MSAC Application 1724

Cardiac technical support services provided by industry employed allied health professionals (IEAPs)

This application form is to be completed for new and amended requests for public funding (including but not limited to the Medicare Benefits Schedule (MBS)). It describes the detailed information that the Australian Government Department of Health requires to determine whether a proposed medical service is suitable.

Please use this template, along with the associated Application Form Instructions to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted. The separate MSAC Guidelines should be used to guide health technology assessment (HTA) content of the Application Form

Should you require any further assistance, departmental staff are available through the Health Technology Assessment Team (HTA Team) on the email below to discuss the application form, or any other component of the Medical Services Advisory Committee process.

Email: hta@health.gov.au
Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation / partnership details (where relevant): Medical Technology Association of Australia (MTAA)

The MTAA is the national association representing companies in the medical technology industry. The MTAA Cardiac Forum (CF) was established to allow members to discuss Prostheses List (PL) reform in relation to cardiac implantable electronic devices. CF members include Medtronic, Abbott, Biotronik, MicroPort CRM and Boston Scientific.

Corporation name: CF

ABN: N/A. Applicant is a forum representing companies in the medical technology industry

Business trading name: N/A. Applicant is a forum representing companies in the medical technology industry

Primary contact name: REDACTED

Primary contact numbers

Business: **REDACTED**

Mobile: **REDACTED**

Email: **REDACTED**

Alternative contact name: REDACTED

Alternative contact numbers

Business: **REDACTED**

Mobile: **REDACTED**

Email: **REDACTED**

2. (a) Are you a consultant acting on behalf on an applicant?

☒ Yes
☐ No

(b) If yes what is the Applicant(s) name that you are acting on behalf of?

The MTAA Cardiac Forum (CF) consisting of Medtronic, Abbott, Biotronik, MicroPort CRM and Boston Scientific

3. (a) Are you a lobbyist acting on behalf of an Applicant?

☐ Yes
☒ No

(b) If yes, are you listed on the Register of Lobbyists?

NA. The Applicant is not a lobbyist acting on behalf of an Applicant

(c) Have you engaged a consultant on your behalf?

NA. The Applicant is a consultant acting on behalf of the CF

Foreword

Cardiac implantable electronic devices (CIEDs) consist of pacemakers (PPMs), implanted cardioverter defibrillators (ICDs), implantable loop recorders (ILRs) and cardiac resynchronisation therapy devices (CRTs). CIEDs require ongoing technical services to ensure patient safety, optimise the outcomes from device therapy and to monitor patients with a range of cardiovascular conditions including bradyarrhythmias, ventricular tachyarrhythmias, atrial fibrillation and advanced systolic heart failure (Wilkoff et al., 2008, Steffen et al., 2019). Globally and in Australia these services are imbedded in CIED standard of care and are endorsed by numerous clinical guidelines, product manuals and statements from physicians and professional organisations (CSANZ, 2017, BHRS, 2020, Lindsay et al., 2008, Wilkoff et al., 2008). Industry employed allied health professionals (IEAPs) are integral to the provision of cardiac services in the public and private Australian healthcare system (outlined in PART 6 – PICO). In both settings, cardiac support services provided by IEAPs are only completed at the request of a treating health care professional (HCP).

CIED patients in the public healthcare system (defined as patients without private health insurance) largely receive cardiac services in public hospitals from a physician supported by hospital-employed cardiac physiologists. Public hospital cardiac physiologists provide technical support for all brands of CIEDs and therefore additional specialised support is required from IEAPs for product specific training and assistance with complex servicing tasks (for example, algorithm optimisation can often only be performed by IEAPs due to their product expertise).

CIED patients in the private healthcare system (defined as patients with private health insurance) receive cardiac services in a range of inpatient and outpatient settings (outlined in PART 6 – PICO, Table 4). In this setting, IEAPs provide essential equipment, perform the majority of CIED servicing tasks, and collaborate directly with the treating physician (IWG, 2020). There are a very limited number of cardiac physiologists (equivalent to the public sector) which support physicians in this setting. Although IEAPs provide support in both systems, **the focus of this application is on reimbursement for cardiac technical support services provided by IEAPs in the private healthcare system** where companies supplying CIEDs take on delivery of most cardiac technical support services.

Based on an independent validation report by KPMG, the total cost of services provided by IEAPs in the private healthcare system is estimated to fall in the range of $86 million and $125 million, with a median total cost of $102.98 million in FY23 (KPMG, 2021)(outlined in PART 8 – COST INFORMATION). This includes training and labour costs along with significant travel time, covering metropolitan, regional and remote locations. Notably, IEAPs provide 24hr servicing for potential troubleshooting or assistance with interpretation of interrogated data for high-risk events or for patients presenting to the emergency department (IWG, 2020).

Even though private physicians can claim reimbursement for cardiac services (MBS items 11719, 11720, 11721, 11725, 11726, 11727, 38213, 11728, 11731), these payments go toward the physician's time only with no reimbursement provided for IEAP technical support. Consequently, the cost for industry to provide the high-quality and vital IEAP services is coming solely from the Prostheses List (PL) benefit for CIEDs, payable at implantation of the devices. However, if the planned PL benefit reductions are implemented, industry will be unable to sustain the existing level of support for device implantation and follow-up technical services.

Agreement between the Government and MTAA to support sponsors and suppliers of medical devices

In October 2017, MTAA entered into an Agreement with the Australian Government to determine a new framework for setting and reviewing PL benefits (Australian Government, 2017). As part of that Agreement, which operated from 15 October 2017 to 31 January 2022, there was a staged reduction of PL benefits. This included a 37.5% benefit (10% being before the 2017 MTAA Agreement) reduction for CIEDs. Unlike other items on the PL, CIEDs have very high lifetime service requirements which are heavily supported by IEAPs. The Agreement recognised that PL benefit reduction may impact the provisions of these services and, consequently, proposed the formation of an industry working group (IWG) to determine how technical support services should be funded. The IWG concluded, in their December 2020 report to government, that the services were clinically essential and necessary but did not provide any recommendations on a funding mechanism.

