to be identical to the comparator but must be substantially equivalent with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labelling, biocompatibility, standards and other characteristics, as applicable. A product may be substantially clinically equivalent if it:

- does not raise new questions of safety or effectiveness
- is not new or novel in design
- has the same intended use as the comparator
- has the same or very similar technological characteristics as the comparator

- has a comparator that has been demonstrated in clinical studies to be safe and effective over a period of time commensurate with its intended use, risk and likelihood of failure

Substantial clinical equivalence does not apply to novel products or high-risk prostheses (e.g. load-bearing or articulating prostheses, a mobile implant or a cardiac stent). Please note that, while a sponsor may claim that a prosthesis listed in the high-risk category in Table 7.1 is substantially clinically equivalent to a listed prosthesis, supporting clinical evidence for high-risk devices should be provided to support an application.

Claims of superiority

Clinical superiority

If a sponsor claims that their product is superior to an appropriate comparator, they will need to submit evidence demonstrating that the product is clinically effective, and also evidence that demonstrates how the new product is clinically superior to the comparator.

If the product represents an incremental change (i.e. improved functionality compared with an existing item that is already on the Prostheses List), sponsors should provide supporting clinical evidence that the product delivers measurably or quantifiably better clinical outcomes relative to the nature of the change, the durability requirements of the product and the potential risk to the patient if the new functionality fails.

In most cases, a successful claim of clinical superiority will result in the product being listed in a new grouping.

Superior clinical performance

Products in the Hip and Knee categories may be eligible for a suffix recognising demonstrated ‘superior clinical performance’. To be eligible for this special type of superior claim, an application must provide:

- a minimum of 10 years follow-up with an appropriate cohort and with an unchanged prosthesis
- appropriate peer-reviewed publications (not from the prosthesis designer) showing greater than 95% survivorship at a minimum of 10 years
- Australian Orthopaedic Association National Joint Replacement Registry data on the performance of the prosthesis

The Hip CAG and Knee CAG will assess claims of superior clinical performance and advise PLAC.

8 Choice of clinical evidence to include in an application

An application should include the best available clinical evidence to demonstrate that the product is comparatively clinically effective. At the very least, evidence must demonstrate that the product is similar in clinical effectiveness to an appropriate comparator.

Assessment of the clinical effectiveness of a product should ideally be based on studies that have been published in peer-reviewed journals. A literature search of peer-reviewed studies is therefore the best way to identify the supporting evidence to include in the application. Unpublished studies may be considered if there are no published studies, depending on the product.

However, sponsors should not necessarily include in the application every study conducted on their product. This section outlines issues that sponsors should consider when choosing the evidence that best supports their application.

8.1 Quality, not quantity

The quality of information provided in the application is more important than the quantity. A single well-designed study with a large cohort published in an international peer-reviewed journal demonstrates a higher level of evidence than several case studies. If a product has been the subject of a large, well-designed, published trial, this may be all the evidence needed to support the application.

The National Health and Medical Research Council has developed a framework to categorise the levels of evidence that are represented by different types of published clinical trials and studies (Table 8.1). Levels of evidence are based on the level of bias that is inherent in different types of studies—the lower the chance of bias in the study, the higher the level of evidence, and the better the basis for clinical assessment.

Table 8.1 Levels of evidence

Level of evidence	Type of study or trial
I(highest)	A systematic review of Level II studies
II	A randomised controlled trial
III –1	A pseudo-randomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: • Nonrandomised experimental trial • Cohort study • Case–control study • Interrupted time series with a control group
III-3	A comparative study without concurrent controls: • Historical control study • Two or more single-arm studies • Interrupted time series without a parallel control group
IV(lowest)	Case series with either post-test or pre-test/post-test outcomes

Source: modified from National Health and Medical Research Council, 2009[1]

However, the level of evidence only refers to individual trials or studies, and is therefore only one component of evidence assessment. The final assessment is based on a judgment about all the trials or studies included as evidence for a particular issue. This is called the 'body of evidence'. Assessment of a body of evidence includes consideration of:[2,3]

- the level of evidence of the trials and studies included (see Table 8.1)
- the number and quality of trials and studies (where quality reflects how well the researchers were able to minimise any bias in study design)
- the size of the effect shown, and whether it demonstrates statistically significant and clinically important outcomes
- the relevance of the trials and studies to the clinical practice situation proposed for the product

Sponsors should consider the body of evidence for their product when choosing the evidence to support their application and include the best evidence available. However, the level and strength of evidence required also depend on the level of perceived risk of major complications associated with use of the product and its potential failure points. The higher the risk, the higher the strength of evidence required to demonstrate safety and clinical effectiveness.

1 NHMRC (2009). NHMRC additional levels of evidence and grades for recommendations for developers of guidelines. National Health and Medical Research Council - additional levels of evidence & grades for recommendations for developers of guidelines

2 Hillier S, Grimmer-Somers K, Merlin T, Middleton P, Salisbury J, Tooher R and Weston A (2011). FORM: an Australian method for formulating and grading recommendations in evidence-based clinical guidelines. *BMC Medical Research Methodology* 11:23.

3 GRADE Working Group (2013). GRADE guidelines: best practices using the GRADE framework.

Although product information should be included in the application, this does not constitute clinical evidence. Published studies should be included, and these will be assessed to determine comparative clinical effectiveness.

Where a sponsor is claiming substantial clinical equivalence, supporting clinical evidence should be included, if available. If it is not provided, the assessing clinicians or PLAC may not accept that the new product is substantially equivalent to the nominated comparator, and the application may not be successful.

8.2 Relevance and focus of the information

To maximise the chances of success, sponsors should **only include information that is relevant to the product under application**. A frequent error in applications is to supply irrelevant data, in the mistaken belief that more paperwork and evidence pertaining to the use of similar products is helpful, when high-quality and relevant data specific to the product would be much more beneficial.

For example, sponsors should include relevant studies that demonstrate the success of the product in a human clinical setting. If the product is associated with a service that improves patient outcomes, this information should be included in the application. It should not be assumed that evidence relating to a similar product or an earlier model of a product will equally apply to a new product.

Data from animal studies may provide an indication of the potential clinical effectiveness of a product, but clinicians generally do not accept it as clinical evidence to support comparative clinical effectiveness. Where only animal studies are provided, the sponsor should explain why no appropriate human studies are available.

Wherever possible, sponsors should provide evidence from studies comparing the use of their product with the use of a comparator product or technology.

If the product uses well-established technology or procedures, it is not necessary to include extensive information about this. For example, cardiac pacemakers have been used for many years for management of arrhythmias and are a well-established treatment, so there is no need to include clinical data about the technology itself. However, it is necessary to demonstrate that the product under application is comparatively clinically effective.

Some Clinical Advisory Groups require certain information about subsets, for example:

- for any soft tissue anchor the SOCAG requests clinical information on the device's pull-out strength and the source of the clinical evidence.
- for plates the SOCAG requests biomechanical data relevant to the device.
- for cardiac aortic valves there are additional evidentiary requirements.

Details on evidence requirements for particular groups of products will be provided in the next update of this document.

8.3 Actual or perceived conflict of interest

Sponsors should consider any conflicts of interest in the information they provide. This includes actual or perceived conflicts of interest that may be apparent in statements from clinicians, studies that were conducted by the sponsor or product designer, or follow-up studies in which the clinicians were financially linked to the product.

Statements by the sponsor or testimonials from clinicians do not demonstrate the clinical effectiveness of a product. These types of information may be included in the application if they are relevant, but they will not be considered as evidence and should be accompanied by published studies.

8.4 Length of follow-up

The length of clinical follow-up should be relative to the life span of the product; that is, products with a longer life span generally require a longer period of follow-up. Follow-up should also be conducted on a suitable number of patients, and should have sufficient statistical power to identify problems with clinical safety or effectiveness.

For products with a relatively short life span (less than 12 months), the length of clinical follow-up should be at least equivalent to the intended product life.

Examples of indicative lengths of clinical follow-up are shown in Table 8.2.

Table 8.2 Indicative lengths of clinical follow-up

Product	Indicative length of follow-up
Major joint replacement prosthesis claiming superior clinical performance	10 years
Major joint replacement prosthesis claiming noninferiority	2 years
Implantable cardiac device	2 years
Bioresorbable screw	1 year
Polypin resorbable bone pin	1 year
Mesh	1 year

8.5 What if there are no studies?

In some instances, evidence that demonstrates clinical effectiveness and outcomes may not be available. For example, products such as internal fixation screws may not themselves have been subject to clinical trial, although the technology of using plates and screws to treat fractures has been. Clinicians will take this into account when assessing these products.

If there is no evidence of a product's comparative safety or effectiveness, it cannot be assumed that there is no potential benefit or harm associated with the product ('absence of evidence is not evidence of absence').

9 Evidence to support a new group benefit

A sponsor who is applying to list a product in a new grouping needs to provide sufficient evidence to support the proposed new group benefit.

There is no specific type of evidence required to support a proposed benefit; however, the higher the quality of the information that is provided, the better the chance that the proposed benefit will be validated.

9.1 Clinical evidence

Where a sponsor is seeking a new grouping on the basis that a new product delivers superior clinical outcomes, the application should provide clinical evidence of the comparison of outcomes. The evidence should quantify the improvements where possible.

The clinical evidence will be assessed by the CAG or Panel to provide advice on clinical effectiveness including any clinical superiority claim. An economic analysis (see also Section 4.6) will be required to inform the determination of the benefit.

Economic and cost analysis studies may be useful in supporting a proposed benefit. These should be provided if they are available.

9.2 Economic and financial information

Economic information is useful to validate a proposed benefit and to demonstrate that it is within a reasonable price range.

Such information can include:

- costs associated with the use of the new prosthesis, compared with the costs associated with the use of the comparator(s)
- prices of the new prosthesis in other markets (both overseas and within Australia)

NB- the cost of manufacture / importation is not considered as part of benefit setting.

9.3 Further development of benefit consideration

The arrangements for considering proposed benefits for new groupings and reviews of current benefits are undergoing further development. Stakeholders will be involved in the development of the arrangements, and any new information requests will be communicated to sponsors.

Part III — Completing an Application to list a new prosthesis

10 Application to List a New Prosthesis – Single Product

10.1 New Prosthesis Device

Product details

Product name

The product name is the name under which the product is sold in Australia and should be as shown on the product information. If the product is a system or a kit, provide the name of the system or kit and the component as the product name (e.g. ACME Hip System—Femoral Head).

If the application is successful, this information will be transcribed onto the Prostheses List.

Description

Include a description of the product that will be recorded on the Prostheses List. The description should be sufficient to enable the reader to identify what the product is and any additional features that are unique to the product.

Because there is limited space on the Prostheses List to record a description, it should be no more than one or two sentences (256 characters or less). Include details that are specific to the product, such as:

- model number
- descriptor for the product or the components of a product (e.g. a spinal system that consists of screws, threaded rod, hex nuts, washer and endplate)
- composition
- any special features

Further details about the product can be appended to the application as an attachment(s).

Size(s)

The product size may be expressed as length, diameter, width, height, number of holes/degrees/dioptres, volume, or other specification of the product or its components, as detailed in the product information or technical documentation. The size information should be concise and accurate.

Failure to provide adequate size information may result in inappropriate grouping of the product.

Catalogue number(s)

List the catalogue number(s) under which the product is sold. A catalogue number must be provided for every component or prosthesis within an application that will become one billing code.

This information will be used to cross-reference with data sources such as the National Joint Replacement Registry (NJRR), and will assist in providing data to the Clinical Advisory Groups (CAGs) and the Panel of Clinical Experts (Panel) for clinical assessment purposes.

Proposed benefit

If your product has a comparator that is already listed on the Prostheses List and you are applying to list your product in the same grouping, the benefit should be the group benefit for the group in which your product is to be listed. You may choose to list the product with a benefit lower than the group benefit.

If your product does not fit into an existing grouping on the Prostheses List, propose a benefit for the new grouping. The evidence you provide with the application should demonstrate why your product should be considered to be clinically superior to or different from the other products on the Prostheses List. See Sections 7 and 8 in this guide for more information about clinical evidence.

ARTG ID number/TGA application number

Only products that are entered on the ARTG can be listed on the Prostheses List—see Criterion 1 of the criteria for listing:

> The product must be entered and current on the Australian Register of Therapeutic Goods.

Provide the product's ARTG number, which can be found on the Therapeutic Goods Administration (TGA) Certificate of Inclusion of a medical device.

To support parallel processing with relevant Australian health technology assessment bodies, sponsors can apply to list a product on the Prostheses List if they are able to provide an ARTG application number issued by the Australian Government Therapeutic Goods Administration. If the sponsor has applied to include the product on the ARTG, tick the box.

If an ARTG application number is provided, sponsors can apply to list a product on the Prostheses List without providing an ARTG registration number or an MBS item number for the professional service associated with the prosthesis. The application will be processed; however, the product will not be listed on the Prostheses List (if recommended) until valid ARTG and/or MBS item numbers have been provided.

Information about the ARTG can be found on the TGA website.

Grouping

Information about grouping schemes for products can be found on the Department's website.

Category

Provide the category in which the product will be listed on the Prostheses List (see Section 2.2 of this guide for a list of categories). Some products may fit into more than one category; sponsors should list the category that will represent the greatest use of the product, as only one billing code can be allocated to the product.

Subcategory

This is sometimes known as the assessment body.

Group

Indicate in which group the product should be listed.

If you believe there is no suitable group for your product on the Prostheses List, please propose a group name here. You will need to provide information with your application to support the proposed group. Your product may or may not be listed in this proposed group.

Subgroup

Indicate the subgroup and suffix that should apply to the product, if necessary.

If you believe there is no appropriate subgroup for your product on the Prostheses List, please propose a subgroup name here. You will need to provide information with your application to support the proposed subgroup. Your product may or may not be listed in this proposed group.

Suffix (es)

Suffixes are used to indicate that products within a group or subgroup have a feature or features that make the product slightly different to others in the group or subgroup. Indicate the appropriate suffix or suffixes for your product here.

If you believe that your product is slightly different to others in the same group or subgroup, and this difference is clinically significant, you can propose a new suffix here. You will need to provide information with your application to support the proposed suffix. Your product may or may not be listed with the proposed suffix.

10.2 Comparators

To demonstrate comparative clinical effectiveness for the product, you must identify at least one comparator. This may be a product or the current treatment or therapy that is most likely to be replaced by the product under application. If there is currently no treatment or therapy for the indication, the comparator will be “nil”.

First, refer to the Prostheses List to identify a listed prosthesis (or more than one) that may be proposed as a comparator(s) for your product. The list can be accessed at the Department’s website.

If no listed prostheses that are similar to your product in form and function can be identified as a comparator, identify a current treatment or therapy (e.g. a drug treatment or medical service) as the most appropriate comparator for your product.

When assessing the relative clinical effectiveness of your product, clinicians may consider another product to be a more appropriate comparator for your product than the one you propose. To ensure that your application progresses smoothly through the process without the need to respond to clinicians’ questions, ensure that you choose an appropriate comparator for your product. If the comparator is already listed on the Prostheses List, this will generally be in the same grouping as the proposed grouping for your product.

Main comparator

If more than one comparator is identified for the product, all of them should be listed in this section, and you should identify which of these is the main comparator(s) for the product—that is, the product that would be most often replaced with the proposed product.

10.3 Medicare Benefits Schedule (MBS) item number and descriptor

Products will be listed on the Prostheses List if there is a Medicare benefit payable for the professional service associated with the implantation or application of the product - see Criterion 3 of the criteria for listing:

> A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist).

Provide the MBS item number and descriptor to verify that the product is used in association with a professional service for which a Medicare benefit is payable.

For a product that can be used for a number of professional services, list up to 10 MBS item numbers for professional services by which the product may be surgically implanted or applied.

MBS item numbers can be found on the Department's website. Choose the downloadable PDF version and use the search facility to find the appropriate MBS items for the product. MBS item descriptors include references to body parts, procedures, and/or diseases or injuries, so searches on these terms may assist.

Please also explain why the MBS items have been selected.

To support parallel processing with relevant Australian health technology assessment bodies, sponsors can apply to list a product on the Prostheses List if they have applied for an MBS item number. If there is no MBS item for the professional service associated with the product, tick the box if an application has been made for the service/s to be assessed by the Medical Services Advisory Committee.

If PLAC recommends listing a product but there is no appropriate MBS item for the professional service, the application will not proceed to listing until an appropriate MBS item has been created for the professional service.

10.4 Product Setting and Product Purpose

Product setting

Criterion 2 of the criteria for listing requires that:

> The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment.

Indicate whether the product is implanted as part of hospital treatment, as part of hospital-substitute treatment or as part of treatment outside a hospital.

If a product is used for treatment outside of hospital (i.e. it is not part of hospital treatment or hospital substitute treatment) it may not satisfy this criterion. If the box (c) is ticked, please provide a description of the setting in which the product is provided.

Product purpose

Criterion 4 of the criteria for listing on the Prostheses List defines the permitted product purposes:

> The product should:
>
> (a) be surgically implanted in the patient and be purposely designed in order to
>
> (i) replace an anatomical body part; or
>
> (ii) combat a pathological process; or
>
> (iii) modulate a physiological process;
>
> or
>
> (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted
>
> or
>
> (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted

Please tick the appropriate box that describes the purpose of the product. If box (b) or (c) is ticked, please also advise the specific surgically implanted prosthesis that the product is used with.

Provide a brief explanation of the function of the product, to support assessment against this criterion.

10.5 Overseas Status and Comparative Clinical Assessment

Overseas status

Please indicate whether authority has been given for the product to be sold in any other country. If the product has authority to be sold in other countries, please advise what authorities have been given (e.g. FDA, CE Mark) if this information is available. This information is used by the clinicians to determine what other health technology assessments (if any) the product has undergone.

Indicate any names that the product is being sold under overseas if these are different from the product name/s to be listed on the Prostheses List.

Comparative Clinical Effectiveness

This section provides the opportunity for the sponsor to state how the clinical effectiveness and cost effectiveness of the new product compares with the comparator.

This is where the sponsor can explain why the new product is clinically equivalent to the comparator, or clinically superior to the comparator, or clinically different. In the explanation the sponsor should refer to the clinical evidence that demonstrates their claims. The clinicians will be looking at the clinical evidence and other information provided with the application to support the sponsor's claims.

10.6 Benefit and Economic Information for the New Grouping

A sponsor only needs to complete this part of the application if they are applying to list the product in a group or with a suffix that is not currently on the Prostheses List.

Clinical Outcomes

In this section, provide information about the quantifiable or measurable clinical difference in clinical outcomes between the new product and the comparator/s. Refer to measurable and/or quantifiable factors relating to patient outcomes, such as recovery time, failure rates, complications and life expectancy.

Any information provided and any claims in this section should be supported by clinical evidence or data.

Cost Savings

In this section, provide information about cost savings that can be realised by using this product rather than the comparator.

Any information provided and any claims in this section should be supported by clinical evidence or data. For example, where a claim is made about reductions in theatre time, hospital stay, post-surgical care costs, fewer complications, reduced revision surgery, evidence should be provided that these are real reductions and not potential or theoretical.

Benefit Rationale

In this section, please explain how the information in the two sections above were used to arrive at the proposed benefit.

Product Utilisation

Please provide information about the actual and projected utilisation of the new product and the cost in local currency.

If the new product has been used in the public health sector in Australia, please provide utilisation data and costs in this table.

Information provided on the projected utilisation over the first two years of listing on the Prostheses List and whether the new product will replace another product is useful to compare with other prostheses on the Prostheses List.

Other Information

This section allows sponsors to provide any other information not already provided to support the proposed benefit for the new product.

10.7 Attachments

This part of the form prompts the sponsor to attach information and evidence to the application to assist with assessment.

An image of the product

A clear image of the product is required for all applications.

If the product is a component of a system, an image of the system should also be provided, with each component clearly labelled.

If the sponsor is applying to list a product in a new group or with a suffix, an image of the product should be provided that clearly identifies and labels the feature that makes the product clinically superior or clinically different to comparators.

Supporting literature

Sponsors must attach clinical papers (if available) with the appropriate follow-up data to support the application.

Sponsors should be judicious in their choice of supporting evidence. One or two papers that satisfy the clinicians' quality requirements and relate directly to the device should be sufficient to support an application. Sponsors should also attach the papers in the order of strength of evidence and relevance to the new product.

Applicants should note that the following types of documents do not constitute clinical evidence:

- product promotional material (brochures and presentations)
- non-peer reviewed papers
- conference poster presentations
- abstracts

While surgical technique documents are not clinical evidence, they can provide useful information for clinicians and these should be provided where available.

Optional attachments

A sponsor can also provide other information that will assist in assessing the application.

Documentation of overseas approvals is useful if it is available.

Product documentation describing the product and how it is used can be useful. The surgical technique can be particularly useful for clinicians to show how the product is implanted and functions correctly.

Reports of economic and cost analysis studies should be provided if they are available to support the proposed benefit for a new grouping. If a sponsor is applying to list a product in an existing grouping, this documentation is not required.

10.8 Submission Declaration

The person completing the application or approving the submission of the application within the sponsor organisation should make this declaration.

11 Application to List a New Prosthesis – Product System

This process is essentially the same as the application to List a New Prosthesis – Single Product. A sponsor can apply to list all components or individual products in the system in this one form.

11.1 Product system name

This is the name of the whole system. For example, if the system is a joint replacement system, the product system name will be the name of the whole system. If the system is a type of screw to be listed in a range of sizes, the product system name will be the name of the screw.

The sponsor will need to complete the following sections for each component or individual product, as this information will be unique. The section in the Guide providing information is in brackets:

- New Prosthesis Device (10.1)
- Comparator(s) (10.2)
- Benefit and economic information for the new grouping (*if applicable)* (10.6)

The following sections can be completed for the system as a whole, as the information will be common to all components and individual products. The section in the Guide providing information is in brackets:

- Medicare Benefits Schedule (MBS) Item(s) and Descriptor(s) (10.3)
- Product Setting and Product Purpose (10.4)
- Overseas Status and Comparative Clinical Effectiveness (10.5)
- Attachments (10.7)
- Submission Declaration (10.8)

12 Application to List a New Prosthesis – Human Tissue

12.1 New Human Tissue

Product Details

Product Name

The product name will be the name of the human tissue item. Most human tissues will be the type of human tissue and how it is presented e.g. bone, chips.

Description

The description will provide more information to describe the human tissue item, as appropriate. If the human tissue item is adequately described by the product name, just repeat the product name here.

Size/s

The size is the size of the human tissue item as it is presented. This is relevant to human tissue items such as bone chips and cubes that are supplied in different quantities. If the human tissue item is supplied as one size only or the size or quantity is not relevant to the benefit, just enter "one size" here.

Proposed benefit

This is the benefit that the human tissue supplier proposes to list on the Prostheses List.

Please explain how you calculated this benefit

The benefit for a human tissue item is set at an amount that recovers the costs involved in supplying the human tissue to the patient. This includes, but is not limited to: costs of retrieval, processing, storage and transport.

Documentation must be provided to support the proposed benefit.

ARTG ID Number

Please provide the ARTG number for the human tissue item.

If the sponsor has applied to the TGA to include the human tissue item on the ARTG, but the item has not yet been included, tick the box.

Category

Human tissue items are currently listed on the Prostheses List in four categories:

- Orthopaedic
- Ophthalmic
- Cardiac
- Dermatologic

Enter the appropriate category for the human tissue item here.

12.2 Comparator(s)

In most cases, this will be another human tissue item on the Prostheses List. Enter the billing code, product name and grouping (or category) in the table.

If the comparator is another treatment or therapy currently available for the indication that the human tissue item will be used for, provide details in the table at (ii).

Please choose a main comparator for the human tissue item.

12.3 Medicare Benefits Schedule (MBS) Item(s) and Descriptor(s)

The information provided at 10.3 – Medicare Benefits Schedule (MBS) Item(s) and Descriptor(s) is also relevant to human tissue items.

12.4 Attachments

An application to list a new human tissue item must be accompanied by information to support the proposed benefit:

- an annual financial statement of the human tissue facility, certified by an accountant; and
- an audited service cost calculation showing the costs attributed to supplying the human tissue to the patient, certified by an accountant. Where possible, this should include actual costs, not estimates.
- an image of the item or type of item.

Information on the actual or projected utilisation of the human tissue item should also be provided, if it is available.

12.5 Submission Declaration

A person submitting the application or approving the application for submission in the organisation should make the two declarations:

- that all the information in the application is true and correct; and
- that the proposed benefit for the human tissue item is calculated on a cost recovery basis only. This ensures compliance with relevant State and Territory legislation regarding the sale of human tissue.

Part IV — Changing an existing listing

13 Application to expand a billing code

This application is for expanding billing codes on Part A or Part C of the Prostheses List. Billing codes for human tissue items on Part B are generally not expanded or compressed.

Please note that this application should not be used if the sponsor is requesting to change size range of a current listing, or adding new sizes. This can be done by applying to Amend a Listing for a Prosthesis Device.

13.1 Details of proposed expansion

Please detail the listing to expand

This section requests details of the prosthesis as it currently appears on the Prostheses List:

Reason for Expansion

There are two options in the application to choose to explain the reason for expanding the billing code. If the reason is neither of these, please explain in the space available.

The rest of the application form asks for information that is essentially the same as for the application to list a new prosthesis.

For each resultant (new) prosthesis stemming from the expansion, please complete the following information. The relevant sections in the Guide that provide information are in brackets:

- Resultant (new) Prostheses Listings (10.1)
- Comparator(s) and Comparative Clinical Effectiveness (10.2 and 10.5)
  Please note that this section needs to be completed only if the sponsor is applying to list the resultant new billing code in a grouping different to the current billing code, or in a grouping that is not currently listed on the Prostheses List.
- Benefit and Economic Information for the New Grouping (10.6)
  Please note that this section needs to be completed only if the sponsor is applying to list the resultant new billing code in a grouping that is not currently listed on the Prostheses List.

13.2 Attachments

This section of the form provides information about the documents that the sponsor should attach to the application.

An image of the product is required to show that the product is the same as that already listed on the Prostheses List. If the sponsor is applying to expand a current listing into billing codes to cover each component, the image should be labelled to show each component.

Supporting literature such as clinical studies is required when the sponsor is applying to list one or more of the resultant (new) listing in a group different to the current billing code. It is particularly important to provide this information to support grouping a resultant (new) listing in a grouping that is not currently listed on the Prostheses List. Supporting literature should be relevant to the product.

Economic and cost analysis studies/reports are useful to support a proposed benefit if a sponsor is applying to list a resultant (new) listing in a grouping that is not currently listed on the Prostheses List. This should be provided if it is available.

Product information and documentation describing the technical specifications and surgical technique can be very useful in assessing requests for listing in a different grouping or with a suffix.

13.3 Submission Declaration

This declaration should be made by the person submitting the application or approving the submission of the application in the organisation.

14 Application to compress billing codes

14.1 Details of proposed compression

Please list the product you wish to compress in the table below:

List all the billing codes you wish to compress, their product names, their associated catalogue numbers, and the current benefit for each product.

Reason for Compression

Please advise why the billing codes are being compressed. There are three options to select from in the form. If the reason is other than one of these, please explain in the space provided.

Proposed Product Details, ARTG ID Number and Grouping

The instructions for these sections of the form are the same as for an application to list a new prosthesis (10.1).

If the proposed compressed billing code will be listed in the same grouping as the original billing codes, at the group benefit or lower, no further information is required.

14.2 Comparator(s) and Comparative Clinical Effectiveness

This section needs to be completed only if the sponsor is proposing to list the compressed billing code in a grouping other than the grouping of any of the current billing codes.

The guidance on completing this section is the same as that for an application to list a new prosthesis – 10.2 – Comparators and 10.5 – Comparative Clinical Effectiveness.

14.3 Benefit and Economic Information for the New Grouping

This section needs to be completed only if the sponsor is proposing to list the new compressed billing code in a grouping that is not currently listed on the Prostheses List.

The guidance on how to complete this section is the same as for an application to list a new prosthesis (10.6).

14.4 Attachments

An image of the product to be listed in the billing code should be attached to the application.

Supporting literature should be attached if it is proposed to list the compressed billing code in a different grouping to any of the current billing codes.

Economic and cost analysis reports should be submitted (if they are available) with the application to support a proposed benefit for a new grouping that is not currently listed on the Prostheses List.

14.5 Submission Declaration

This declaration should be made by the person submitting the application or approving submission of the application for the organisation.

15 Application to Amend a Listing – Prosthesis Device

15.1 Amend Prosthesis Device

In this section, the sponsor provides details of the product as it is proposed to be listed after the amendment.

Please provide the billing code of the product to be amended.

The guidance on the other information requested in this section on *Proposed Product Details*, *ARTG number* and *Grouping* is the same as for an application to list a new prosthesis (10.1)

Reason for Amendment

Please indicate the reason why the billing code details are being amended. There are a number of options provided to select from:

- changing the product name
- changing the description
- changing the size range available in the billing code
- changing the grouping of the product

If the reason for amending the billing code details is anything other than these, please explain in the space provided.

15.2 Comparator(s) and Comparative Clinical Effectiveness

This section needs to be completed only if the sponsor is proposing to list the amended billing code in a grouping other than the current grouping of billing code.

The guidance on completing this section is the same as that for an application to list a new prosthesis – 10.2 – Comparators and 10.5 – Comparative Clinical Effectiveness.

15.3 Benefit and Economic Information for the New Grouping

This section needs to be completed only if the sponsor is proposing to list the billing code in a grouping that is not currently listed on the Prostheses List.

The guidance on how to complete this section is the same as for an application to list a new prosthesis (10.6).

15.4 Attachments

An image of the product is required.

Supporting literature should be attached if it is proposed to list the amended billing code in a different grouping to the current listing.

Economic and cost analysis reports should be submitted (if they are available) with the application to support a proposed benefit if the amended billing code is proposed to be listed in a grouping that is not currently listed on the Prostheses List.

15.5 Submission Declaration

This declaration should be made by the person submitting the application or approving submission of the application for the organisation.

16 Application to Amend a Listing – Human Tissue

16.1 Amend Human Tissue

Current Product Details

Please provide the billing code, product name and description of the human tissue item to be amended.

If there is more than one human tissue item to be amended, please provide the information in a table.

Please also indicate the main reason for the amendment. There are three options to choose from:

- Change in benefit
- Change to the description
- Change in size(s)

Proposed product details, ARTG ID and Category

The guidance for completing this section of the form is the same as for an Application to List a New Prosthesis – Human Tissue (12.1)

16.2 Attachments

An image of the human tissue item should be attached.

If the amendment is a change in the benefit, documentation providing financial and cost information must be provided to support the proposed benefit. An annual financial statement of the facility or company supplying the human tissue must be attached. An audit of the service cost calculation, certified by an accountant, must also be supplied. The audit statement should provide details of the actual costs involved in supplying the human tissue to the patient where possible, rather than projections.

16.3 Submission Declaration

A person submitting the application or approving the application for submission in the organisation should make the two declarations:

- that all the information in the application is true and correct; and
- that the proposed benefit for the human tissue item is calculated on a cost recovery basis only. This ensures compliance with relevant State and Territory legislation regarding the sale of human tissue.

17 Application to transfer or duplicate a current listing

This form can be used to transfer a current listing from one sponsor to another, or for a sponsor to list a prosthesis that is already listed by another sponsor.

The information required in the form is self-explanatory.

A sponsor can request to transfer or duplicate a listing before the ARTG inclusion has been transferred or the sponsor has an ARTG inclusion for a duplicated product. The transfer or duplication of the billing code will not be finalised until the sponsor has an ARTG number.

In addition to the form, the transfer process requires authority from the original sponsor. Specifically, the transfer process requires that the receiving sponsor must supply a letter of authority from the original sponsor providing approval for the transfer of the billing code.

When applying to duplicate a listing, the manufacturer, GMDN and intended use stated on the ARTG certificate must match original listing.

Please note, sponsors may have to wait until the next publication of the Prostheses List for the transfer to take effect if a valid ARTG number is not supplied by the ARTG cut-off (as published in the PHI Circular).

18 Application to Delete a Listing

The ‘Application to delete a current listing’ form is used to have a product deleted from the Prostheses List. All details of the product are removed from the Prostheses List by this amendment, including product name, description, size, billing code and benefit.

Sponsors should list the billing codes, product names and catalogue numbers of the products they wish to delete from the Prostheses List.

19 Abbreviations and key terms

A detailed glossary of health technology assessment terminology used by the Australian Government Department of Health is available on the Department's website.