The May 2021 Federal Budget announced further reforms to the PL supported by the Independent Hospital Pricing Authority (IHPA). As a result, further reductions to PL benefits are planned to commence from 1st July 2022. Device suppliers have expressed strong concern that in this environment of reduced benefit reimbursement, industry's ability to sustain the existing level of cardiac services will be significantly compromised. As outlined in the attached letter of support from 114 cardiac clinicians (roughly estimated at a third of all implanting physicians/electrophysiologists in Australia), without appropriate funding of cardiac technical support services provided by IEAPs, there will be a disastrous void with no parallel system to replace these services.

Unlike typical MSAC evaluations, this application is seeking long-term efficient funding of cardiac technical support services, which are part of the standard clinical practice for optimising CIED therapy in Australia. The focus of this application is to confirm the clinical relevance, need and benefit of cardiac technical support services provided by IEAPs and to present potential funding mechanisms as requested by the Department of Health.

Overview of cardiac technical support services

CIEDs encompass battery powered electronic devices for diagnosis, treatment and monitoring of a range of cardiovascular conditions including bradyarrhythmias, ventricular tachyarrhythmias, atrial fibrillation and advanced systolic heart failure (Steffen et al., 2019). The implantation of these devices is associated with numerous current MBS items.

To obtain optimal device performance and longevity, CIEDs are checked on a regular basis. This regular evaluation (cardiac services) is required to assess and optimise CIED performance and safety, identify and correct any device system abnormalities, anticipate the need for elective CIED replacement, monitor cardiac arrhythmias and physiologic parameters, and communicate information related to CIED monitoring to involved physicians and other healthcare providers where appropriate (Wilkoff et al., 2008).

There are between 1 and 4 scheduled cardiac services that occur each year per patient, based on guidelines by the Cardiac Society of Australia and New Zealand (CSANZ)(CSANZ, 2017). These scheduled services occur every 3-6 months for PPMs, ICDs and CRTs and 6-12 months for ILRs. In addition, there may be unscheduled cardiac device checks if a patient develops new symptoms, or if an event was detected via remote monitoring (Wilkoff et al., 2008).

The current standard of care for cardiac services within the Australian private healthcare setting involves IEAP technical support. Although the treating physician is ultimately responsible for making any clinical decisions relating to cardiac servicing, IEAPs provide essential equipment and are tasked with undertaking most of the cardiac support servicing in the Australian private healthcare system (details outlined in PART 6 – PICO, Table 4). These services are endorsed by numerous international and local clinical guidelines, product manuals and statements from professional organisations (CSANZ, 2017, BHRS, 2020, Lindsay et al., 2008, Wilkoff et al., 2008). Most services provided in the public setting are performed by a cardiac physiologist employed by the public facility.

Cardiac technical support services enable patients to achieve the best possible clinical outcomes. IEAPs work very closely with patients adjusting their device programming to help improve cardiac symptoms and function, preventing deterioration to the extent of rehospitalisation. Additionally, cardiac services prevent CIED battery depletion and inappropriate CIED therapy along with facilitating the treatment, monitoring and optimisation of therapy in patients. This results in an array of improved patient clinical outcomes (detailed in PART 6 – PICO) including:

- Increased survival
- Decreased clinical events (heart failure, stroke, chest infection, pacemaker syndrome, pre-syncope)
- Improved patient reported outcomes (quality of life)
- Reduced adverse events (infection, death)
- Reduced costs associated with device replacement
- Reduced time in hospital

Independent Validation of Technical Service Costs

MTAA contracted KPMG to determine the resource requirements of cardiac technical services in the private healthcare system in Australia. This was done using data supplied by cardiac device companies and publicly available sources (discussed in PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION and PART 8 – COST INFORMATION). KPMG modelled the cost of providing IEAP technical services in the private healthcare system based on these inputs. By KPMG's analysis, the total cost of services provided by IEAPs in FY20 fell in the range of $66 million to $96 million, with a median cost of $78.59 million. The total costs by FY23 are expected to fall in the range of $86 million and $125 million, with a median total cost of $102.98 million. This service valuation report was largely informed by industry data collected over a six-week period in 2019 (KPMG, 2021).

Proposal for transitional funding with reassessment commitments

Services provided by IEAPs are already part of standard clinical practice and are endorsed by numerous international and local clinical guidelines, product manuals and statements from professional organisations (outlined in

PART 4 – SUMMARY OF EVIDENCE). Additionally, aggregated industry data collected over a six-week period in 2019 demonstrates the significant service burden for clinically necessary technical services provided by IEAPs (discussed in PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION and PART 8 – COST INFORMATION). To supplement this evidence, the CF has also proposed several activities to decrease any residual uncertainty relating to the provision and cost of these services including;

- A compulsory industry wide accreditation process to ensure standardised service delivery
- Further data collection relating to the clinical benefit of cardiac technical services
- A comprehensive data collection process regarding the extent and type of services delivered by IEAPs. A 3-year time period would be required to capture the expected lifetime activity and seasonality of these services

After a transitional period of 3 years, CF proposes a reassessment by the Department of Health, where data from above list will be provided and used to inform the development of a long-term, sustainable funding mechanism for cardiac services.

Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of Pharmacy Practice Incentives (PPI). In the meeting minutes "MSAC suggested that funding for the current PPI programs (SS, DAAs and CIs) could continue while […] protocols for novel ways to enhance services were developed by the pharmacy sector" (*6CPA PPI Final MSAC minutes, p4*).

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

4. Application title

Cardiac technical support services provided by IEAPs.