Term	Definition
ARTG	Australian Register of Therapeutic Goods: a computer database of therapeutic goods within which medicines and medical devices must be entered as 'registered' or 'listed' goods before they may be supplied in, or exported from, Australia
Benefit	The amount that a private health insurer is required to pay for a prosthesis on the Prostheses List that is provided to a privately insured patient with appropriate cover as part of hospital treatment or hospital-substitute treatment.
Billing code	A reference code allocated to a listed prosthesis
CAG	Clinical Advisory Group
Comparator	The prosthesis on the Prostheses List, or treatment or therapy, that use of a new prosthesis would potentially replace. If there is no current treatment or therapy, the comparator is nothing
Description	Detail specific to the product, which could include: • model number • descriptors for the product or product components—for example, a spinal system that consists of screws, threaded rod, hex nuts, washer and endplate • composition • any special features
Duplication	The creation of a new billing code (for a different sponsor) for a prosthesis that already exists on the Prostheses List. The result is two different billing codes (for different sponsors) for the one prosthesis. This may occur when two or more companies are sponsors for a given product in Australia (also known as parallel importing)
Federal Register of Legislative Instruments	An authoritative database established under s. 20 of the *Legislative Instruments Act 2003* containing legislative instruments, explanatory statements for legislative instruments made on or after 1 January 2005 and compilations of legislative instruments in electronic form. It is accessible via the internet
Group	The level of classification of a prosthesis on the Prostheses List below 'category'. Within categories, products are grouped according to similar clinical effectiveness. For simplicity, product groups and subgroups are identified numerically
Group benefit	The benefit paid for all prostheses that are classified in the same category, group, subgroup and suffix
Grouping	The full classification of a prosthesis on the Prostheses List, including category, group, subgroup and suffix
Hospital-substitute treatment	Treatment that substitutes for hospital treatment; it is any combination of nursing, medical, surgical, podiatric surgical, diagnostic, therapeutic, prosthetic, pharmacological, pathology or other services intended to manage a disease, injury or condition
Medical devices	The legislation does not include the term 'medical devices'. In this document, the terms 'product(s)', 'prosthesis(es)' and 'medical device(s)' are used interchangeably

Term	Definition
Medicare Benefits Schedule (MBS)	The MBS lists and describes the professional services for which a Medicare benefit is payable, the amount of that benefit, and any conditions applying to the use of that service. The MBS changes from time to time to reflect, for example, the availability of new medical technologies, changing medical practice and the government's current policy parameters for determining which professional services are eligible or ineligible for Medicare benefits
NJRR	National Joint Replacement Registry
Panel	Panel of Clinical Experts
PLAC	Prostheses List Advisory Committee
Product	In this document, the terms 'product(s)', 'prosthesis(es)' and 'medical device(s)' are used interchangeably
Product name	The name under which the product is sold in Australia
Prostheses List category	The clinical-use category that primarily reflects the purpose for which a product is listed on the Prostheses List
Prosthesis	The legislation does not define 'prosthesis'. In this document, the terms 'product(s)', 'prosthesis(es)' and 'medical device(s)' are used interchangeably
Size	May be expressed as length, diameter, width, height, holes, degrees, dioptres, volume or other specification of the product or its components, as detailed in product information or technical documentation
Small business	Businesses employing fewer than 20 employees
Sponsor	Manufacturer, supplier or importer responsible for: • the supply of a product/prosthesis/medical device in Australia • submitting the manufacturer's evidence of conformity to the TGA • applying for entry of the product on the ARTG. In this document, the sponsor is also the person or company who makes an application to list a prosthesis on the Prostheses List
System	A product comprising two or more components
TGA	Therapeutic Goods Administration
Utilisation	The number of products (prostheses) used in a given period of time

Appendix A: Version Control

This table is to record the document's history as changes are made.

Version	Date	Distribution	Change Description
February 2017	February 2017	Published	February 2017 version replaces the December 2015 version.
February 2017, Revision 1	13 June 2019	Published June 2019	• Minor grammatical changes throughout. • Addition of version control tables and updated advice on the feedback and update process. • All instances of 'Private Health Insurance Branch' replaced with 'Office of Health Technology Assessment Branch'. • 1.2 and 2.1, – Updated the definition of Part C of the Prostheses List to reflect the cardiac ablation devices. • 1.2 and 2.4 – Updated details on the Prostheses List cycle. • 1.2 – Updated the sentence relating to the Part B to reflect that some parts of the Guide to relate to Part B. • Table 2.1, criterion 5, changed 'of similar' clinical effectiveness to non-inferior. • 3.1 – Updated narrative on PLAC membership • 3.2 – removing references to HESC, removed reference to the urogenital CAG and updated the role of the Department of Health to reflect changed assessment arrangements. • Updated Figure 4.1. • 4.2 – Removed reference to the application forms on the Department's website. • 4.5 – updated for when an application is assessed by clinicians and CAGs. • 4.6 – Removed the paragraph on HESC. • 4.7 – Added information on assessment of requests for increased benefits or a new group, subgroup or suffix. • 4.8 – Changed narrative on parallel processing and ARTG numbers. • 4.9 – Removed content in relation to requests for administrative review of the process • 4.10 – updated what is to occur when a prosthesis is no longer on the ARTG • 4.11 – updated details on key events and timeframes to reflect new listing cycle • 5 – Text on the application process has changed to better reflect the use of PLMS for applications.

Version	Date	Distribution	Change Description
			• 6 – minor edits to on provision of health technology assessment for clinical effectiveness. Removed comparison of prostheses assessment to other health technology assessments. • 7.5 – minor edit to 'superior clinical performance' to remove the reference to benefit premium. • 8.2 – additional example of information required for some clinical advisory groups. • 9 – minor changes to reflect the quality of information provided, including removing reference to HESC. • 12 – removal of reference to adopting ICCBBA ISBT 128 global standards for naming conventions. • 15.4 – text changed to *require* an image of the product as an attachment.
February 2017, Revision 2	6 November 2019	Published November 2019	• 1.2 – Clarification that Midnight Sunday refers to the time in between Sunday and Monday. • 1.3 – Minor grammatical change to first paragraph. • 2.1 – Criteria for listing in Part C updated to reflect the addition of surgical cardiac ablation devices. • 2.4 – Clarification that '10 days' refers to 10 business days. • 3.1 – Re-introduced text to reflect medical device industry representation in PLAC's membership • 4.12 – Advice provided on timeframes for deletions, duplications or transfers. • 4.5 – Removed reference to applications bypassing CAG where two clinicians agree on the recommendation and reverted to previous wording. • 4.6 – Reference to HESC removed. • 4.6 – Change to date from 2019 to 2019-2020. • 4.7 – Wording on Parallel Processing largely reverted to the previous wording. • 6 – Sponsors are now invited to contract a HTA assessment but are not required to do so. • 8.2 – Note added advising that evidence requirements will be considered in the next revision of this document. • 9.1 – Updated to reflect an economic analysis informs a determination of a benefit.
February 2017, Revision 3	17 February 2020	Published February 2020	• 4.11 – Updated NJRR Levy Imposed date. • 5 – Updated to reflect transition from AUSkey to myGovID. • Updated contact details.

COMMITTEE-IN-CONFIDENCE

Prostheses List Advisory Committee

Agenda item 8.1.2 – Review of surgical guides and biomodels

ISSUES

s 47C

[redacted]

BACKGROUND

There are 21 billing codes for surgical guides and 14 billing codes for biomodels are currently listed on the Prostheses List, in groupings: 07.02.02.04; 07.02.05.07; 07.02.06.06, 07.02.07.05, and 07.02.09. They are single use devices used in planning and decision making both pre and intra-operatively.

The question regarding surgical guides and biomodels has been included, among other things, in the *Prostheses List Reforms – Consultation Paper No 1*, questioning whether these devices meet the PL criteria for listing. The feedback and responses to this consultation paper are being considered as part of the Prostheses List reforms.

If the conclusion is made that surgical guides and biomodels meet the revised PL criteria for listing under the reforms, the PL benefits will be aligned with the prices paid in public hospitals.

Further characterisation of the issues is required to determine the optimal policy response. It is proposed that a review of these devices is conducted to inform consideration of whether surgical guides and biomodels should be eligible for listing on the PL.

The matters to be considered include:

- Benefits and risks associated with the use of these devices;
- Nature of the comparator (ie no guide, or other surgical devices not on the PL);
- Understanding current patterns and future trends in device usage;
- Views regarding optimal role in clinical practice;
- Sources of clinical evidence and expert advice.

From: s22
To: FLYNN, Elizabeth; s22 ; s22 ; s22 ; s22
Cc: s22
Subject: FW: FOR INFORMATION: PROSTHESES LIST POST-LISTING REVIEW OF SURGICAL GUIDES AND BIOMODELS - UPDATE [SEC=OFFICIAL]
Date: Thursday, 1 September 2022 6:06:35 PM
Attachments: image001.png
SURGICAL GUIDES AND BIOMODELS – BILLING CODES AND PRODUCT NAMES AS PER PL JULY 2022.pdf
image006.png
image007.png

Folks

Thank you all for your assistance and guidance on this matter and as a result we have made significant progress towards commencing the post-listing review on surgical guides and biomodels.

For your information I have sent this email (s22) to the sponsors of billing codes/products that are within the scope of this post-listing review. The sponsors were blind copied in the email, so for your information only the following sponsors were included:

Sponsor	Primary contact	Email address
AA-Med Pty Ltd	s47F	
Anatomics Pty Ltd		
DIGITAL DENTAL NETWORK PTY LTD		
Johnson & Johnson Medical Pty Ltd		
KLS Martin Australia Pty Limited		
Maxoniq		
More Group Pty Ltd		
SPECIFICA PTY LTD		
Stryker Australia Pty Ltd		

I will let you know whether or not we receive any responses to this advice.

Regards

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

From: s 47E(d)
Sent: Thursday, 1 September 2022 5:57 PM
Cc: s47E(d) @Health.gov.au>
Subject: FOR INFORMATION: PROSTHESES LIST POST-LISTING REVIEW OF SURGICAL GUIDES AND BIOMODELS - UPDATE [SEC=OFFICIAL]

Dear Sponsor

On 22 July 2022, we informed you about the commencement of the post-listing review of surgical guides and biomodels currently listed on the Prostheses List (the Review). This letter is to provide you with an update on the progress of the Review, the Terms of Reference (ToRs) and how sponsors can engage and provide information and evidence to support the Review.

Terms of Reference:

Stage One

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the Prostheses List (PL), including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and their clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of Terms of Reference 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL. Findings regarding eligibility may differ between products and clinical circumstances.

Stage Two

5. Subject to the findings of Terms of Reference 4, review the cost-effectiveness of surgical guides and biomodels currently listed on the PL.

Review Process

The Department is in the final stages of engaging an external consultant to undertake the relevant research and write a report addressing the above **Stage One ToRs**. The consultant will collate information and evidence addressing the ToRs, which will be incorporated into a draft report to be considered by the Department. This report will consider submissions from sponsors, stakeholders and consumers, expert advice, evidence obtained from the literature review and other relevant evidence. Sponsors will be given an opportunity to comment on the draft report. These sponsor comments will be considered alongside the draft report prior to finalisation. The review findings will subsequently be communicated to sponsors.

Timeframes

The consultant will work towards preparing a draft report for circulation later in 2022 and will contact you shortly with further details on submitting your evidence to this Review.

The ToRs for this Review will be published on the PL reforms webpage shortly inviting consumers

and stakeholders to provide information and evidence to the Review ToRs.

Further Information on Submissions to the ToRs

Stakeholder consultation addressing the ToRs will be conducted early in the Review process. Sponsors along with other relevant stakeholders will be contacted by the consultant and invited to provide information and evidence addressing the above ToRs Stage One. In particular any information and evidence that can assist the consultant, such as:

1. Evidence regarding the comparative safety, clinical benefits and clinical effectiveness of surgical guides and biomodels, when compared to "standard of care" or surgery without their use; and
2. Information on whether (and if so why) surgical guides and biomodels are essential as an integral single-use aid for implanting a medical device, and their current role in clinical practice.

The review relates to the devices (billing codes and product names) as listed in the PL July 2022 included in **Attachment A**.

Privacy

When preparing a submission to the Review, please consider if the information to be provided is commercially sensitive and identify this clearly in your documents. Any commercially sensitive or private information will be redacted before sharing with other sponsors and publication of the draft and final reports.

The Department of Health will not publish submissions, or parts of submissions, which contain personal information, offensive language, potentially defamatory material or copyright infringing material. Responsibility for copyright in submissions resides with the author(s), not with the Department of Health and Aged Care.

All commercially sensitive information in submissions provided to the external consultant shall be regarded as Confidential Information and appropriate facilities will be available on site to store that material securely.

If you have any questions, please send an email to s47E(d) @health.gov.au.

Regards

PL Reviews Secretariat

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
E: s47E(d) @Health.gov.au
Location: Sirius Building 9.N.101
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

s22

From: s22
Sent: Wednesday, 7 September 2022 11:55 AM
To: s 47F ; s47E(d)
Cc: ; s47E(d)
Subject: RE: Confidentiality and conflict deeds [SEC=OFFICIAL]

Thank you for providing these s 47F We are gathering the background documents to send to you as soon as possible.

In addition to CC s47E(d) @health.gov.au, are you also able to cc s47E(d) @health.gov.au. This will ensure both area's of the Department involved in this review can see and respond to your questions.

Kind regards,
s22

From: s 4 @ahaconsulting.com.au>
Sent: Wednesday, 7 September 2022 8:52 AM
To: s22 @health.gov.au>; s22 @health.gov.au>
Cc: s47F @ahaconsulting.com.au>
Subject: Confidentiality and conflict deeds

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Please find attached the confidentiality deeds for our AHA team members: me, s47F

Note that our expert advisor, s47F, is external to AHA. We have not formally engaged her for this work yet, but will ensure she signs the agreement when we do. We do not plan to share any confidential information with her (her role will be confined to advising on the systematic review).

Please let me know if you have any questions or need more information. We look forward to receiving the relevant program documentation and stakeholder details as discussed at yesterday's meeting.

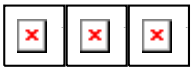
Kind regards,

s 47

s 47F | Associate Director
Head of Evaluation and Advisory
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: s 47F

E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au



Please note I don't work on Fridays

Please consider the environment before printing this email.

From: s22
To: s22 ; s22 ; s22 ; s 47F ; s47F
Cc: s22 ; FLYNN, Elizabeth; s47F s47F
Subject: Initial meeting for the Surgical Guides and Biomodels Review [SEC=OFFICIAL]

Hello,

See below the webex link and a rough agenda for an initial discussion regarding the surgical guides and biomodels review.

Please feel free to forward to others in Australian Healthcare Associates who need to attend.

* Objectives for the Review: develop a deeper understanding of the department's objectives
* Methodology and the development of the research protocol, including the possibility of the department connecting us with surgical expertise for ad hoc advice on technical terminology, given the highly specialised subject matter.
* Consultation: Confirm stakeholders and discuss any sensitivities for effective stakeholder engagement.

* Mode of contact with sponsors

* Background documents: discuss access arrangements and confidentiality requirements for background documentation
* Data requirements
* discuss project risks and mitigation strategies
* confirm the frequency and mode of contact between AHA and the department
* Report format and confirm requirements for deliverables
* Other questions

Kind regards,

s22

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Join meeting s22

More ways to join:

Join from the meeting link

s22

Join by meeting number

Meeting number (access code): s22

Meeting password: s22

Tap to join from a mobile device (attendees only)
s22 Australia Toll

Join by phone
s22 Australia Toll
Global call-in numbers s22

Join from a video system or application
s22
You can also dial s22 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial s22

If you are a host, click here s22 to view host information.

Need help? Go to https://help.webex.com <https://help.webex.com>

From: s22
To: s22 s22 ; s47F ; s 47F
Cc: s22 ; FLYNN, Elizabeth; s47F s47F
Subject: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Join meeting s22

More ways to join:

Join from the meeting link

s22

Join by meeting number

Meeting number (access code): s22

Meeting password: s22

Tap to join from a mobile device (attendees only)
s22

Join by phone
s22 Australia Toll
Global call-in numbers s22

Join from a video system or application
Dial s22
You can also dial s22 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial s22

If you are a host, click here s22 to view host information.

Need help? Go to https://help.webex.com <https://help.webex.com>

s22

From: s47E(d)
Sent: Friday, 2 September 2022 1:44 PM
To: s47F @ahaconsulting.com.au'; s47G @ahaconsulting.com.au'; s47F @ahaconsulting.com.au'
Cc: s22 ; s22
Subject: Successful applicant for the Review of Surgical Guides and Biomodels on the Prostheses List
Attachments: AHA Confidentiality and conflict deed - Organisation agreement .docx; AHA Official Order Surgical guides and biomodels.pdf

Dear Australian Healthcare Associates,

Thank you for your response to our Request for Quotation (RFQ) for the Review of Surgical Guides and Biomodels on the Prostheses List (PL). I am pleased to advise that the delegate has accepted the quotation as providing value for money, and will now offer an Official Order for the work.

A copy of the proposed Official Order is attached. Please review this document and, when satisfied it accurately reflects your proposal, sign and return the copy to me, along with the confidentiality and conflict Deed. Please note – as outlined in the RFQ, the department will sign your scanned copy of the Official Order (if you choose to send it this way) as if it was an original document delivered by ordinary mail. When counter signed by the department, the scanned copy of the Official Order will be legally binding. If you do not want the scanned copy to be considered the official copy, then please return your signed copy by post to:

s22
Post-market Review Section
Department of Health
PO Box 9848 (MDP 910)
Canberra ACT 2601

I will then arrange for our delegate to countersign the Official Order and return a copy to you for your records.

Details of the Official Order will be posted on the AusTender website after signing by both parties. Your organisation should not incur any expense before both parties have signed the Official Order.

Please contact me if you have any queries or concerns relating to the proposed Official Order prior to signing, or would like feedback on your response.

Kind Regards
s22 (on behalf of s22)

s22
Technology Assessment and Access Division | Health Resourcing Group
Office of Health and Technology Assessment Policy and Programs Branch
Email: s22 @health.gov.au
Australian Government, Department of Health and Aged Care
PO Box 100
Woden ACT 2606

SCHEDULE 6
OFFICIAL ORDER

Australian Government

Department of Health

Official Order/Contract details for Review of surgical guides and biomodels (SGBs) currently listed in the Prostheses List (PL)

Under Deed of Standing Offer – Standing Offer Notice SON3676958
Reference ID: Health/ E22-200107

Customer details	**Contractor details**
Commonwealth of Australia As represented by the Department of Health and Aged Care ABN: 83 605 426 759 MDP 910, GPO Box 9848 Canberra ACT 2601	Australian Healthcare Associates (AHA) ABN 82 072 790 848 Level 6, 140 Bourke St, Melbourne VIC 3000 Locked Bag 32005, Collins Street East, VIC 8006
Customer Contract Liaison Officer: Assistant Director, Post-market Review Section, currently s22 Telephone: s22 Email: s22 @health.gov.au	**Contractor Contract Liaison Officer:** Director: currently s47F Telephone: s47F Email: s47F @ahaconsulting.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 ***Commonwealth of Australia as represented by the Department of Health and Aged Care*** and ***Australian Healthcare Associates*** dated ***31 March 2020.***

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	As per Item 1 of the Official Order
Cost	s 47 (GST Inclusive)
Date services to commence on	Countersigning by the Department of Health and Aged Care
Date services to be completed by	30 March 2023
Extension Option	An extension option may be available for a further period not exceeding 30 June 2023.

Invoices are to be issued to s47E(d) **@health.gov.au with attention to the Customer Contract Liaison Officer named above.**

1. The Services and subcontractors

The evaluator is to undertake a systematic literature review and clinical review of surgical guides and biomodels currently listed on the Prostheses List (PL). The review aims to inform whether they are eligible for PL listing, and if further cost-effectiveness review is required.

The Surgical Guides and Biomodels under the following PL groups and subgroups are to be included:

- 07.02.02.04 Cranium;
- 07.02.05.07 Mandible, Maxilla and Temperomandibular Joint (TMJ); and
- 07.02.09 Craniomaxillofacial.

The review will consider their role in clinical practice, utilisation patterns and the evidence for their comparative safety, clinical benefits and clinical effectiveness. The review will provide the department with the research evidence and clinical advice necessary to answer Terms of Reference 1 – 4 and support decision-making on eligibility.

Four phases have been planned to answer the key review questions and their sub-questions as follows:

- Phase 1: Plan the review
- Phase 2: Review the PL surgical guides and biomodels place in clinical practice (Q1)
- Phase 3: Conduct a rapid, targeted systematic review (Q2)
- Phase 4: Prepare reports on information and evidence (Q3)

Stakeholders may include sponsors, other medical device industry representatives, private health insurance representatives, private hospital representatives, consumer representatives and clinicians (including clinical experts).

The outcome of this research should include:

- Analyses of the products in the above PL groupings and whether they are considered eligible for PL listing according to the 'criteria for listing' in the Prosthesis List Guide (including but not limited to whether they are 'essential' to the implanted device). Finding regarding eligibility may differ between products and clinical circumstances.
- Identify policy issues that may arise from these findings.

The services include:

Conduct research activities to address Terms of Reference 1-4 listed below:

Terms of Reference:

Stage One

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the Prostheses List (PL), including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and their clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of Terms of Reference 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL, which may differ between products and clinical circumstances.

Stage Two

5. Subject to the findings of Terms of Reference 4, review the cost-effectiveness of surgical guides and biomodels currently listed on the PL.

Questions to be addressed:

Q1: Review the role in clinical practice of surgical guides and biomodels currently listed on the PL. In undertaking this work, the Contractor will consider the following areas of interest to the department, but will not be limited by them:

- Review guidance documents (Australian and international).
- Seek input from relevant organisations and experts using qualitative research methodology.
- Invite sponsors and stakeholders to provide relevant information and evidence and review and incorporate this correspondence in the Report where applicable.

Q2: Conduct a targeted, systematic literature review of the clinical evidence of surgical guides and biomodels currently listed on the PL. In undertaking this work, the Contractor will consider the following areas of interest to the department, but will not be limited by them:

- Undertake a systematic literature review to identify evidence regarding the comparative safety, clinical benefits and clinical effectiveness of surgical guides and biomodels (the appropriate comparator may be standard of care, or no guide).
- Clearly identify and analyse the benefit/s of surgical guides and biomodels compared to the comparator, including clinical outcomes and surrogate outcomes (such as time in surgery).
- Analyse the safety and comparable clinical effectiveness of different types of surgical guides and biomodels and identify the circumstances in which surgical guides and biomodels provide clinical benefit. Compare this to the PL utilisation of surgical guides and biomodels.
- Include a quality assessment and description of the limitations of included trials or observational studies.
- Compare Australian surgical outcomes in maxillofacial surgeries to those of countries where surgical guides and biomodels are not used or have different utilisation patterns.

Q3: Based on the information and evidence in questions 1 and 2, compile information to support the Department to assess whether surgical guides and biomodels meet the PL guide criteria. This includes specific advice on whether they are a device essential for implantation. This may vary between devices and clinical circumstances.

The Contractor will provide the following deliverables:

1. Research protocol

The contractor will be required to prepare a systematic review protocol describing the timelines of the work plan and intended methodology, including:

- inclusion/exclusion criteria
- outcomes of interest
- timeframes
- quality assessment of included studies

- qualitative research proposal to seek expert advice

The protocol must be approved by the Department prior to the contractor progressing with the remaining aspects of the work.

2. Draft Report

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

- an index and glossary with definitions for key clinical terms
- an executive summary
- a technical written report outlining:
  - the methodology used in searching for relevant literature, and identifying relevant literature from sponsor and stakeholder submissions
  - the methodology used for the desktop/ qualitative research (ie key document analysis, stakeholder submissions, and analysis of expert opinion).
  - quality assessment of the evidence used in the report
  - results and conclusions from all evidence considered
- reference list and appendices

3. Final report

The Contractor will submit 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 project. This report should include identification of Commercial in Confidence (CIC) information for redaction.

2. Time frame

The contractor is required to provide the Services in accordance with the timeframes specified in the table below. The Contractor may supply the deliverable earlier than the previous negotiated time frame. The Final Document for any deliverable must be of a standard acceptable to the Department.

If the Contractor cannot resolve or come to an agreement the Department may at its discretion enforce its rights under the Deed of Standing Offer including Schedule 2 Clause 3.

(Annexure 1)

Deliverable	**Date Due**	**Payment** (GST Inclusive)
Research Protocol	16 September 2022	s 47
Draft report	14 November 2022	
Final report	22 December 2022	

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 with the agreed deliverables in the Official Order
b) identify the reasons for not meeting the agreed deliverables

c) identify the component/s that cannot be delivered within the agreed timeframes
d) advise the Post-Market Review team in writing identifying the risk and seek a resolution agreeable to both the Department and the Contractor.

If agreed by both parties, this Official Order may be extended for a further period not exceeding 30 June 2023.

3. Fees, allowances and costs

The total fee for the Services is s 47 (GST incl) payable by the following instalments:

- s 47 following delivery of the research protocol report (as described in Item 8 [Contract Material]); and
- s 47 following delivery of a draft report (as described in Item 8 [Contract Material]).
- s 47 following delivery of a final report (as described in Item 8 [Contract Material]) and following customer evaluation and acceptance of final report.

The due date for payment is 30 days after delivery of a correctly rendered invoice to the Customer.

4. Specified Personnel

The personnel who will work on this project are:

s 47F	Project Director
s47F	Project Manager
s47F	Senior consultant
s47F	Senior consultant
s47F	Consultant
s47F	Consultant
s47F	Consultant
s47F	Expert advisor

The Specified Personnel must produce to the relevant contract manager from the Department of Health and Aged Care a current National Police Certificate, which is no greater than 6 months old, by the contract commencement date. If any disclosable outcomes are mentioned in the certificate, the Department may delay proceeding with the Work Order until an assessment can be conducted.

5. Customer Material to be provided by Customer

The Department will provide the Contractor with the relevant documentation and material required to deliver the Services after the countersigning of the Official Order or as soon as available thereafter.

All contract materials provided to the contractor being relevant data, existing information or any other materials will be regarded as Confidential Information, and appropriate facilities must be available on site to store that material securely and to comply with all reasonable requirements.

The following existing data and information will be made available to the contractor

- Departmental utilisation Review of surgical guides and biomodels presented to the May 2022 Prosthesis List Advisory Committee (PLAC) meeting.
- Deidentified and summarised Hospital Case Mix data
- Deidentified and summarised Medicare Benefits Schedule (MBS) data
- Correspondence (including evidence) from sponsors and stakeholders.

6. Existing Material

The Department will provide the contractor with any existing material required to undertake the work including background documents for desktop review and analysis.

7. Contract Material

Deliverables

1. Research protocol
2. Draft Report
3. Final report

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).

The report deliverables are to be provided in .doc or .docx format and:

- 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).

8. Confidential Information

All contract material provided to the Contractor shall be regarded as Confidential Information and appropriate facilities must be available on site to store that material securely and to comply with all reasonable requirements.

9. Customer facilities and assistance

The contractor will liaise with the Customer on a fortnightly basis, either by telephone or workshops or videoconference or by email, and seek guidance as required. Meetings are offered to answer emerging questions as needed. Initial meeting to be scheduled around 5th September 2022.

10. Invoice procedures

- all in voices to be submitted in PDF to s47E(d)
- and CC: s22 @health.gov.au
- valid billing name: Department of Health and Aged Care
- valid biller: name must appear on ABR website as entity/business or trading name
- valid ABN (if applicable)
- valid 10-digit Purchase Order Number (e.g. 45xxxxxxxx). This will be provided by the Contract Liaison Officer after the Official Order has been executed
- 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.

11. Other Terms and Conditions

A Police Check is required if the specified personnel accessing confidential information.

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:

.....
Date

by:

.....
Printed name of signatory

.....
Signature

.....
Position of signatory

in the presence of:

.....
Printed name of witness

.....
Signature

SIGNED for and on behalf of **Australian Healthcare Associates (AHA),** ABN 82 072 790 848 ***[insert Contractor's ABN]***, in accordance with section 127 of the *Corporations Act 2001* on: ***[You will need to insert the appropriate signature block according to the type of legal entity – see the Guide to the Standard Contract for Services. This signature block is* only *appropriate when the Contractor is a company incorporated under the Corporations Act with several directors or a director and secretary who are separate persons. Also please seek further advice if you are dealing with an individual person (i.e. sole trader) or a trustee]***

.....
Date

by:

.....
Printed name of Director

.....
Signature of Director

and:

.....
Printed name of Director/Secretary

.....
Signature of Director/Secretary

s22

From: s47E(d)
Sent: Wednesday, 8 February 2023 3:49 PM
To: s 47F @moredent.com.au
Cc: s47G @ahaconsulting.com.au; s47F @moredent.com.au; s47F @moredent.com.au; s47F @moredent.com.au; s47E(d)
Subject: RE: Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback [SEC=OFFICIAL]

Dear s 47F

Thank you for your email regarding the review of surgical guides and biomodels currently listed on the Prostheses List.

The consultation on the draft report for the review of surgical guides and biomodels currently listed on the Prostheses List closed on 3 February 2023. AHA will consider the feedback received to inform the final report. The Department will use the final report to determine the appropriate policy response as well as recommendations to the delegate of the Minister for Health and Aged Care. The review findings will subsequently be communicated to affected sponsors prior to implementation. Further specific details about the questions asked of stakeholders will be available in the final report which is due to be provided to the Department in March 2023.

We have included a list of the stakeholders consulted for the review in the Appendix A of the draft report.

Regards

Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: s47E(d) @health.gov.au
Location: Sirius Building s22
GPO 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: s 47F @moredent.com.au>
Sent: Thursday, 2 February 2023 9:57 AM
To: s47G @ahaconsulting.com.au>
Cc: s47F @moredent.com.au>; s47F @moredent.com.au>; s47F @moredent.com.au>
Subject: RE: Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback

Dear Surgical guides and biomodels review team,

Thank you for assisting us in providing feedback on the draft report.

Could you please provide us with a copy of the interview questions asked of the 13 or 14 Oral and Maxillofacial Surgeons who you consulted with in your review process?

Could you please also advise how the review process was publicised to this specialty to solicit their consultation?

We have recently had a lot of feedback from Oral and Maxillofacial Surgeons who were unaware of this review and would like to provide submissions either on their own or as a group. We believe that these submissions will be sent through to you within the next week or so.

Kind regards,

s 47F

s 47F
Business Development Manager
BDSc (hons) FRACDS LLB (dis)
s 47F @moredent.com.au

1300 724 410
Level 8, West Tower, 608 St Kilda Rd, Melbourne, 3004

s22

From: s47F @ahaconsulting.com.au>
Sent: Monday, 19 December 2022 12:11 PM
To: s47E(d) ; s22
Subject: RE: SGB Review - New timelines [SEC=OFFICIAL]

Hi s22
I did try and recall my previous email – the final report will be due on the 3 March 2023.
Kind regards,
s47F

From: s 47F
Sent: Monday, 19 December 2022 11:00 AM
To: s47F
Cc: s22 ; s47E(d) ; s22 ; s22 ; s22 ; s47E(d) ; s 47F
Subject: RE: SGB Review - New timelines [SEC=OFFICIAL]
Good Morning s47F
Hope you had a lovely weekend!
I am following up from our meeting last week. We haven't heard from you regarding the new timeframes (given that we agreed to extend the timeframe until 3 Feb 2023 for stakeholders to provide feedback on the draft report) and whether emails have gone out to stakeholders advising of the extension.
As agreed during the meeting, appreciate if you could please confirm the new dates for reports.
Thanks
s22

From: s47F @ahaconsulting.com.au>
Sent: Monday, 12 December 2022 10:49 AM
To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Subject: SGB Review - More Group

Good morning,
We received two emails on Friday 9 December 2022 from s 47F, More Group that we would like to discuss at our meeting tomorrow.
In the first email, s 47F requested that:
" Due to end of year constraints and Christmas closures in our own and other organisations we need to consult with it will be impossible to meet the 6 January 2023 deadline for feedback. We believe that we can properly consider the draft report, consult with any relevant third parties and provide our feedback by Friday 30 January 2023."
This email also asked why we structured the systematic review to exclude other systemic reviews, meta-analyses and studies on devices equivalent to those listed on the PL and provided further evidence, which we can address.
In the second email, s 47F asked: "Further to my previous email, can you please advise what legal expertise you employed to interpret the relevant legislation, regulations and explanatory notes?"
We would like to discuss the request for an extension, the circulation of the report to third parties and any comments you may have on the question of legal expertise.
Kind regards,
s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s22
Sent: Monday, 7 November 2022 3:52 PM
To: s47F
Cc: s22 ; s 47F ; s22 ; s22 ; s22 ; s47E(d)
Subject: RE: SGB review - additional data questions

Hi s47F
Thank you for this request.
I have forwarded it to our data expert s22 (Cced). s22 advises that we can provide this data from the HCM dataset. It should be available to you by this Friday at the latest.
I have also forwarded the invite to tomorrow's meeting to s22 and he will join at 10.15 to discuss any queries you may have. If we can't cover off on everything tomorrow you can arrange a subsequent meeting with him.
Best Regards
s22

From: s47F
Sent: Monday, 7 November 2022 10:31 AM
To: s
2
Cc: s
2 ; s 47F
Subject: SGB review - additional data questions

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Thanks for offering to facilitate an additional departmental data request. The following outlines the additional data sought to our previous extract (20220606 – Surgical guides and biomodels – Final Tables):

1. An update of the selected Surgical Guides and Biomodels, by Sponsor, by Financial Year table with Digital Dental Network data included
2. The Top 20 MBS codes for utilisation, separated for surgical guides and biomodels
3. Top 20 PMBS codes for utilisation, separated for surgical guides and biomodels
4. Utilisation by individual sponsor for top 20 MBS codes
5. Utilisation by individual sponsor for top 20 PMBS codes
6. Number of items used by top 20 MBS codes, separated for surgical guides and biomodels
7. Break down Private overnight hospital separations into:
    a. Separations with a length of stay (LOS) of 1 day (or less)
    b. Separations with a length of stay (LOS) of 1 or more days
    c. Separations which included an admission to intensive care or high dependency unit (if possible)
8. Number of items used per hospital separation, separated by:
    a. LOS of 1 day (or less)
    b. LOS of 1 or more days.

We are happy to discuss this request further with your data team member if required.

Kind regards,
s47F

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

SCHEDULE 6
OFFICIAL ORDER

Australian Government

Department of Health

Official Order/Contract details for Review of surgical guides and biomodels (SGBs) currently listed in the Prostheses List (PL)

Under Deed of Standing Offer – Standing Offer Notice SON3676958
Reference ID: Health/ E22-200107

Customer details	**Contractor details**
Commonwealth of Australia As represented by the Department of Health and Aged Care ABN: 83 605 426 759 MDP 910, GPO Box 9848 Canberra ACT 2601	Australian Healthcare Associates (AHA) ABN 82 072 790 848 Level 6, 140 Bourke St, Melbourne VIC 3000 Locked Bag 32005, Collins Street East, VIC 8006
Customer Contract Liaison Officer: Assistant Director, Post-market Review Section, currently s22 Telephon Email: s22 @health.gov.au	**Contractor Contract Liaison Officer:** Director: s47F Telephone Email: s47F @ahaconsulting.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 ***Commonwealth of Australia as represented by the Department of Health and Aged Care*** and ***Australian Healthcare Associates*** dated ***31 March 2020.***

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	As per Item 1 of the Official Order
Cost	s 47 GST Inclusive)
Date services to commence on	Countersigning by the Department of Health and Aged Care
Date services to be completed by	30 March 2023
Extension Option	An extension option may be available for a further period not exceeding 30 June 2023.