5. Provide a succinct description of the medical condition relevant to the proposed service (no more than 150 words – further information will be requested at Part F of the Application Form)

Cardiovascular disease is the leading cause of death worldwide. In 2017, it was found that there were 43,447 deaths (27% of all deaths) in Australia attributable to diseases of the circulatory system and there were more than 1.1 million hospitalisations in 2015-16 (11% of all hospitalisations) due to cardiovascular disease (Australian Bureau of Statistics, 2018).

CIEDs encompass battery powered electronic devices for diagnosis, treatment and monitoring of a range of cardiovascular conditions including bradyarrhythmias, ventricular tachyarrhythmias, atrial fibrillation and advanced systolic heart failure (Steffen et al., 2019). Typically, these devices are implanted in patients at risk of sudden cardiac death or suffering from chronic heart failure.

CIEDs currently encompass the following device categories:

- PPM - monitor the heartbeat and deliver electrical impulses to prompt the heart to beat at a normal rate.
- ICDs - track the heart rate and deliver an electric shock to restore a normal heartbeat.
- CRTs - there are two types of CRT devices which are both used to restore heart failure inducing dysynchrony between the left and right ventricles of the heart. Depending on your heart failure condition, a CRT pacemaker (CRT-P) or a CRT defibrillator (CRT-D) may be indicated.
- ILRs - track and record the heart over several years to assess if a patient is experiencing symptoms that are related to abnormal cardiac rhythms.

6. Provide a succinct description of the proposed medical service (no more than 150 words – further information will be requested at Part 6 of the Application Form)

To obtain optimal device performance and longevity, CIEDs are serviced on a periodic basis. This regular evaluation is required to assess and optimise CIED performance and safety, identify and correct any device system abnormalities, anticipate the need for elective CIED replacement, monitor cardiac arrhythmias and physiologic parameters, and communicate information related to CIED monitoring to involved physicians and other healthcare providers where appropriate (Wilkoff et al., 2008).

There are between 1 and 4 scheduled cardiac services that occur each year per patient, based on guidelines by CSANZ (CSANZ, 2017). This occurs every 3-6 months for PPMs, ICDs and CRTs and 6-12 months for ILRs. In addition, there may be unscheduled cardiac device checks if a patient develops new symptoms, or if an event was detected via remote monitoring (Wilkoff et al., 2008).

It is standard of care for IEAPs to provide technical support for cardiac services within the Australian private healthcare setting. Although the treating physician is ultimately responsible for making any clinical decisions relating to cardiac technical servicing, IEAPs provide essential equipment and undertake the majority of the tasks required for cardiac device servicing in the Australian private healthcare system.

IEAPs engage in a range of servicing tasks for unscheduled and scheduled cardiac technical services including:

- Data retrieval
- Device interrogation
- Interpretation of interrogation results
- Algorithm optimisation
- Device reprogramming /device reprogramming recommendations to HCPs

- Troubleshooting
- Electrical conduction tests
- Ongoing device education and support to patients
- Documentation and communication with relevant HCPs
- Remotely monitoring patients
- Review diagnostics/EGM

Although physician services are subsidised through Medicare for periodic in-office as well as remote examinations of CIED patients, cardiac support services provided by IEAPs are unfunded, despite the necessity of the services and the need for a highly trained technician to provide them.

(a) Is this a request for MBS funding?

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of medical devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

(b) If yes, is the medical service(s) proposed to be covered under an existing MBS item number(s) or is a new MBS item(s) being sought altogether?

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

(c) If an amendment to an existing item(s) is being sought, please list the relevant MBS item number(s) that are to be amended to include the proposed medical service/technology:

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

(d) If an amendment to an existing item(s) is being sought, what is the nature of the amendment(s)?

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

(e) If a new item(s) is being requested, what is the nature of the change to the MBS being sought?

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

(f) Is the proposed service seeking public funding other than the MBS?

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

(g) If yes, please advise:

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of implanted cardiac devices. As requested by the Department of Health, a description of potential funding pathways together with a summary of their advantages and limitations is presented in Table 1.

Table 1 Funding mechanisms for cardiac support services provided by IEAPs

Description	Advantages	Limitations
Medicare Benefits Schedule (MBS)		
• MBS provides benefits for an extensive range of medical and allied health services, procedures, consultations and diagnostic services. • Services are usually implemented following an evaluation (MSAC HTA) based on evidence of clinical need, clinical relevance, comparative safety and effectiveness (vs. current standard of care), and cost.	• Funding decisions are done in a systematic and transparent way and are linked to the cost-effectiveness of a service • Allied health MBS item structure may be applicable to cardiac services, involving a referral from a primary physician. • Current MBS data collection frameworks should enable utilisation of cardiac support services to be readily implemented. • Private Health Insurer reimbursement of the difference between MBS fees and the Medicare rebate could represent a pro rata approach to fund cardiac technical support services over time.	• Medicare rebates do not cover the full cost of medical services and large gap payments may lead to high out-of-pocket expenses for patients. Notably, a service provided out of hospital generally attracts a benefit of 85% of the schedule fee. • As the MBS is funded by the taxpayers, this option would involve the public cross funding private patients. • Currently there is no compulsory training requirements for IEAPs. However, to increase certainty of the high-quality and standardised level of care that IEAPs are delivering to patients, CF will commit to developing a compulsory industry wide accreditation process for IEAPs. • Cardiac services are already established as standard of care in Australia clinical practice, with the cost of the physician component of this service subsidised through Medicare. Consequently, the usual HTA approach is not appropriate for evaluating this service.
Private health insurance		
• Private health insurance can pay on the basis of per diems, case payment (often with the same DRG system used in public hospitals), or a mixture of both. • Funding by private health insurers could involve this existing payment model or by the development of new models appropriate for cardiac technical services.	• Private health insurance currently covers some of the admitted patient cost for private patients in private or public hospitals (i.e., the difference between Medicare rebates and MBS fees). • Insurer data collection systems could be used to monitor cardiac service utilisation. • Allied health private health insurance funding structure may be applicable to cardiac services, involving a referral from primary physician. • PHI currently deliver CDMPs which could incorporate IEAP servicing	• Private health insurance does not cover medical services that are provided out of hospital. • Requires an ongoing costly referral process where the need is continuous and not periodic.
Diagnosis related group (DRG)		
• DRGs are a classification system for admitted patient care used for funding and payment purposes.	• Relies on existing infrastructure and data. • Introduces a benchmark price (Increased competition) and in the context of Activity-based Funding is centred on improving the efficiency	• DRGs are a classification system for admitted acute patient care. • Lack granularity given that several different procedures are often mapped to the same DRG. This limits the usefulness of data

Description	Advantages	Limitations
• They group together patients with related and/or similar diagnoses and procedures, incurring similar treatment costs.	of healthcare delivery, reducing costs of care, minimising avoidable variation, and enabling transparency and innovation. • Used as part of a global budget in the Australian public sector and increasingly in the Australian private sector.	collected and will not accurately represent the variation in cardiac services performed (e.g., ward checks, MRI checks). • DRG-based case payments enable funding that can focus on optimising revenue for the provider at the potential expense of not using the most clinically appropriate (and often higher cost) device. This is at odds with the physician-led model of private healthcare which allows the physician to choose any item listed on the PL based on their patient's characteristics. • Implementation needs are extensive – including development of appropriate patient coding system, determination of an 'efficient price' for cardiac services and updating of hospital coding systems. • Considerable administrative burden on smaller and day hospitals to become coders when many of them do not play this role currently.
Revised Prostheses List benefit review mechanism		
• Under this option the PL benefits for the device would be benchmarked on a periodic basis against public prices with adjustments for market differences including the post implant cardiac technical services. This cost would be updated periodically to adjust for annual CPI inflation.	• Including the cost to the cardiac device companies for their involvement for the full life of the patient or CIED included in the initial device payment is the model that exists within most countries. Typically, these services are captured in a 'one-off' upfront payment for services, with no further cost borne by private health insurers, and costs not increased to adjust for inflation or any other factors that could impact cardiac service provision. • A modified public-private referencing model could be used to achieve efficient benefit setting on the PL without removing the unique characteristics of the private market. This is the approach that has been used by IHPA. • Could be implemented largely within the existing PL framework. • Rapid benefit adjustment is possible if there are large differences between the public and private prices.	• PL benefits typically do not cover medical services – however, the Department of Health could look to integrate elements of the MBS services data collection system to capture cardiac technical services. • Requires establishment of an evidence-based mechanism to adjust device benefits to include a proportion for the provision of services.

Abbreviations: CDMP= Chronic disease management programs; CIED=cardiac implantable electronic device; CPI=Consumer Price Index; DRG=diagnosis related groups; HTA=Health Technology Assessment; IHPA= Independent Hospital Pricing Authority; MBS=Medicare Benefits Schedule; PHI=private health insurance; PL= Prostheses List; PLAC=Prostheses List Advisory Committee

The CF consider modifying the revised PL benefit review approach to be the most appropriate mechanism for funding cardiac support services. In this approach, as previously proposed by the MTAA, PL benefits are benchmarked on a periodic basis against public prices with adjustments for market differences and the provision of cardiac support services. Given that cardiac technical support services in the public sector are funded from within hospital budgets whilst there is no equivalent funding mechanism in the private sector, to protect the sustainability of these services this cost would need to be accounted for when adjusting the PL benefits. As recommended in the MTAA submission in response to the Department's Consultation Paper: *Options for Reforms and Improvements to the Prostheses List*, the cost of cardiac technical support services should be calculated separately but paid for through the device on the PL (MTAA, 2021). The approach achieves efficient pricing whilst still accounting for the differences between funding in the public and private healthcare system.

7. What is the type of medical service/technology?

NA. IEAP provided cardiac technical support services have not been previously considered by MSAC and do not fit under any of the listed subcategories (therapeutic medical service, investigative medical service, single consultation medical service, global consultation medical service, allied health service, co-dependent technology, hybrid health technology). However, parallels can be made between allied health and cardiac technical support as both services are only provided at the request of a treating physician by professionals that hold specific accreditation relevant to their industry.

8. For investigative services, advise the specific purpose of performing the service

NA. IEAP provided cardiac support services are not considered to be investigative medical services.

9. Does your service rely on another medical product to achieve or to enhance its intended effect?

☐ Pharmaceutical / Biological
☒ Prosthesis or device
☐ No

10. (a) If the proposed service has a pharmaceutical component to it, is it already covered under an existing Pharmaceutical Benefits Scheme (PBS) listing?

NA. IEAP provided cardiac support services do not include a pharmaceutical component

(b) If yes, please list the relevant PBS item code(s):

NA. IEAP provided cardiac support services do not include a pharmaceutical component

(c) If no, is an application (submission) in the process of being considered by the Pharmaceutical Benefits Advisory Committee (PBAC)?

NA. IEAP provided cardiac support services do not include a pharmaceutical component

(d) If you are seeking both MBS and PBS listing, what is the trade name and generic name of the pharmaceutical?

(e) NA. IEAP provided cardiac support services do not include a pharmaceutical component

11. (a) If the proposed service is dependent on the use of a prosthesis, is it already included on the Prostheses List?

☒ Yes
☐ No

(b) If yes, please provide the following information (where relevant):

CIEDs encompass PPMs, ICDs, CRTs and ILRs. These devices are listed on the PL under the following subcategories

- PPMs - 08.04, 08.05, 08.09, 08.10, 08.11, 8.16

- ICDs - 08.01, 08.02, 08.03, 08.07, 08.09, 08.10, 8.16
- CRTs - 08.03, 08.06, 8.16
- ILR - 8.14, 8.16

Billing code(s): Multiple.
Trade name of prostheses: Multiple
Clinical name of prostheses: Multiple
Other device components delivered as part of the service: As confirmed by a board of industry representatives and cardiac physicians, equipment and consumables involved in the servicing of cardiac devices in the private healthcare system are largely provided by industry. An example of additional device component delivered as part of the service includes a multi-use programmer which can produce a report and electrocardiogram (ECG).