Invoices are to be issued to s47E(d) **@health.gov.au with attention to the Customer Contract Liaison Officer named above.**

1. The Services and subcontractors

The evaluator is to undertake a systematic literature review and clinical review of surgical guides and biomodels currently listed on the Prostheses List (PL). The review aims to inform whether they are eligible for PL listing, and if further cost-effectiveness review is required.

The Surgical Guides and Biomodels under the following PL groups and subgroups are to be included:

- 07.02.02.04 Cranium;
- 07.02.05.07 Mandible, Maxilla and Temperomandibular Joint (TMJ); and
- 07.02.09 Craniomaxillofacial.

The review will consider their role in clinical practice, utilisation patterns and the evidence for their comparative safety, clinical benefits and clinical effectiveness. The review will provide the department with the research evidence and clinical advice necessary to answer Terms of Reference 1 – 4 and support decision-making on eligibility.

Four phases have been planned to answer the key review questions and their sub-questions as follows:

- Phase 1: Plan the review
- Phase 2: Review the PL surgical guides and biomodels place in clinical practice (Q1)
- Phase 3: Conduct a rapid, targeted systematic review (Q2)
- Phase 4: Prepare reports on information and evidence (Q3)

Stakeholders may include sponsors, other medical device industry representatives, private health insurance representatives, private hospital representatives, consumer representatives and clinicians (including clinical experts).

The outcome of this research should include:

- Analyses of the products in the above PL groupings and whether they are considered eligible for PL listing according to the 'criteria for listing' in the Prosthesis List Guide (including but not limited to whether they are 'essential' to the implanted device). Finding regarding eligibility may differ between products and clinical circumstances.
- Identify policy issues that may arise from these findings.

The services include:

Conduct research activities to address Terms of Reference 1-4 listed below:

Terms of Reference:

Stage One

1. Analyse the role in clinical practice of surgical guides and biomodels currently listed on the Prostheses List (PL), including future trends in clinical use.
2. Review the evidence base for the use of surgical guides and biomodels currently listed on the PL, with a focus on comparative clinical effectiveness and their clinical benefits.
3. Consider the current utilisation of surgical guides and biomodels listed on the PL.
4. Based on the findings of Terms of Reference 1, 2 and 3, advise if surgical guides and biomodels meet the eligibility criteria for listing on the PL, which may differ between products and clinical circumstances.

Stage Two

5. Subject to the findings of Terms of Reference 4, review the cost-effectiveness of surgical guides and biomodels currently listed on the PL.

Questions to be addressed:

Q1: Review the role in clinical practice of surgical guides and biomodels currently listed on the PL. In undertaking this work, the Contractor will consider the following areas of interest to the department, but will not be limited by them:

- Review guidance documents (Australian and international).
- Seek input from relevant organisations and experts using qualitative research methodology.
- Invite sponsors and stakeholders to provide relevant information and evidence and review and incorporate this correspondence in the Report where applicable.

Q2: Conduct a targeted, systematic literature review of the clinical evidence of surgical guides and biomodels currently listed on the PL. In undertaking this work, the Contractor will consider the following areas of interest to the department, but will not be limited by them:

- Undertake a systematic literature review to identify evidence regarding the comparative safety, clinical benefits and clinical effectiveness of surgical guides and biomodels (the appropriate comparator may be standard of care, or no guide).
- Clearly identify and analyse the benefit/s of surgical guides and biomodels compared to the comparator, including clinical outcomes and surrogate outcomes (such as time in surgery).
- Analyse the safety and comparable clinical effectiveness of different types of surgical guides and biomodels and identify the circumstances in which surgical guides and biomodels provide clinical benefit. Compare this to the PL utilisation of surgical guides and biomodels.
- Include a quality assessment and description of the limitations of included trials or observational studies.
- Compare Australian surgical outcomes in maxillofacial surgeries to those of countries where surgical guides and biomodels are not used or have different utilisation patterns.

Q3: Based on the information and evidence in questions 1 and 2, compile information to support the Department to assess whether surgical guides and biomodels meet the PL guide criteria. This includes specific advice on whether they are a device essential for implantation. This may vary between devices and clinical circumstances.

The Contractor will provide the following deliverables:

1. Research protocol

The contractor will be required to prepare a systematic review protocol describing the timelines of the work plan and intended methodology, including:

- inclusion/exclusion criteria
- outcomes of interest
- timeframes
- quality assessment of included studies

- qualitative research proposal to seek expert advice

The protocol must be approved by the Department prior to the contractor progressing with the remaining aspects of the work.

2. Draft Report

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

- an index and glossary with definitions for key clinical terms
- an executive summary
- a technical written report outlining:
  - the methodology used in searching for relevant literature, and identifying relevant literature from sponsor and stakeholder submissions
  - the methodology used for the desktop/ qualitative research (ie key document analysis, stakeholder submissions, and analysis of expert opinion).
  - quality assessment of the evidence used in the report
  - results and conclusions from all evidence considered
- reference list and appendices

3. Final report

The Contractor will submit 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 project. This report should include identification of Commercial in Confidence (CIC) information for redaction.

2. Time frame

The contractor is required to provide the Services in accordance with the timeframes specified in the table below. The Contractor may supply the deliverable earlier than the previous negotiated time frame. The Final Document for any deliverable must be of a standard acceptable to the Department.

If the Contractor cannot resolve or come to an agreement the Department may at its discretion enforce its rights under the Deed of Standing Offer including Schedule 2 Clause 3.

(Annexure 1)

Deliverable	**Date Due**	**Payment** (GST Inclusive)
Research Protocol	16 September 2022	s 47
Draft report	14 November 2022	
Final report	22 December 2022	

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 with the agreed deliverables in the Official Order
b) identify the reasons for not meeting the agreed deliverables

c) identify the component/s that cannot be delivered within the agreed timeframes
d) advise the Post-Market Review team in writing identifying the risk and seek a resolution agreeable to both the Department and the Contractor.

If agreed by both parties, this Official Order may be extended for a further period not exceeding 30 June 2023.

3. Fees, allowances and costs

The total fee for the Services is s 47 GST incl) payable by the following instalments:

- s 47 following delivery of the research protocol report (as described in Item 8 [Contract Material]); and
- s 47 following delivery of a draft report (as described in Item 8 [Contract Material]).
- s 47 following delivery of a final report (as described in Item 8 [Contract Material]) and following customer evaluation and acceptance of final report.

The due date for payment is 30 days after delivery of a correctly rendered invoice to the Customer.

4. Specified Personnel

The personnel who will work on this project are:

s 47F	Project Director
	Project Manager
	Senior consultant
	Senior consultant
	Consultant
	Consultant
	Consultant
	Expert advisor

The Specified Personnel must produce to the relevant contract manager from the Department of Health and Aged Care a current National Police Certificate, which is no greater than 6 months old, by the contract commencement date. If any disclosable outcomes are mentioned in the certificate, the Department may delay proceeding with the Work Order until an assessment can be conducted.

5. Customer Material to be provided by Customer

The Department will provide the Contractor with the relevant documentation and material required to deliver the Services after the countersigning of the Official Order or as soon as available thereafter.

All contract materials provided to the contractor being relevant data, existing information or any other materials will be regarded as Confidential Information, and appropriate facilities must be available on site to store that material securely and to comply with all reasonable requirements.

The following existing data and information will be made available to the contractor

- Departmental utilisation Review of surgical guides and biomodels presented to the May 2022 Prosthesis List Advisory Committee (PLAC) meeting.
- Deidentified and summarised Hospital Case Mix data
- Deidentified and summarised Medicare Benefits Schedule (MBS) data
- Correspondence (including evidence) from sponsors and stakeholders.

6. Existing Material

The Department will provide the contractor with any existing material required to undertake the work including background documents for desktop review and analysis.

7. Contract Material

Deliverables

1. Research protocol
2. Draft Report
3. Final report

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).

The report deliverables are to be provided in .doc or .docx format and:

- 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).

8. Confidential Information

All contract material provided to the Contractor shall be regarded as Confidential Information and appropriate facilities must be available on site to store that material securely and to comply with all reasonable requirements.

9. Customer facilities and assistance

The contractor will liaise with the Customer on a fortnightly basis, either by telephone or workshops or videoconference or by email, and seek guidance as required. Meetings are offered to answer emerging questions as needed. Initial meeting to be scheduled around 5th September 2022.

10. Invoice procedures

- all in voices to be submitted in PDF to s22, s47E(d)
- and CC: s22 @health.gov.au
- valid billing name: Department of Health and Aged Care
- valid biller: name must appear on ABR website as entity/business or trading name
- valid ABN (if applicable)
- valid 10-digit Purchase Order Number (e.g. 45xxxxxxxx). This will be provided by the Contract Liaison Officer after the Official Order has been executed
- 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.

11. Other Terms and Conditions

A Police Check is required if the specified personnel accessing confidential information.

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:

5TH SEPT 2022
Date

by:

ELIZABETH FLYNN
Printed name of signatory

s22
Signa

ASSISTANT SECRETARY
Position of signatory

in the presence of:

s22
Printed name of witness

s22
Signature

SIGNED for and on behalf of **Australian Healthcare Associates (AHA),** ABN 82 072 790 848 ***[insert Contractor's ABN]***, in accordance with section 127 of the *Corporations Act 2001* on: ***[You will need to insert the appropriate signature block according to the type of legal entity – see the Guide to the Standard Contract for Services. This signature block is only appropriate when the Contractor is a company incorporated under the Corporations Act with several directors or a director and secretary who are separate persons. Also please seek further advice if you are dealing with an individual person (i.e. sole trader) or a trustee]***

5 September 2022
Date

by:

s 47F
Printed name of Director

s47F
Signature of Director

and:

s 47F
Printed name of Director/Secretary

s47F
Signature of Director/Secretary

AHA **first meeting 06/09/2022** at 1330 pm

Attendees:

Department of Heath and Aged Care	AHA
s22	s47F
Elizabeth Flynn	
s22	

Agenda:

- Objectives for the Review: develop a deeper understanding of the department's objectives
- Methodology and the development of the research protocol, including the possibility of the department connecting us with surgical expertise for ad hoc advice on technical terminology, given the highly specialised subject matter.
- Consultation: Confirm stakeholders and discuss any sensitivities for effective stakeholder engagement.
  - *Mode of contact with sponsors*
- Background documents: discuss access arrangements and confidentiality requirements for background documentation
- Data requirements
- discuss project risks and mitigation strategies
- confirm the frequency and mode of contact between AHA and the department
- *Report format and* confirm requirements for deliverables
- *Other questions*

Minutes (notes):

- AHA : Can be flexible with changes and addition to project
- EF : gave context : Listing on PBS and Prosthesis list undergoing HTA assessment
  Cost more on prosthesis list make it similar to Public Health system
  High sensitivity project maybe aim to set up triggers in the system for listing
- s22 question of eligibility for listing on prosthesis list
  Have background documents to give to AHA + Framework R/V prosthesis list
  Looking for benefits and reimbursement
  Implantable definition VS criteria as **essential**
  Listed vs restriction and **conditions** to be listed
  Have list of key stakeholders Australia and New Zealand dentist / max fax surgeons
  MBS item number covers medical services not dental
  Clinically indicated for cancer/ trauma/ congenital malformation
  Outcome: may affect sustainability in private health insurance and new applications for SGBs
  Looking to find: **Clear answers and strategy** also **comparative safety and cost effectiveness**
- Studies when comparative studies done with or without use of SGB's
  Software planning prior surgery- 2013
- s22 Will share application for prosthesis and **PLAC utilisation review: CONFIDENTIAL**

- TEMPLATE TO ADDRESS questions by ToR

s22

From: s47E(d)
Sent: Wednesday, 21 September 2022 4:46 PM
Subject: FOR INFORMATION: PROSTHESES LIST POST-LISTING REVIEW - SURGICAL GUIDES AND BIOMODELS [SEC=OFFICIAL]

Good afternoon Sponsors

Following our update on 1 September 2022 which included advice about the terms of reference for the post-listing review of Surgical Guides and Biomodels, the Department has completed engagement of an external consultant, Australian Healthcare Associates (AHA), to undertake stage 1 of this review.

Commencing this week, AHA will be inviting stakeholders to participate in consultations including the provision of product information. The stakeholders include Department officials, clinical experts, peak bodies and sponsors. AHA's consultation approach will enable the exploration of key matters relevant to the terms of reference.

AHA will tailor the consultation materials to each stakeholder group.

We encourage your participation in this consultation and note that the Department plans to release the draft report from this review seeking sponsors views and feedback.

Any questions or concerns about this post-listing review, please contact us by emai s47E(d) @health.gov.au .

Regards

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

Celebrating 100 YEARS OF HEALTH 1921 - 2021
Building a stronger, healthier country
Yesterday today and tomorrow

s22

From: s22
Sent: Tuesday, 29 November 2022 1:53 PM
To: s47F @ahaconsulting.com.au; s47F @ahaconsulting.com.au
Cc: s22 ; s22 ; s4
Subject: Contract extension for Surgical guides and Biomodels [SEC=OFFICIAL]

Dear AHA consulting,

Due to accommodating 4 weeks for stakeholders feedback slippage in final report, the Department is extending the term of the contract to **30 March 2023** under the same Terms and Conditions of the existing arrangement.
Please note there will be no additional funds, or services under his extension period.
If you agree to the extension period , please rely to this email.

Kind Regards
s22

s22
Post Market Review Section
Office of Health Technology Assessment and Policy Branch
Technology Assessment and Access Division | Health Financing Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Canberra ACT 2601, Australia

s22

From: s22
Sent: Monday, 24 October 2022 12:35 PM
To: s47F
Cc: s s E(d) ; s22
Subject: New due date for draft report [SEC=OFFICIAL]

Hi s47F

As discussed last week, the Department is happy to adjust the deliverable date for the draft report for the Surgical Guides and Biomodels review. The new date is **Friday 18 November 2022** (or before start of business on Monday 21 November 2022).

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
☎ s22 | s22 @health.gov.au
Location: s22 , 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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.

s22

From: s22
Sent: Friday, 31 March 2023 4:18 PM
To: s47F ; s22 ; s22
Cc: s22 ; s22 ; s47E(d) ; s22 ; s 47 F
s22
Subject: RE: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

Dear s47F
Thank you for your work!
I confirm we have received your email including the final report.
Wish you a nice weekend!
s22

Post Market Review Section
Genomics and Health Technology Assessment Policy Branch

Technology Assessment and Access Division | Health Financing Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Canberra ACT 2601, Australia

From: s47F @ahaconsulting.com.au>
Sent: Friday, 31 March 2023 3:09 PM
To: s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>
Subject: RE: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

Hi s22 and s22

We are pleased to provide you with the final accessible copies of both the redacted Final Report and the Executive Summary as promised.

Thanks once again for the opportunity to contribute to this important work.

Best wishes with the project,

Kind regards,

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111

M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

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s22

From: s22
Sent: Wednesday, 22 March 2023 10:09 AM
To: s47F
Subject: RE: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

Thanks s47F

This is as it is a 'just in case' we need it accessible in the future so next week is great. Thank you for accommodating us.

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 22 March 2023 7:37 AM
To: s22 @health.gov.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>
Subject: RE: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Thanks for your email.

I hope you are well too. We can provide you with an accessible version of the redacted report by the end of next week. I hope that will fit your timelines.

Kind regards,
s47F

From: s22 @health.gov.au>
Sent: Tuesday, 21 March 2023 10:33 AM
To: s47F @ahaconsulting.com.au>; s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F ; s22 @health.gov.au>
Subject: RE: Surgical Guides and Biomodels Review Final Report and Executive Summary [SEC=OFFICIAL]

Hi s47F

Hope you have been well! I have just returned from leave and had a look at the report, thanks for your great work on this project.

Before we close of the invoice are you able to provide an accessible copy of the redacted report in case we need to publish it in its entirety in the future?

Kind regards,
s22

Post-market Review Section

Technology Assessment and Access Division | Health Resourcing Group
Genomic and Health Technology Assessment Policy Branch
Australian Government Department of Health and Aged Care
☎ s22 | s22 @health.gov.au
Location: s22 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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: s47F @ahaconsulting.com.au>
Sent: Friday, 17 March 2023 5:16 PM
To: s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Subject: Surgical Guides and Biomodels Review Final Report and Executive Summary

Hi s22

We are delighted to provide you with a copy of the full Final Report and a redacted version of the Final Report. We have made a few minor changes, principally bringing forward summary findings into the Executive summary.

I have also attached a separate accessible Executive Summary, which you may choose to publish. We have revised the table of contents to match the Executive Summary and removed the reference to the report structure. Please let us know if you prefer the table of contents from the full report or the inclusion of the report structure. This can be easily changed if you need.

If there are no further changes we will take these deliverables to mean that we have fulfilled your requirements for this project.

It has been a pleasure to work with you all and we would be keen to be notified when you decide to publish the summary report.

We do have a standard feedback form which we ask all clients to complete at the end of any project. I will send this through in the near future and would appreciate if you provide some brief feedback on the conduct of this project.

Best wishes with the next stage of the review process and thanks once again.