Although the aggregated industry data collected over a six-week period in 2019 (included in the KPMG CIED service valuation report) demonstrated the number and cost of services provided by IEAPs, the use of other device components delivered as part of the service was not captured. Given the clinical necessity of these services, it is proposed that a transitional funding arrangement is established during which CF will commit to a robust data collection process to accurately measure the number, type, duration, and cost for each service (including the use of other device components delivered as part of the service). After this transitional period, it is proposed that the value of IEAP provided cardiac support services is reassessed.

Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of PPI (*6CPA PPI Final MSAC minutes, p4*).

(c) If no, is an application in the process of being considered by a Clinical Advisory Group or the Prostheses List Advisory Committee (PLAC)?

N/A. IEAP provided cardiac support services are dependent on the use of multiple prosthesis which are already included on the PL.

(d) Are there any other sponsor(s) and / or manufacturer(s) that have a similar prosthesis or device component in the Australian marketplace which this application is relevant to?

N/A. IEAP include all industry employed physiologists, irrespective of the sponsor/manufacturer. This application has been prepared on behalf of CF, who represents all companies with CIEDs on the PL

(e) If yes, please provide the name(s) of the sponsor(s) and / or manufacturer(s):

N/A. IEAP include all industry employed physiologists, irrespective of the sponsor/manufacturer.

12. Please identify any single and / or multi-use consumables delivered as part of the service?

As confirmed by a board of industry representatives and cardiac physicians, equipment and consumables involved in the servicing of cardiac devices in the private healthcare system are largely provided by industry. An example of single and / or multi-use consumables delivered as part of the service include paper, batteries, and sanitation wipes.

Although the aggregated industry data collected over a six-week period in 2019 (included in the KPMG CIED service valuation report) demonstrated the number and cost of services provided by IEAPs, the use of single and/or multi-use consumables delivered as part of the service was not captured. Given the clinical necessity of these services, it is proposed that a transitional funding arrangement is established during which CF will commit to a robust data collection process to accurately measure the number, type, duration, and cost for each service (including the use of single and / or multi-use consumables delivered as part of the service). After this transitional period, it is proposed that the value of IEAP provided cardiac support services is reassessed.

Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of PPI (*6CPA PPI Final MSAC minutes, p4*).

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

13. (a) If the proposed medical service involves use of a medical device, in-vitro diagnostic test, pharmaceutical product, radioactive tracer, or any other type of therapeutic good, please provide details

Type of therapeutic good: Medical device (PPM, ICD, CRT, ILR)
Manufacturer's name: Multiple
Sponsor's name: Multiple

(b) Has it been listed on the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)? If the therapeutic good has been listed on the ARTG, please state the ARTG identification numbers, TGA-approved indication(s), and TGA-approved purpose(s).

CIEDs encompass PPMs, ICDs, CRTs and ILRs which are classified under the ARTG product categories of "Medical Device AIMD" or "Medical Device Class III". The ARTG ID for these devices are listed under the PL under the following subcategories.

- PPMs - 08.04, 08.05, 08.09, 08.10, 08.11, 8.16
- ICDs - 08.01, 08.02, 08.03, 08.07, 08.09, 08.10, 8.16
- CRTs - 08.03, 08.06, 8.16
- ILR - 8.14, 8.16

ARTG ID: Multiple
TGA approved indication(s), if applicable: Multiple
TGA approved purpose(s), if applicable: Multiple

(c) If a medical device is involved, has the medical device been classified by TGA as a Class III OR Active Implantable Medical Device (AIMD) under the TGA regulatory scheme for devices?

☒ Class III
☒ AIMD
☐ NA

(d) Is the therapeutic good classified by TGA for Research Use Only (RUO)?

No

14. (a) <u>If not listed on the ARTG</u>, is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

N/A. All CIEDs involved in cardiac technical support services are listed on the ARTG.

(b) If the therapeutic good is <u>not ARTG listed</u>, is the therapeutic good in the process of being considered by TGA?

NA. All CIEDs involved in cardiac technical support services are listed on the ARTG.

(c) If the therapeutic good is NOT in the process of being considered by TGA, is an application to TGA being prepared?

N/A. All CIEDs involved in cardiac technical support services are listed on the ARTG.

PART 4 – SUMMARY OF EVIDENCE

15. Provide one or more recent (published) high-quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement', please do not attach full text articles; just provide a summary.

There are characteristics of cardiac services which mean that a usual clinical trial-informed HTA approach does not apply:

- Cardiac technical services are an essential component of CIED devices to ensure ongoing patient safety and to optimise the outcomes from device therapy. Given that servicing is a product requirement for CIEDs, cardiac servicing has largely not been considered separately from the evidence on the device itself. Notably, CIEDs were first approved by the TGA, MSAC and PLAC based on safety and effectiveness evidence on devices where cardiac technical services were an integral and standard component of ongoing CIED therapy.
- Current standard of care for cardiac services within the Australian healthcare setting involves technical support provided by IEAPs. Hence, any type of clinical trial that involved comparing CIED therapy with technical support to CIED therapy without it would clearly be unethical (e.g., a double-blind clinical trial)
- A typical double-blind clinical trial would not represent the realities of current CIED use and technical support. This is a result of the diversity of cardiac technical support services provided by IEAPs which have evolved in parallel with CIEDs which have and will continue to undergo incremental changes.

As a result, there is no formal evidence of the specific impact of IEAP provided cardiac support services on health outcomes, however, the role of supporting cardiac physiologists in the performance of cardiac technical servicing has been well established in international and local clinical guidelines (Table 2). Two guidelines explicitly note the importance of IEAPs in performing this role (Lindsay et al., 2008, Wilkoff et al., 2008).

Additionally, the importance of supporting staff in the provision of cardiac support services in the Australian setting has been previously acknowledged by MSAC in their assessment of remote monitoring of CIED where they noted that 'diagnostic testing of the device is likely to be managed by a technician on behalf of the cardiologist' (MSAC, PSD 1197, p2).

Furthermore, clinical trials that have been published in the last 10 years demonstrating the survival benefit of CIED implantation in certain populations with heart disease have contributed to the establishment of numerous clinical guidelines from peak cardiac bodies which support their use (Bardy et al., 2005, Moss et al., 2002, Kirchhof et al., 2016). Appropriately servicing CIEDs is a product requirement listed in device manuals (examples provided in Table 3) and it is reasonable to assume that in the absence of servicing, these devices will not operate in the manner to which they were assessed and approved by TGA, MSAC and PLAC. Without the necessary technical support there are potential significant impacts on overall patient health outcomes.

Although current standard of care for cardiac services within the Australian private healthcare setting involves IEAP technical support and these services are already considered clinically necessary by several clinical guidelines, CF acknowledge that further clinical evidence may decrease uncertainty relating to clinical benefit. Given the clinical necessity of cardiac technical support services provided by IEAPs, it is proposed that a transitional funding arrangement is established during which CF will commit to further data collection. Following this transitional period, CF will commit to reassessment by the Department of Health where data will be provided, and a longer-term funding mechanism can be proposed and decided.

Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of PPI. In the meeting minutes "MSAC suggested that funding for the current PPI programs (SS, DAAs and CIs) could continue while […] protocols for novel ways to enhance services were developed by the pharmacy sector" (*6CPA PPI Final MSAC minutes, p4*).

Table 2 Clinical guidelines to support the use of the proposed service

Publication type	Author (Year), country	Title	URL	Summary
Clinical guideline	CSANZ (2017), Australia	Guidelines for advanced sub-specialty training in Cardiac Implantable Electronic Devices (CIEDs): selection, implantation, and follow-up	https://www.csanz.edu.au/wp-content/uploads/2017/03/Sub-spec-Training-CIED_2017-March.pdf	Guideline notes that CIED service/training centres should include appropriate technical support personnel. Recommend 1-4 annual check-ups depending on the device. PPM and ICDs should be serviced every 3-6 months. ILRs should be serviced every 6-12 month.
Clinical guideline	BHRS (2020), UK	Clinical standards and guidelines for the follow-up of cardiac implantable electronic devices (CIEDs) for cardiac rhythm management	https://bhrs.com/wp-content/uploads/2020/02/BHRS-CIED-FU-Standards-FEB-2020-FINAL-1.pdf	Guideline outlines CIED serving requirements and notes that these services should be performed by cardiologists and trained technical support personnel. Recommends an immediate check-up within 72 hours after CIED implantation occurs (preferably within 24 hrs) and, depending on the device type, follow-up frequency may range between 3 months and a year.
Clinical guideline	BHRS (2020), UK	Standards for insertion, follow-up and explant of implantable loop recorders (ILRs) by non-medical staff	https://bhrs.com/wp-content/uploads/2020/10/BHRS-ILR-Standards-for-Insertion-revised.pdf	Guideline outlines ILR servicing requirements and note that these services should be performed by cardiologists and trained technical support personnel. Recommends a check-up around 4-6 weeks post implant. Onward follow-up where remote, should involve a three-monthly review unless alerts are noted before this time (symptomatic event). Where follow-up is not remote, patients should be seen at intervals determined by the Consultant and implanting team, often at 3-monthly intervals.
Clinical guideline	ESC (2021), Europe	Guidelines on cardiac pacing and cardiac resynchronisation therapy	https://www.escardio.org/Guidelines/Clinical-Practice-Guidelines/Cardiac-Pacing-and-Cardiac-Resynchronization-Therapy	Guideline outlines CIED servicing requirements and the value of ongoing remote device management (to provide earlier detection of clinical problems or technical issues).
Clinical guideline	Lindsay et al. (2008), USA	Heart Rhythm Society Policy Statement Update: Recommendations on the Role of Industry Employed Allied Professionals (IEAPs)	https://www.hrsonline.org/guidance/clinical-resources/2008-heart-rhythm-society-policy-statement-update-recommendations-role-industry-employed-allied	Provides recommendations on the role of IEAP's in the clinical environment. Outlines that IEAP are highly trained to provide technical expertise on the implant, use, and operation of their proprietary equipment specific to their company. Supersedes the 2001 HRS publication on the role of IEAPs.

Publication type	Author (Year), country	Title	URL	Summary
Expert consensus statement	Wilkoff et al. (2008), Europe and USA	HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations	https://academic.oup.com/europace/article/10/6/707/661858	Statement outlines CIED serving requirements. Provides brief overview on the responsibility of IEAPs in cardiac services. Statement notes that in many practices, IEAPs take responsibility for a great deal of patient follow-up. In some situations, they were expected to staff the patient follow-up sessions, and at times do independent programming, i.e., program the patient without the physician being immediately available. Indicated that the minimum frequency of CIED in person or remote monitoring: • PPM: 72 hours of CIED implantation (In Person), 2–12 weeks post implantation (In Person), every 3–12 months (In Person or Remote), every 1–3 months at signs of battery depletion • ICDs: 72 hours of CIED implantation (In Person), 2–12 weeks post implantation (In Person), every 3–6 months (In Person or Remote), every 1–3 months at signs of battery depletion (In Person or Remote) • CRT-P: 72 hours of CIED implantation (In Person), 2–12 weeks post implantation (In Person), every 3–12 months (In Person or Remote), every 1–3 months at signs of battery depletion (In Person or Remote) • CRT-D: 72 hours of CIED implantation (In Person), 2–12 weeks post implantation (In Person), every 3–6 months (In Person or Remote), every 1–3 months at signs of battery depletion (In Person or Remote) • ILR: Every 1–6 months depending on patient symptoms and indication (In Person or Remote)