Kind regards,
s47F

From: s22 @Health.gov.au>
Sent: Wednesday, 15 March 2023 3:57 PM
To: s47F @ahaconsulting.com.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Subject: RE: A couple of quick of quick questions regarding the Surgical Guides and Biomodels Review Final Report [SEC=OFFICIAL]

s47F

Thank you for your email. We are happy for you to do the final checks and re-issue the final report to us before the end of this week.

We are currently working through the handling of the final report. I am expecting that we would likely publish the Executive summary up to page 17 to capture the approach to the review as well as the findings.

If you want to make this section of the report accessible, that would be a great help to us. We are not likely to be ready to publish for at least another week or so.

Regards

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

Celebrating 100 YEARS OF HEALTH 1921 - 2021
Building a stronger, healthier country
Yesterday today and tomorrow

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 15 March 2023 3:53 PM
To: s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Subject: A couple of quick of quick questions regarding the Surgical Guides and Biomodels Review Final Report

Hi s22

I am just tying up some loose ends with this project and have a couple of questions:

- In the final report, we noticed that a summary point did not carry through into the Executive Summary. We would like to do some final checks and send you a final version of the report before the end of this week. Would this work for you?
- We'd also like to check with you whether you are planning to publish the report as we have not yet made the document accessible. We would be grateful if you could you let us know whether you require the report (or its parts) to be made accessible, and if so, by when.

We are happy to chat to you about this if required.

Thanks once again,
Kind regards,

s47F

| Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

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s22

From: s22
Sent: Wednesday, 14 September 2022 3:01 PM
To: s47F s47E(d)
Cc:
Subject: RE: Documents for AHA [SEC=OFFICIAL]
Attachments: Conflict of Interest Declaration.doc

Hi s47F

It was nice to talk to you earlier. Attached is a COI form that can be adapted for stakeholder interviews.

In regards to your questions I have sought input form our medical officer and the PL review area. I am finishing for the week, but someone will call you back or email you the answers to your questions shortly.

Many thanks,
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
☎ s22 | s22@health.gov.au
Location: s22, 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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: s47 @ahaconsulting.com.au>
Sent: Tuesday, 13 September 2022 3:06 PM
To: s22 @health.gov.au>
Subject: RE: Documents for AHA [SEC=OFFICIAL]

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Hi s22
Tomorrow morning is fine
Thanks s47F

From: s22 @health.gov.au>
Sent: Tuesday, 13 September 2022 3:04 PM
To: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>

Cc: s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Documents for AHA [SEC=OFFICIAL]

Hi s47F

I am just about to leave for the day (my part-time hours are 9-3pm Mon-Wed). I can all you first thing tomorrow if that works?

Thanks,
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 13 September 2022 2:57 PM
To: s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Cc: s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Documents for AHA [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Thanks for sending through this additional information.

Now that I am back on board, I can pick up the day-to-day communications from here.

s22 I did have a question which I would like to discuss with you. Could you give me a call on s 47F when it suits you.

Kind regards,
s47F

From: s22 @health.gov.au>
Sent: Tuesday, 13 September 2022 11:55 AM
To: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Cc: s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: RE: Documents for AHA [SEC=OFFICIAL]

Hi s 47F

I hope you are going well. Attached is the report template and below additional information for the review. I will send the COI form you requested through soon (we are just seeing if we can find a shorter form to use than our usual one).

In the **template for the report** there is a 'background' section. s22 has suggested the RFQ (introduction and background sections) has wording that can be used for the 'context for the review' and 'why review' sections. In addition, the PL reforms webpage and Post-listing review framework may provide some wording on the review process. If you have any questions about the report template please don't hesitate to ask.

Below are **additional contact details for clinical experts**.

- s47F [redacted]

Here is the **Purchase Order (PO) number** to reference when invoicing the Department: 4500149437

Research protocol feedback - For your information s22 [redacted] (our medical advisor) is on leave next week so will be unable to attend the meeting on the 20th to provide feedback on the research protocol. If you find yourself in a position to send through the protocol or a draft this week (ideally before Friday), Jeff has offered to send some comments through via email before he leaves. If you are unable that is ok (I know this is ahead of the due date), and we will provide feedback from other Departmental staff on the 20th. I will also set up a meeting when he is back on the 27th so that we can all check in.

If you have any questions or would just like to chat before s22 [redacted] goes on leave please let me know and I can organise.

Many thanks,

s22 [redacted]

s22 [redacted]
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
☎ s22 [redacted] | s22 [redacted] @health.gov.au
Location: s22 [redacted], 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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 [redacted] @health.gov.au>
Sent: Thursday, 8 September 2022 2:37 PM
To: s47F [redacted] @ahaconsulting.com.au>; s22 [redacted] @health.gov.au>; s47F [redacted] @ahaconsulting.com.au>
Cc: s47F [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @Health.gov.au>; s22 [redacted] @health.gov.au>
Subject: RE: Documents for AHA [SEC=OFFICIAL]

Hi s47F [redacted]
We are reviewing the standard PBS medicine PMR template and making some changes so that it is more in line with this PL review. We will try and get this and the COI form to you early next week.

Kind regards
s22 [redacted]

From: s47F @ahaconsulting.com.au>
Sent: Thursday, 8 September 2022 2:26 PM
To: s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Cc: s47 @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: [ATTACHMENT UNSCANNED]RE: Documents for AHA [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Received with thanks.

I think the only other item we discussed at the start-up meeting was the reporting template the department uses for post-listing reviews – if you could send through that would be great.

Also, if you have an example conflict of interest form that we could adapt for our consultations with experts that would be helpful.

Kind regards,

s47F

From: s22 @health.gov.au>
Sent: Wednesday, 7 September 2022 3:28 PM
To: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Cc: s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: FW: Documents for AHA [SEC=OFFICIAL]

Hi s47F (and s47F

Please see attached initial background information from the Department. Please treat all information provided by the Department (that is not already publicly available) as confidential information.

- Prostheses List Post listing Review Framework
- List of billing codes and product names.
- Most recent correspondence with sponsors (email)
- Sponsor and stakeholder list
- Utilisation review (title: PLAC 32 Surgical Guides and Biomodels) and background tables
- Prosthesis list guide
- link to reforms webpage The Prostheses List reforms | Australian Government Department of Health and Aged Care.
- Published articles/papers for some background

List of clinical experts (this may be added to):

s47F

s47F

In our meeting yesterday, I also indicated we would be able to share some sponsor applications but unfortunately we cannot do so. If you think this information is necessary to inform the review, perhaps this can be requested this from sponsors when they submit evidence.

I hope you are feeling better soon s47F

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
☎ s22 s22 @health.gov.au
Location: s22 , 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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s22

From: s22
Sent: Wednesday, 15 March 2023 3:57 PM
To: s47F
Cc: s22 ; s22 ; s22 ; s22 ; s47E(d) ; s22 ; s 47F
Subject: RE: A couple of quick of quick questions regarding the Surgical Guides and Biomodels Review Final Report [SEC=OFFICIAL]

s47F

Thank you for your email. We are happy for you to do the final checks and re-issue the final report to us before the end of this week.

We are currently working through the handling of the final report. I am expecting that we would likely publish the Executive summary up to page 17 to capture the approach to the review as well as the findings.

If you want to make this section of the report accessible, that would be a great help to us. We are not likely to be ready to publish for at least another week or so.

Regards

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

Celebrating 100 YEARS OF HEALTH 1921 - 2021

Building a stronger, healthier country
Yesterday today and tomorrow

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 15 March 2023 3:53 PM
To: s22 @Health.gov.au>
Cc: s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>; s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Subject: A couple of quick of quick questions regarding the Surgical Guides and Biomodels Review Final Report

Hi s22

I am just tying up some loose ends with this project and have a couple of questions:

- In the final report, we noticed that a summary point did not carry through into the Executive Summary. We would like to do some final checks and send you a final version of the report before the end of this week. Would this work for you?
- We'd also like to check with you whether you are planning to publish the report as we have not yet made the document accessible. We would be grateful if you could you let us know whether you require the report (or its parts) to be made accessible, and if so, by when.

We are happy to chat to you about this if required.

Thanks once again,
Kind regards,

s47F

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s22
Sent: Friday, 10 March 2023 10:53 AM
To: s47F @ahaconsulting.com.au; s47F @ahaconsulting.com.au
Cc: ; s22 ; ; s22 ; s22 ; s47E(d)

Subject: AHA Surgical Guides and Biomodels Final Report

Dear s47F
Dear s47F ,

On behalf of the Department I would like to Thank you for your hard work!

We do accept the final report and we don't think there is a need for a meeting next week. However we will stay in contact by email in case of any questions.

This fulfill the terms of our contract and will wait for your final invoice.

We endeavour to work with you in the future and appreciate your expertise!

Kind Regards
s22

Post Market Review Section
Genomics and Health Technology Assessment Policy Branch

Technology Assessment and Access Division | Health Financing Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Canberra ACT 2601, Australia

s22

From: s22
Sent: Monday, 6 March 2023 10:48 AM
To: s47F ; s47F
Cc: ; ; s22 ; s22 ; s47E(d)
Subject: RE: Delay in receiving the Final Reports [SEC=OFFICIAL]

Dear s47F

Thank you heaps for your work!
The draft did show in our email inboxes this morning , maybe was awaiting clearance as it is an external email and after hours?!

However we won't be able to review it till late this week as it is busy week for everyone.
We will need to reschedule our meeting , would Tuesday/ Wednesday next week same time be good for you and your team?

Kind Regards and Thank you for all your work again!
s22

Post Market Review Section
Genomics and Health Technology Assessment Policy Branch
Technology Assessment and Access Division | Health Financing Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Canberra ACT 2601, Australia

From: s47F @ahaconsulting.com.au>
Sent: Monday, 6 March 2023 9:38 AM
To: s22 @Health.gov.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>
Subject: Delay in receiving the Final Reports

Hi s22

I apologise that the Final Reports were delayed. The documents were sent Friday evening, but it seems AHA's IT system held these emails back as detailed below.

I understand these documents have now been released. Please let me know if you have not received them.

Kind regards,
s47F

From: s47F @ahaconsulting.com.au>
Sent: Monday, 6 March 2023 10:30 AM

To: s47F @ahaconsulting.com.au>
Subject: [AHA IT] Re: FW: We found suspicious files in a message

PPA Support Centre

##- Please type your reply above this line -##

s47F (AHA IT)
Mar 6, 2023, 10:30 GMT+11

Hi s47F

It appears that there is currently an issue with sending multiple attachments outside of the org, some emails are being held randomly which caused your issue Friday night.

We are in contact with our account manager at Mimecast to rectify this issue.

I will keep you updated!

Thanks,
s47F

s47F (AHA IT)
Mar 6, 2023, 09:25 GMT+11

Hi s47F

Sorry but it doesn't look like it - i'll release and check out what happened

Thanks
s47F

s47F
Mar 6, 2023, 09:17 GMT+11

Hi IT
I sent these final reports to the department on Friday night, but received this message.
Does this mean- they got through?

s47F

From: Postmaster and Abuse Reporting s 47G
Sent: Friday, 3 March 2023 7:52 PM
To: s47F @ahaconsulting.com.au>
Subject: We found suspicious files in a message

Message contains suspicious files

Attachment Protect found suspicious files in this message.

Files
Actions log based on feedback.docx (174.1 KB)
PL review final report_clean.docx (891.9 KB)
PL Review final report_Redacted.pdf (1.4 MB)
PL review final report_tracked.docx (1.0 MB)

Message Details

From

s47F @ahaconsulting.com.au

Subject

Review of surgical guides and biomodels currently listed on the Prostheses List - Final Report

Sent

Mar 03 2023 19:10

Status

Gateway Action - Hold, User Action - None

Policy

Default Outbound Attachment Protect Definition

Regards
AHA IT

From: s22
To: s22 ; s22 ; s47F ; s 47F
Cc: s22 ; FLYNN, Elizabeth; s47F ; s47F ; s22
Subject: Canceled: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]
Importance: High

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

From: s22
To: s 47F ; s47F ; s22 ; s22 ; s22
Cc: s22 ; FLYNN, Elizabeth; s22 ; s47F
Subject: RE: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]
Date: Tuesday, 24 January 2023 10:45:00 AM

Hi s 47F
I am happy to cancel the meeting if there are no issues to discuss.
We can schedule meetings on as needed basis if there is anything to discuss before consultation closes.
Hope 2023 has been going smoothly for you!
Cheers,
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 24 January 2023 8:38 AM
To: s22 @health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>
Subject: RE: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning all
I hope 2023 is treating you well so far.
We have a meeting scheduled for 11am this morning. We would be comfortable cancelling this meeting as we don't have anything in particular to discuss. As you know, the consultation period is open until 3 Feb. At this stage, we've received 4 responses from clinical experts, and have been advised by one sponsor that they will not be providing feedback.
We'd be happy to delay meeting until our next scheduled meeting on 7 Feb, but are, of course, happy to meet today if you wish.
Kind regards

s 47F | Associate Director
Head of Evaluation and Advisory
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Please note I don't work on Fridays
Please consider the environment before printing this email.

From: s22 @health.gov.au>
Sent: Monday, 9 January 2023 10:13 AM
To: s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Subject: RE: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

Hi s 47F

Yes I can cancel this meeting until the meeting on the 24th of January. The regular fortnightly catch-up was extended to the new final report due date, however we don't need to catch up until the 24th unless there are any specific questions you have (or if others in this email have any issues they would like to discuss).

Kind regards,

s22

From: s47F @ahaconsulting.com.au>
Sent: Monday, 9 January 2023 8:24 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s22 @Health.gov.au>; FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Subject: RE: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

Hi s22

I have our catch-up meeting scheduled in our calendar for tomorrow 10 January. I know at our last meeting we agreed to meet on 24th January. At this stage, we don't have any updates. Do you still want to meet tomorrow?

Kind regards,

s47F

-----Original Appointment-----
From: s47F **On Behalf Of** s22
Sent: Wednesday, 4 January 2023 8:53 AM
To: s47F
Subject: FW: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]
When: Occurs every 2 week(s) on Tuesday effective 20/09/2022 until 7/03/2023 from 10:00 AM to 11:00 AM (UTC+10:00) Brisbane.
Where:

Hi s47F

Can you add these to your diary thanks – I wont be at the next meeting but s 47 will be.

s47F

-----Original Appointment-----

From: s22 @health.gov.au>

Sent: Tuesday, 6 September 2022 3:02 PM

To: s22 ; s22 ; s22 ; s47F ; s 47F ; s22

Cc: s22 ; FLYNN, Elizabeth; s47F ; s47F ; s22

Subject: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

When: Occurs every 2 week(s) on Tuesday effective 20/09/2022 until 7/03/2023 from 10:00 AM to 11:00 AM (UTC+10:00) Brisbane.

Where:

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

Note: I have extended the dates for this check-in as the timelines for the final report have changed.

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

s22

More ways to join:

Join from the meeting link

s22

Join by meeting number

Meeting number (access code): s22

Meeting password: s22

Tap to join from a mobile device (attendees only)

s22 Australia Toll

Join by phone

s22 Australia Toll

s22

Join from a video system or application

Dial s22

You can also dial s22 and enter your meeting number.

If you are a host, s22 to view host information.

Need help? Go to https://help.webex.com

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From:	s22
To:	s22 ; s22 ; s47F ; s 47F ; s22
Cc:	s22 ; FLYNN, Elizabeth; s47F ; s47F s22 s22
Subject:	Canceled: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]
Importance:	High

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Note: I have extended the dates for this check-in as the timelines for the final report have changed.

s22

From: s22
Sent: Monday, 9 January 2023 10:13 AM
To: s47F ; s22 ; s22 ; s22
Cc: ; FLYNN, Elizabeth; s22 s 47F ; s47F
Subject: RE: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

Hi s47F

Yes I can cancel this meeting until the meeting on the 24th of January. The regular fortnightly catch-up was extended to the new final report due date, however we don't need to catch up until the 24th unless there are any specific questions you have (or if others in this email have any issues they would like to discuss).

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From: s47F @ahaconsulting.com.au>
Sent: Monday, 9 January 2023 8:24 AM
To: s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s @Health.gov.au>; FLYNN, Elizabeth <Elizabeth.Flynn@health.gov.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Subject: RE: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

Hi s22

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Kind regards,
s47F

-----Original Appointment-----
From: s47F **On Behalf Of** s22
Sent: Wednesday, 4 January 2023 8:53 AM
To: s47F
Subject: FW: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]
When: Occurs every 2 week(s) on Tuesday effective 20/09/2022 until 7/03/2023 from 10:00 AM to 11:00 AM (UTC+10:00) Brisbane.
Where:

Hi s47F
Can you add these to your diary thanks – I wont be at the next meeting but s 47 will be.
s47F

-----Original Appointment-----
From: s22 @health.gov.au>
Sent: Tuesday, 6 September 2022 3:02 PM
To: s22 ; s22 ; s22 ; s47F ; s 47F s22
Cc: s22 ; FLYNN, Elizabeth; s47F ; s47F ; s22
Subject: Catch between the Department and AHA - Surgical Guides and Biomodels review [SEC=OFFICIAL]

When: Occurs every 2 week(s) on Tuesday effective 20/09/2022 until 7/03/2023 from 10:00 AM to 11:00 AM (UTC+10:00) Brisbane.
Where:

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Note: I have extended the dates for this check-in as the timelines for the final report have changed.