Abbreviations: BHRS=British Heart Rhythm Society; CIED=Cardiac Implantable Electronic Device; CSANZ=Cardiac Society of Australia and New Zealand; EHRA=European Heart Rhythm Association; ESC=European Society of Cardiology; ICD=Implantable Cardioverter Defibrillators; HRS=Heart Rhythm Society; IEAP=Industry Allied Health Professional; ILR=Implantable Loop Recorders; PPM=Pacemaker

Table 3 Example CIED manuals

Device category	Product name	Company	URL	Summary
PPM	Azure™ S SR MRI SureScan™ W3SR01	Medtronic	https://manuals.medtronic.com/content/dam/emanuals/crdm/M977345A001B_view.pdf	As 3 months is the recommended follow-up interval published in local and international clinical guidelines, Medtronic products are designed to provide at least 3 months between RRT and EOS.
	Assurity MRI	Abbott Medical*	https://manuals.sjm.com/Search-Form?re=North-America&cc=US&ln=EN&ct=professional&qry=Assurity&ipp=10	Instruction for use describes the optional pre-implant testing and device programming needs. Abbott recommends that device check frequency should be determined by a patient treating clinician according to that patient's needs.
	Edora 8 ProMRI	Biotronik	https://manuals.biotronik.com/emanuals-professionals/?country=AU&productGroup=Pacemaker&product=Pacemaker/Edora/Edora_AU	Following the lead in growth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician using the programmer (in-office follow-up). The next in-office follow-up should be carried out once a year and no later than 12 months after the last in-office follow-up. Home monitoring can replace the in-office check-up under certain circumstances.
	Alizea SR and DR PPMs	MicroPort	https://fccid.io/YSG1311/User-Manual/Manual-20200710-184202-UA10414A-user-4860490	Annual physician check-ups are recommended with check-ups reduced to three months when the programmer is less than or equal to 1 months.
	Manual covers all Boston Scientific PPMs	Boston Scientific	359251-003_Brady_Pacer_PTM_en-AUS_S.pdf (bostonscientific.com)	Device should be followed up one month after discharge and then annually while supplemented by remote monitoring. Check-ups should occur every three months once it enters the final year of function.
ICD	Visia AF MRI™ S VR SureScan™ DVFC3D4	Medtronic	https://manuals.medtronic.com/content/dam/emanuals/crdm/M980312A001A_view.pdf	As 3 months is the recommended follow-up interval published in local and international clinical guidelines, Medtronic products are designed to provide at least 3 months between RRT and EOS.
	Gallant	Abbott Medical*	https://manuals.sjm.com/Search-Form?re=North-America&cc=US&ln=EN&ct=professional&qry=Gallant&ipp=10	Testing at the time of implant and before hospital discharge is described in the instructions for use. Abbott recommends that device check frequency should be determined by a patient treating clinician according to that patient's needs.
	Ilesto 5/7 ProMRI	Biotronik	https://manuals.biotronik.com/emanuals-professionals/?country=AU&productGroup=Icd&product=Icd/Ilesto/Ilesto_add	Following the lead in growth phase, approximately 3 months after implantation, the first follow-up should be carried out by the physician using the programmer (in-office follow-up). The next in-office follow-up should be carried out once a year and no later than 12 months after the last in-office follow-up. Home monitoring can replace the in-office check-up under certain circumstances.
	Platinium DR ICD	MicroPort	https://www.microportmanuals.com/flipbook/PDF-1209861/platinium-dr.html	It is recommended that a routine follow-up examination be done one month after discharge and then every three months until the device nears the replacement date.
	Emblem S-ICD	Boston Scientific	https://www.bostonscientific.com/content/dam/elabeling/crm/92346972-001A_EMBLEM_S-ICD_Programmer_PUM_en_S.pdf	The device has an inbuilt beeper that can be used to monitor function remotely. If the beep is not audible to the patient, then a check-up every three months is recommended.

Device category	Product name	Company	URL	Summary
ILR	REVEAL® DX 9528	Medtronic	https://manuals.medtronic.com/content/dam/emanuals/crdm/WCM_PROD081165.pdf	In line with clinical guidelines, Medtronic recommends that the first patient follow-up session should occur 3 months after implantation. The frequency of subsequent sessions depends on the patient's condition and the number of arrhythmia episodes that occur. If the battery status is "Ageing", Medtronic advises that a patient follow-up session should be scheduled within 3 months.
	Confirm RX	Abbott Medical*	https://manuals.sjm.com/Search-Form?re=North-America&cc=US&ln=EN&ct=professional&qry=Confirm%20RX&ipp=10	The instructions for use states that "*The frequency of patient remote monitoring and follow-up visits depends on the patient's condition and should be determined by the healthcare practitioner".* Abbott recommends that device check frequency should be determined by a patient's treating clinician according to that patient's needs.
	BioMonitor	Biotronik	https://manuals.biotronik.com/emanuals-professionals/?country=AU&productGroup=ImplCardMon&product=ImplCardMon/BioMonitor/BioMonitor	Follow-up is recommended three months after implant and then annually with regular remote monitoring in between.
	LUX-Dx Insertable Cardiac Monitor System	Boston Scientific	https://www.bostonscientific.com/content/dam/bostonscientific/Rhythm%20Management/portfolio-group/lux-dx/ICM-User-Manual-US.pdf	Clinician directed follow-ups with remote monitoring available from once a week to once a year.
CRT	Serena™ CRT-P MRI SureScan™ W1TR05	Medtronic	https://fccid.io/LF5BLEIMPLANT2/User-Manual/User-Manual-3375090.pdf	As 3 months is the recommended follow-up interval published in local and international clinical guidelines, Medtronic products are designed to provide at least 3 months between RRT and EOS.
	Any Abbott Medical CRT device	Abbott Medical*	https://manuals.sjm.com/Search-Form?re=Australia&cc=AU&ln=EN&ct=professional&qry=CRT&ipp=10	It is the physician's discretion to prescribe an in-clinic follow-up session to supplement the data from a remote follow-up session.
	Inventra CRT-D	Biotronik	https://manuals.biotronik.com/emanuals-professionals-rest/manual/Icd/Tach70/Inventra_US/US/en/B?type=manual	Due to longevity concerns, it is recommended the physician schedule a patient follow-up visit every 3 months.
	Plantinium CRT-D	MicroPort	https://www.microportmanuals.com/flipbook/PDF-1209845/platinium-crt-d.html	It is recommended that a routine follow-up examination be done one month after discharge and then every three months until the device nears the replacement date.
	Manual covers various types of Boston Scientific ICDs	Boston Scientific	https://www.bostonscientific.com/content/dam/elabeling/crm/359255-003_Brady_CRT-P_PTM_en-AUS_S.pdf	Device should be followed up one month after discharge and then annually while supplemented by remote monitoring. Check-ups should occur every three months once it enters the final year of function.