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

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s22

Join by meeting number
Meeting number (access code): s22
Meeting password: s22

Tap to join from a mobile device (attendees only)
s22 Australia Toll

Join by phone
s22 Australia Toll
s22

Join from a video system or application
Dial s22
You can also dial s22 and enter your meeting number.

If you are a host, s22 to view host information.

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From:	s22
To:	s22 ; s22 ; s47F s 47F s22
Cc:	s22 FLYNN, Elizabeth; s47F s47F s22
Subject:	Canceled: Catch between the Department and AHA - Surgical Guides and Biomodels review
Importance:	High

This is an invitation to a fortnightly catch-up between the Department and AHA for the surgical guides and biomodels review. We can be flexible with times and dates as needed.

Note: I have extended the dates for this check-in as the timelines for the final report have changed.

s22

From: s47E(d)
Sent: Monday, 19 December 2022 11:00 AM
To: s47F
Cc: s47E(d) ; s47E(d) ; s22 ; s22 ; s22 ; s47E(d) ;
Subject: RE: SGB Review - New timelines [SEC=OFFICIAL]

Good Morning s47F

Hope you had a lovely weekend!

I am following up from our meeting last week. We haven't heard from you regarding the new timeframes (given that we agreed to extend the timeframe until 3 Feb 2023 for stakeholders to provide feedback on the draft report) and whether emails have gone out to stakeholders advising of the extension.

As agreed during the meeting, appreciate if you could please confirm the new dates for reports.

Thanks
s22

From: s47F @ahaconsulting.com.au>
Sent: Monday, 12 December 2022 10:49 AM
To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: SGB Review - More Group

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning,

We received two emails on Friday 9 December 2022 from s 47F More Group that we would like to discuss at our meeting tomorrow.

In the first email, s 47F requested that:

" Due to end of year constraints and Christmas closures in our own and other organisations we need to consult with it will be impossible to meet the 6 January 2023 deadline for feedback. We believe that we can properly consider the draft report, consult with any relevant third parties and provide our feedback by Friday 30 January 2023."

This email also asked why we structured the systematic review to exclude other systemic reviews, meta-analyses and studies on devices equivalent to those listed on the PL and provided further evidence, which we can address.

In the second email, s 47F asked: "Further to my previous email, can you please advise what legal expertise you employed to interpret the relevant legislation, regulations and explanatory notes?"

We would like to discuss the request for an extension, the circulation of the report to third parties and any comments you may have on the question of legal expertise.

Kind regards,

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
@ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s22
Sent: Thursday, 1 December 2022 3:25 PM
To: s 47F ; s22 ; s22 ; s47F
Cc: s47E(d)
Subject: RE: Contract extension for Surgical guides and Biomodels [SEC=OFFICIAL]

Hi s 47F
I have checked with the PLR policy area and they agree we can be a little flexible around the due date of the 30 January 2023 for the final report.
Thanks for all your hard work.
s22

From: s47F @ahaconsulting.com.au>
Sent: Thursday, 1 December 2022 9:52 AM
To: s22 @health.gov.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>
Cc: s22 @health.gov.au>; s47E(d) @Health.gov.au>
Subject: RE: Contract extension for Surgical guides and Biomodels [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

30 January seems a reasonable due date to us.

It would be good to retain some flexibility given that the volume/complexity of feedback is unknown at this stage.

Kind regards

s 47

From: s22 @health.gov.au>
Sent: Wednesday, 30 November 2022 11:12 AM
To: s 4 @ahaconsulting.com.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>
Cc: s22 @health.gov.au>; s47E(d) @Health.gov.au>
Subject: RE: Contract extension for Surgical guides and Biomodels [SEC=OFFICIAL]

Hi s 47 and all,

No you haven't misunderstood. I understand in the meeting that occurred last week you indicated you had capacity to have the final report due late January or early February.

Would a date of 30 January 2023 be suitable for the due date of the final report?

s22 and s22 – is this a date that would work for you?

Kind regards,
s22

From: s47 @ahaconsulting.com.au>
Sent: Wednesday, 30 November 2022 10:08 AM
To: s22 @Health.gov.au>; s47F @ahaconsulting.com.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>
Subject: RE: Contract extension for Surgical guides and Biomodels [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22
Thanks for your email. As shown in the excerpt from the official order below, the current contract end date is 30 March 2023 so I don't believe an extension is required at this stage. We understand we will need to adjust the due date for the final report.
Please let me know if I've misunderstood.
Kind regards
s47

Date services to commence on	Countersigning by the Department of Health and Aged Care
Date services to be completed by	30 March 2023
Extension Option	An extension option may be available for a further period not exceeding 30 June 2023.

Invoices are to be issued to s22 @health.gov.au with attention to the Customer Contract Liaison Officer named above.

From: s22 @Health.gov.au>
Sent: Tuesday, 29 November 2022 1:53 PM
To: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Cc: s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>
Subject: Contract extension for Surgical guides and Biomodels [SEC=OFFICIAL]

Dear AHA consulting,

Due to accommodating 4 weeks for stakeholders feedback slippage in final report, the Department is extending the term of the contract to **30 March 2023** under the same Terms and Conditions of the existing arrangement.
Please note there will be no additional funds, or services under his extension period.
If you agree to the extension period , please rely to this email.

Kind Regards
s22

s22
Post Market Review Section
Office of Health Technology Assessment and Policy Branch

Technology Assessment and Access Division | Health Financing Group
Australian Government Department of Health and Aged Care
E: s22 @health.gov.au
Canberra ACT 2601, Australia

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

s22

From: s22
Sent: Wednesday, 30 November 2022 9:27 AM
To: s47F ; PL Reviews; s 47F ; s22 ; s22 ; s22 ; ; s47L(d) ;
Cc: s47F
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

Dear s47F
Yes please only info related to specific sponsor that the email/pdf is addressed to can be visible in Appendix F.
As mentioned by s22 and s22 the report is to be addressed to The Department of Health and Aged Care (DOHAC).
Thank you for your hard work!
s22

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 30 November 2022 7:48 AM
To: s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s22 @Health.gov.au>
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Thanks for this feedback.

I just wanted to clarify your comment regarding what we will send sponsors. We have redacted Appendix F of the draft report. In addition to the redacted draft report, we will send a separate PDF to each sponsor that only has the information from Appendix F that relates to that sponsor.

Kind regards,
s47F

From: s47E(d) @Health.gov.au>
Sent: Tuesday, 29 November 2022 4:43 PM
To: s 47 @ahaconsulting.com.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>; s22 @Health.gov.au>
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

Hi s 47

We understand that you will include the information relevant to each sponsor in the body of an email.

One minor update for your consideration please - on page 55 of pdf, reference to M26.5 (4th sentence in the first para) needs to be M26.10 as in table 12.

Please also find additional comments below form PMR section:

Comments from PMR
Redactions

- Key findings for ToR 3 dot point 4 (in executive summary and ToR 3) – redact expenditure for 2013-14 as this was only one sponsor.
- Table 15. Please also redact 2016-17 line due to low number of sponsors in breakdown of surgical guides/biomodels categories. Total should be ok to keep.
- Figure 3 – should start from 2016-17 financial year (expenditure figures for earlier years are redacted in the table, so will need to be consistent with graphs).

Minor edits

- s22 comments page 49 - Table 13 would suggest that the overall average for biomodels is 26% for the 2013-14 to 2020-21 period. Remains at 22% in report. Ask AHA to confirm which is correct
- Suggest use' Surgical guides and Biomodels' all over the document for consistency (currently the term 'Biomodels and surgical guides' is used aswell)
- Once Craniomaxillofacial used as the abbreviation CMF, use CMF all over for consistency
- HCP in glossary not HCP1
- Separation definition already exist in glossary may remove from page 51 pdf version

Thank you for your hard work!

Kind regards
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 8:35 AM
To: s @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Subject: Updated draft: review of surgical guides and biomodels (redacted version)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning s22 and team,

Please find attached a PDF version of the draft I sent last night, with redactions.

Kind regards,

s
47

s 47F Associate Director
Head of Evaluation and Advisory
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Please note I don't work on Fridays

Please consider the environment before printing this email.

s22

From: s47E(d)
Sent: Wednesday, 30 November 2022 12:40 PM
To: s47F ; s22 ; PL Reviews; s 47F s22 ; s22 ; s47E(d) ;
Cc: s47F ; s22
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]
Attachments: Consultation draft email templates.docx

Good Afternoon s47F

Thanks for your email. Please find our response to your questions below.

Kind regards
s22

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 30 November 2022 11:24 AM
To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s22 @Health.gov.au>
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning,

Thank you for all your comments on the draft report. We are now finalising the draft report to be circulated today, but I wanted to check the following:

- Are we to expect any more comments from the department? No further comments from the department
- Could you confirm if you are happy with the email templates? Yes, happy with the email templates. Please send the consultation draft report to all stakeholders listed in section 4, but no need to send the report to departmental stakeholders.
- Do we include the stakeholders that we invited but who we did not consult (ie those in section 4 of the template document), as well as s47F in the stakeholder circulation list? Yes, please include the stakeholders listed in the section 4, no need to send the report to s47F
- Would you like to see a copy of the final redacted PDF before we send out the documents? No, the department has already provided the comments

Kind regards,
s47F

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s22
Sent: Wednesday, 30 November 2022 6:32 AM
To: s47E(d) ; s 47F ; s22 ; s22 ; s22 ; s47E(d)
Cc: ; ; s22
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

Hi
I've read through the report and have minimal additional to add.
Please note that the PL was funder $22m over 4 years (makes more sense with a timeframe) – this could be added a couple of times.
Some minor formatting issues - there are 2 page 1s; top of p 46 under 2.3 – need to specify the correct section number.
As per s22 email, please remove the statement "Report to PLAC" from the front cover – the report is for the Department and will be shared with PLAC for feedback and further advice.
Thanks
s22

From: s47 @Health.gov.au>
Sent: Tuesday, 29 November 2022 4:49 PM
To: s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>; s22 @Health.gov.au>
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

Hello,

Apologies I forgot to attach the reports – there are comments in the word doc from PMR team.

Thanks & regards
s22

From: s47 @Health.gov.au>
Sent: Tuesday, 29 November 2022 4:43 PM
To: s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s47E(d) @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>; s22 @Health.gov.au>
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

Hi s47

We understand that you will include the information relevant to each sponsor in the body of an email.

One minor update for your consideration please - on page 55 of pdf, reference to M26.5 (4th sentence in the first para) needs to be M26.10 as in table 12.

Please also find additional comments below form PMR section:

Comments from PMR
Redactions

- Key findings for ToR 3 dot point 4 (in executive summary and ToR 3) – redact expenditure for 2013-14 as this was only one sponsor.
- Table 15. Please also redact 2016-17 line due to low number of sponsors in breakdown of surgical guides/biomodels categories. Total should be ok to keep.
- Figure 3 – should start from 2016-17 financial year (expenditure figures for earlier years are redacted in the table, so will need to be consistent with graphs).

Minor edits

- s22 comments page 49 - Table 13 would suggest that the overall average for biomodels is 26% for the 2013-14 to 2020-21 period. Remains at 22% in report. Ask AHA to confirm which is correct
- Suggest use' Surgical guides and Biomodels' all over the document for consistency (currently the term 'Biomodels and surgical guides' is used aswell)
- Once Craniomaxillofacial used as the abbreviation CMF, use CMF all over for consistency
- HCP in glossary not HCP1
- Separation definition already exist in glossary may remove from page 51 pdf version

Thank you for your hard work!

Kind regards
s22

From: s47 @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 8:35 AM
To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Subject: Updated draft: review of surgical guides and biomodels (redacted version)

Good morning s22 and team,

Please find attached a PDF version of the draft I sent last night, with redactions.

Kind regards,

s47

s 47F | Associate Director
Head of Evaluation and Advisory
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Please note I don't work on Fridays

Please consider the environment before printing this email.

s22

From: s22
Sent: Thursday, 1 December 2022 9:31 AM
To: s47F
Cc: s22 ; s47E(d) ; s22 ; s 47F ; s22 ; s22 ; s47E(d)
Subject: RE: Surgical Guides and Biomodels Review - Consultation draft report [SEC=OFFICIAL]

s47F

Thank you for your email confirming the release of the draft report to the agreed stakeholders.

Further to the request from s47F of PHA to share the draft report with his member funds, the Department does not approve this request on the basis that the purpose of the consultation is to provide those stakeholders that were invited and/or participated in the consultation during the development of the report an opportunity to review how their contribution has been reflected. Given that PHA's member funds were not party to the initial consultation, then it would not be appropriate to include them in the review of the draft report.

Happy for you to go back to s47F on this basis otherwise I am happy to reach out to him and discuss.

Regards

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

Celebrating 100 YEARS OF HEALTH 1921 - 2021

Building a stronger, healthier country
Yesterday today and tomorrow

From: s47F @ahaconsulting.com.au>
Sent: Wednesday, 30 November 2022 5:41 PM
To: s47E(d) @Health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s22 @Health.gov.au>
Subject: Surgical Guides and Biomodels Review - Consultation draft report

Good afternoon,

I am pleased to report that we have circulated the consultation draft report to all stakeholders as agreed. Attached is a copy of the redacted report for your records.

We have already received a reply from s47F, Private Healthcare Australia who has asked if he can circulate the draft report to his member health funds. Could you advise on this please.

Thanks to all who provided feedback and assistance in this process.

Kind regards,

s47F

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Review of surgical guides and biomodels currently listed on the Prostheses List

This document outlines the proposed relevant email list, template (based on the draft sent by the department) and attachments for the consultation draft report. It is structured as follows:

- Section 1: Sponsors
- Section 2: Surgeons/Clinical experts
- Section 3: Other stakeholders
- Section 4: Stakeholders invited but who did not respond.

We would appreciate if the department could review these templates and confirm whether you would like us to send the consultation draft to:

- some or all of these stakeholders listed in section 4
- departmental stakeholders who participated in the focus group but have not seen the draft report, namely: s47F s47F and s47F .

1. Sponsors

DDN	s47F	
Johnson & Johnson	s47F	
KLS Martin Australia	s47F	
Maxoniq	s47F	
More Group	s47F	
Specifica	s47F	
Stryker	s47F	
Anatomics	s47F	
AA-Med	s47F	

Email template for sponsors who made a submission

Subject line: **Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback**

Attachments:

- Draft report with all product sponsor information redacted as pdf
- Sponsor specific attachment that includes specific product and utilisation information

Dear [Name of Sponsor]

Thank you for your involvement to date in this review currently being conducted by Australian Healthcare Associates (AHA) for the Department of Health and Aged Care.

We are providing stakeholders, including all sponsors, with the opportunity to comment on the draft report. Please find attached the Draft Report for *Review of surgical guides and biomodels currently listed on the Prostheses List*, and individual utilisation data, in PDF format.

If you wish to comment on any aspect of the Draft Report, please forward your response to s 47G by **12pm AEDT** on **Friday 6 January 2023**.

The Draft Report will be presented to the Prostheses List Advisory Committee (PLAC) on 15 December 2022 to seek their initial feedback.

Please note that your response may consist of up to:

- **four A4 pages of text with font size of no less than 11; and**
- **two A4 pages of tables/graphs/graphics**

Please ensure any comments regarding errors of fact are included in dot points clearly at the beginning of your response.

The contents of this email and the attached reports have been provided for the sole purpose of facilitating comment on the Review Surgical Guides and Biomodels on the Prostheses List draft report. The draft report must remain confidential and cannot be shared with any third party, published or used in any reports or records other than to construct a response. This report will be published when finalised, however that version of the report may contain further redactions.

Should you have any further queries, please contact us at s 47G

Regards,

Surgical Guides and Biomodels Review Team

Email template for the sponsor who did not make a submission

Subject line: **Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback**

Attachments:

- Draft report with all product sponsor information redacted as pdf
- Sponsor specific attachment that includes specific product and utilisation information

Dear [Name of Sponsor]

As you are aware, Australian Healthcare Associates (AHA) has been engaged by the Department of Health and Aged Care to conduct the *Review of Surgical Guides and Biomodels currently listed on the Prostheses List*.

We are providing stakeholders, including all sponsors with the opportunity to comment on the draft report. Please find attached the Draft Report for *Review of surgical guides and biomodels currently listed on the Prostheses List*, and individual utilisation data, in PDF format.

If you wish to comment on any aspect of the Draft Report, please forward your response to s 47G by **12pm AEDT** on **Friday 6 January 2023**.

The Draft Report will be presented to the Prostheses List Advisory Committee (PLAC) on 15 December 2022 to seek their initial feedback.

Please note that your response may consist of up to:

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Please ensure any comments regarding errors of fact are included in dot points clearly at the beginning of your response.

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Should you have any further queries, please contact us at s 47G

Regards,

Surgical Guides and Biomodels Review Team

2. Surgeons/clinical experts

s47F	

Subject line: **Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback**

Attachment:

- Draft report with all product sponsor information redacted as pdf

Dear [Name of surgeon]

Thank you for your involvement in this review currently being conducted by Australian Healthcare Associates (AHA) for the Department of Health and Aged Care.

We are providing stakeholders with the opportunity to comment on the draft report. Please find attached the Draft Report for the *Review of surgical guides and biomodels currently listed on the Prostheses List*, in PDF format.

Should you choose to provide feedback on the draft report, we would also appreciate your views on the following issues that have emerged during the review:

- Our understanding of complex craniomaxillofacial (CMF)procedures where surgical guides and biomodels are considered essential for implanting a prosthesis, as outlined in Section 4.3 (Product Alignment with PL criteria under Criterion 4). If we have missed any categories/types of procedures (complex or simple) or if there are errors in terminology, please let us know.
- We would like to better understand if there are instances where multiple surgical guides and/or biomodels may be essential for implanting a prosthesis. Based on input to date, we have suggested that no more than 2 surgical guides and 2 biomodels would be required for complex CMF procedures.
- Any other comments you would like to provide.

Please forward your response by reply email, or to s 47G by **12pm AEDT** on **Friday 6 January 2023**.

Please note that your response may consist of up to:

- **four A4 pages of text with font size of no less than 11; and**
- **two A4 pages of tables/graphs/graphics**

Please ensure any comments regarding errors of fact are to be included in dot points clearly at the beginning of your response.

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Should you have any further queries, please contact us at s 47G

Kind regards,

AHA Surgical Guides and Biomodels Review Team

3. Other stakeholders

Medical Technology Association of Australia	s47F	
Private Healthcare Australia	s47F	
Neurosurgical Society of Australasia (referred by Royal Australasian College of Surgeons)	s47F	
Australian Health Services Alliance (AHSA)	s47F	
Members Health Fund Alliance (MHFA)	s47F	
Day Hospitals Australia	s47F	
CSIRO Biomedical Materials Translational Facility	s47F	

Subject line: **Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback**

Attachments:

- Draft report with all product sponsor information redacted as pdf

Dear [Name of stakeholder]

Thank you for your involvement in this review currently being conducted by Australian Healthcare Associates (AHA) for the Department of Health and Aged Care.

Please find attached the Draft Report for the *Review of surgical guides and biomodels currently listed on the Prostheses List*, in PDF format.

We are providing stakeholders with the opportunity to comment on the draft report. Should you wish to contribute, please forward your response by reply email, or to s 47G by **12pm AEDT** on **Friday 6 January 2023**.

Please note that your response may consist of up to:

- **four A4 pages of text with font size of no less than 11; and**
- **two A4 pages of tables/graphs/graphics**

Please ensure any comments regarding errors of fact are included in dot points clearly at the beginning of your response.

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Should you have any further queries, please contact us at s 47G

Kind regards,

AHA Surgical Guides and Biomodels Review Team

4. Stakeholders who were invited to participate, but did not respond.

The following provides the list of stakeholders who were invited to be consulted but did not respond, and could be included in the consultation subject to departmental advice.

TGA	s47F	Nil response	s47F
Royal Australasian College of Surgeons	s47F	Sent representative from neurosurgical society	s47F
Consumer Health Forum	s47F	Nil response	s47F
Speech Pathologist Association	s47F	Nil response	s47F
Biomedical Engineers of Australia		Nil response	s47F
Clinical Expert	s47F	Nil response	s47F
Clinical Expert	s47F	Nil response	s47F

Subject line: **Review of surgical guides and biomodels currently listed on the Prostheses List – Draft report for feedback**

Attachments:

- Draft report with all product sponsor information redacted as pdf

Dear [Name of stakeholder]

As you may be aware, Australian Healthcare Associates (AHA) has been engaged by the Department of Health and Aged Care to conduct the *Review of Surgical Guides and Biomodels currently listed on the Prostheses List*.

We are providing stakeholders with the opportunity to comment on the draft report. Please find attached the Draft Report for the review, in PDF format.

Should you wish to contribute, please forward your response by reply email, or to s47G by **12pm AEDT** on **Friday 6 January 2023**.

Please note that your response may consist of up to:

- **four A4 pages of text with font size of no less than 11; and**
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Please ensure any comments regarding errors of fact are included in dot points clearly at the beginning of your response.

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Should you have any further queries, please contact us at s 47G

Kind regards,

AHA Surgical Guides and Biomodels Review Team

s22

From: s47E(d)
Sent: Tuesday, 29 November 2022 9:24 AM
To: s 47F ; s22 ; s47E(d) ; s22 s22 ; s22 ; s22
Cc: ;
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version)

Good Morning s 47

Thanks very much for sending through the report within the timeframe, appreciated!
Just a minor update to consider, on page 23 of the pdf copy of the report, under B.1.1 it should be Appendix B (and not A).

Kind regards
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 8:35 AM
To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Subject: Updated draft: review of surgical guides and biomodels (redacted version)

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Good morning s22 and team,

Please find attached a PDF version of the draft I sent last night, with redactions.

Kind regards,

s22

s22 | Associate Director
Head of Evaluation and Advisory
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Please note I don't work on Fridays

Please consider the environment before printing this email.

s22

From: s 47E(d)
Sent: Tuesday, 29 November 2022 4:43 PM
To: s 47F ; s22 s47E(d) ; s22 s22 s22
Cc: ; ; s22
Subject: RE: Updated draft: review of surgical guides and biomodels (redacted version) [SEC=OFFICIAL]

Hi s 47

We understand that you will include the information relevant to each sponsor in the body of an email.

One minor update for your consideration please - on page 55 of pdf, reference to M26.5 (4th sentence in the first para) needs to be M26.10 as in table 12.

Please also find additional comments below form PMR section:

Comments from PMR
Redactions

- Key findings for ToR 3 dot point 4 (in executive summary and ToR 3) – redact expenditure for 2013-14 as this was only one sponsor.
- Table 15. Please also redact 2016-17 line due to low number of sponsors in breakdown of surgical guides/biomodels categories. Total should be ok to keep.
- Figure 3 – should start from 2016-17 financial year (expenditure figures for earlier years are redacted in the table, so will need to be consistent with graphs).

Minor edits

- s22 comments page 49 - Table 13 would suggest that the overall average for biomodels is 26% for the 2013-14 to 2020-21 period. Remains at 22% in report. Ask AHA to confirm which is correct
- Suggest use' Surgical guides and Biomodels' all over the document for consistency (currently the term 'Biomodels and surgical guides' is used aswell)
- Once Craniomaxillofacial used as the abbreviation CMF, use CMF all over for consistency
- HCP in glossary not HCP1
- Separation definition already exist in glossary may remove from page 51 pdf version

Thank you for your hard work!

Kind regards
s22

From: s 4 7 @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 8:35 AM
To: s22 @health.gov.au>; s47E(d) @Health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Cc: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
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s 47F | Associate Director
Head of Evaluation and Advisory
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
E: s 47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Please note I don't work on Fridays

Please consider the environment before printing this email.

s22

From: s47E(d)
Sent: Tuesday, 29 November 2022 12:23 PM
To: s47F ; PL Reviews; s 47F ; s22 s22 ; s22 ; ; s47L(d) ;
Subject: RE: SGB review - Draft email templates

Hi s47F

Thanks for forwarding the details in preparation for the circulation of the draft report.

Unless you have been advised of the updated contacts, I have noted the following for the sponsors list (change in emails/contacts, the rest looks okay).

Sponsor	Primary contact	Email address
AA-Med Pty Ltd	s47F	
Anatomics Pty Ltd	s47F	
Maxoniq	s47F	
More Group Pty Ltd	s47F	
SPECIFICA PTY LTD	s47F	

In addition, I was thinking that the report also need to go to the following key stakeholders:

Type	Organisation	Contact name	Email
Private hospitals	APHA – Australian Private Hospitals Association	s47F	
	CHA – Catholic Health Australia	s47F	
Medical practitioners	AMA – Australian Medical Association	s47F	

s22 /s22 – are you able to please confirm whether the report needs to go to these additional key stakeholders.

Thanks & regards
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 11:20 AM
To: s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Subject: SGB review - Draft email templates

Good morning,

Thanks s22 for forwarding your email template for the circulation of the consultation draft report.

The attached document includes the proposed circulation list, attachments and email template for your review. We have tailored the email for each stakeholder group and have included some queries for your consideration (see attached).

Kind regards,

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M: s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s22
Sent: Tuesday, 29 November 2022 2:23 PM
To: s47F ; PL Reviews; s 47F ; s22 ; s22 ; s22 ; s47E(d)
Subject: RE: SGB review - Draft email templates [SEC=OFFICIAL]

Thank you s47F

We don't need the consultation to extend to DOHAC staff s22 and s22 .

Otherwise the draft emails and stakeholder lists provided appear to be accurate.

Regards

s22
Director, Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
M: s22
Location: Sirius Building s22
GPO Box 9848, Canberra ACT 2601, Australia

The Department of Health acknowledges 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 elders past and present.

Celebrating 100 YEARS OF HEALTH 1921 - 2021
Building a stronger, healthier country
Yesterday today and tomorrow

From: s 47 @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 11:20 AM
To: s 47 @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
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Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M s47F
E: s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

Please consider the environment before printing this email.

s22

From: s47E(d)
Sent: Tuesday, 29 November 2022 3:51 PM
To: s47F ; s47E(d) ; s 47F ; s22 ; s22 ; s22 ; s22 ; s47L(d)
Subject: RE: SGB review - Draft email templates [SEC=OFFICIAL]

Thanks s47F for the clarification.

Kind regards
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 3:22 PM
To: s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Subject: RE: SGB review - Draft email templates

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Thanks s22

Please see our suggested actions in relation to each contact:

Sponsor	Primary contact	Email address	AHA response
AA-Med Pty Ltd	s47F		We have been communicating with s47F as a current contact on a different email
Anatomics Pty Ltd	s47F		This is a new contact – s47F has been responding to our emails, so propose to send the document to s47F
Maxoniq	s47F		This is a new contact – s47F has been responding to our emails, so propose to send the document to s47F
More Group Pty Ltd	s47F		Current contact
SPECIFICA PTY LTD	s47F		New contact – s47F has been responding to our emails, so propose to send the document to s47F

In addition, I was thinking that the report also need to go to the following key stakeholders:

Type	Organisation	Contact name	Email	
Private hospitals	APHA – Australian Private Hospitals Association	s47F		Known contact – was part of the group consultation with s47F We can include

				s47F in the email.
	CHA – Catholic Health Australia	s47F		s47F was nominated to speak for CHA. We will include s47F in the email.
Medical practitioners	AMA – Australian Medical Association	s47F		New contact – We will include s47F

Kind regards,
s47F

From: s47E(d) @Health.gov.au>
Sent: Tuesday, 29 November 2022 12:23 PM
To: s4 @ahaconsulting.com.au>; s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Subject: [SEC=OFFICIAL] RE: SGB review - Draft email templates

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	CHA – Catholic Health Australia	s47F	
Medical practitioners	AMA – Australian Medical Association	s47F	

s22 /s22 – are you able to please confirm whether the report needs to go to these additional key stakeholders.

Thanks & regards
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 29 November 2022 11:20 AM
To: s47E(d) @Health.gov.au>; s47F @ahaconsulting.com.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s47E(d) @health.gov.au>
Subject: SGB review - Draft email templates

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Kind regards,

s47F | Senior Consultant
Australian Healthcare Associates

Level 6, 140 Bourke Street, Melbourne, VIC 3000
Locked Bag 32005, Collins Street East, VIC 8003
T: 1300 242 111
M s47F
E s47F @ahaconsulting.com.au
W: www.ahaconsulting.com.au

s22

From: s22
Sent: Monday, 28 November 2022 2:53 PM
To: s47F
Cc: s 47F ; s47E(d) ; s22 ; s22 ; s22 ; s22

Subject: Email template for stakeholder feedback [SEC=OFFICIAL]
Attachments: email template to request stakeholder feedback on draft report

Hi s47F

I hope you were able to enjoy your weekend.

Please see attached a template to request stakeholder feedback on the draft report that you can adapt for use later this week. The email includes standard words on keeping the report confidential while in draft form.

In addition, are you able to send through a copy of a stakeholder list the report will be emailed to? Apologies if you have already sent this via some other avenue and I have missed it.

Kind regards,
s22

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
☎ s22 | s22 @health.gov.au
Location: s22, 160 Ann Street, Brisbane QLD 4000
PO Box 9848, Brisbane QLD 4000, Australia

Work hours: Mon, Tues, Wed 9am-3pm

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.

s22

From: s47E(d)
Sent: Thursday, 24 November 2022 9:40 AM
To: s47F @ahaconsulting.com.au; s47F @ahaconsulting.com.au
Cc: s47E(d) ; s22 ; s22
Subject: Notification to Sponsors: FOR INFORMATION: Notice on upcoming Draft report – Surgical guides and biomodels

Good morning s47F & s 47

This is to advise you that we have sent out the attached email to the surgical guides and biomodels sponsors, indicating that they will receive the draft report on 30 Nov 2022.

Appreciate your hard work!

Thanks & regards
s22

From: s47E(d) @Health.gov.au>
Sent: Wednesday, 23 November 2022 5:20 PM
Subject: FOR INFORMATION: Notice on upcoming Draft report – Surgical guides and biomodels
Importance: High

Dear Sponsor

Update: Prostheses List Post-listing review of Surgical guides and biomodels – Upcoming draft report

On 21st September 2022 the Department advised you that we had engaged an external consultant, Australian Healthcare Associates (AHA) to undertake the post-listing review of surgical guides and biomodels.

AHA has completed the review and is preparing the Draft report that will be circulated to all stakeholders on Wednesday 30th November 2022. This consultation will invite you to review the report and provide your response by close of business Friday 6th January 2023.

The purpose of this consultation is to obtain feedback and views on the draft report to help finalise the report. Following this the report outcomes will be considered by the Prostheses List Advisory Committee (PLAC) and the Minister's delegate.

We encourage your participation in this consultation. You will continue to receive updates about the progress of this review.

Kind regards,

Prostheses List Reform Taskforce

Technology Assessment & Access Division | Health Resourcing Group
Australian Government Department of Health and Aged Care
E: s47E(d) @health.gov.au
Location: Sirius Building s22
GPO 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: s22 s22 s 47F ; s47F s22 s22 s22
Subject: Discuss approach to stakeholder consultation for the surgical guides and biomodels review with AHA

Good morning,

This meeting is to discuss the approach to stakeholder consultation for the surgical guides and biomodels review with AHA.

Kind regards,

s22

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Join meeting s22

More ways to join:

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s22

Join by meeting number

Meeting number (access code): s22

Meeting password: s22

Tap to join from a mobile device (attendees only)
s22 Australia Toll

Join by phone
s22 Australia Toll
Global call-in numbers s22

Join from a video system or application
s22
You can also dial s22 and enter your meeting number.

Join using Microsoft Lync or Microsoft Skype for Business

Dial s22

If you are a host, click here s22 to view host information.

Need help? Go to https://help.webex.com <https://help.webex.com>

s22

From: s22
Sent: Wednesday, 23 November 2022 10:30 AM
To: s47F ; s22 ; s 47F
Cc: s47E(d) ; ; s22 ; ; s47F
Subject: RE: Feedback on SGBM draft report [SEC=OFFICIAL]

Hi s47F

Thank you for your email. Since the meeting yesterday the PL area have discussed internally that the report should go to all stakeholders, but with extended timeframes.

Do you have time at 3:30pm (Melbourne and Canberra time) this afternoon for a quick discussion to clarify dates, timing and approach? I should have confirmed times/approach for you by then.

Many thanks,
s22

From: s47F @ahaconsulting.com.au>
Sent: Tuesday, 22 November 2022 3:55 PM
To: s22 @health.gov.au>; s22 @health.gov.au>; s47F @ahaconsulting.com.au>
Cc: s47E(d) @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>; s47F @ahaconsulting.com.au>
Subject: RE: Feedback on SGBM draft report [SEC=OFFICIAL]

REMINDER: Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Thanks s22

In the timeframes you sent us, you advised the following:

- **25 November:** Report sent to stakeholders (by AHA). 2 weeks to respond - limit 4 pages of text and 2 pages of tables.
- **9 December**: Stakeholder responses due.

If the document is to go to all stakeholders, we propose to send PDF versions and limit responses to 4 pages of text and 2 pages of tables. Could you confirm that this is acceptable to the department?

Kind regards,
s47F

From: s22 @health.gov.au>
Sent: Tuesday, 22 November 2022 4:07 PM
To: s22 @health.gov.au>; s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>

Cc: s47E(d) @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @Health.gov.au>
Subject: RE: Feedback on SGBM draft report [SEC=OFFICIAL]

Hi All,

Please see attached my comments on the report.

Many thanks for a great report.

Kind regards,
s22

From: s22 @health.gov.au>
Sent: Tuesday, 22 November 2022 3:01 PM
To: s47F @ahaconsulting.com.au>; s47F @ahaconsulting.com.au>
Cc: s47 @Health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>; s22 @health.gov.au>
Subject: Feedback on SGBM draft report [SEC=OFFICIAL]

s47F and s47
As per meeting just now.
Thanks
s22

s22

Medical Adviser

Technology Assessment and Access Division
Health Resourcing Group
Australian Government Department of Health
T: s22 | E: s22 @health.gov.au
Location: s22 595 Collins Street, Melbourne
GPO Box 9848 MDP 122, Melbourne VIC 3001, Australia

The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.