Abbreviations: CRT=Cardiac Resynchronisation Therapy; CIED=Cardiac Implantable Electronic Device; EOS=End of Service; ICD=Implantable Cardioverter Defibrillators; ILR=Implantable Loop Recorders; PPM=Pacemaker; RRT=Recommended Replacement Time

* Note: In January 2017 Abbott Medical acquired St Jude Medical (SJM) – hence some websites and products + associated resources retain SJM Branding

pPART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

16. **List all appropriate professional bodies/organisations representing the health professionals who provide the service. For MBS-related applications ONLY, please attach a brief 'Statement of Clinical Relevance' from the most relevant college/society.**

    Attached to this application is a letter of support from 114 cardiac clinicians (roughly estimated at a third of all implanting physicians/electrophysiologists in Australia). This letter includes a consensus statement relating to the clinical relevance and need for cardiac technical support services provided by IEAPs.

17. **List any professional bodies / organisations that may be impacted by this medical service (i.e. those who provide the comparator service):**

    NA. In the absence of cardiac technical support services provided by IEAPs, CIED servicing would not be able to be performed and therefore there is no appropriate comparator for the proposed medical service.

18. **List the consumer organisations relevant to the proposed medical service (noting there is NO NEED to attach a support letter at the 'Application Lodgement' stage of the MSAC process):**

    Hearts4heart

19. **List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed medical service:**

    NA. IEAPs include all industry employed cardiac physiologists, irrespective of the sponsor/manufacturer. This application has been prepared on behalf of CF, who represents all companies with CIEDs on the PL.

20. **Nominate two experts that can be contacted about the proposed medical service, and current clinical management of the condition:**

    Name of expert 1: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

    Name of expert 2: **REDACTED**

    Telephone number(s): **REDACTED**

    Email address: **REDACTED**

    Justification of expertise: **REDACTED**

    Please note that the Department may also consult with other referrers, proceduralists and disease specialists to obtain their insight.

PART 6 – PICO

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

21. Define the medical condition, including providing information on the natural history of the condition and a high-level summary of associated burden of disease (in terms of both morbidity and mortality):

Cardiovascular disease is the leading cause of death worldwide. In 2017, it was found that there were 43,447 deaths (27% of all deaths) in Australia attributable to diseases of the circulatory system and there were more than 1.1 million hospitalisations in 2015-16 (11% of all hospitalisations) due to cardiovascular disease (Australian Bureau of Statistics, 2018).

CIEDs encompass battery powered electronic devices for diagnosis, treatment and monitoring of a range of cardiovascular conditions including bradyarrhythmias, ventricular tachyarrhythmias, atrial fibrillation and advanced systolic heart failure (Steffen et al., 2019).

Bradyarrhythmia (dangerously slow heart rate) is caused by the deterioration of the sinus node or the conduction system. This results in slow or no signals coming from the sinus node (sick sinus syndrome) or prevents signals from the atria reaching the ventricles (heart block) (Kusumoto et al., 2019). Tachyarrhythmia (abnormally fast heart rate) is caused by extra and abnormal electrical impulses that can arise in the atria, ventricles, conduction system, or from abnormal connections between the atria and the ventricles (Stewart et al., 2015). Atrial fibrillation is an irregular and often very rapid heart rhythm (arrhythmia) that can lead to blood clots in the heart associated with increased risk of stroke or systemic embolism and death (Yaghi and Kamel, 2017).

Cardiac arrhythmias that are not transient or reversible require constant clinical monitoring. Diagnosis delays occurring from lapses in providing medical assistance may increase risks of adverse outcomes such as heart failure, stroke or sudden cardiac death among people with certain arrhythmias. This is particularly relevant among high-risk patients, such as those with structural heart disease, in whom early detection of arrhythmia is critically important to enable interventions to decrease risks of adverse outcomes. Hence CIEDs, including PPMs, ICDs and ILR, have become increasingly important devices in the management of cardiac arrhythmias.

PPMs are implantable devices that transmit electrical impulses via a lead to the heart to maintain appropriate heart rate. They are used to treat both bradycardia and tachycardia. The basic architecture of pacemakers includes a pulse generator that houses a microcomputer and a long-lasting battery (Stevenson and Voskoboinik, 2018).

ICDs apply the same basic function and design as pacemakers but are calibrated to respond to only life-threatening deviations from the natural heart rhythm. When the ICD detects a life-threatening tachyarrhythmia, such as ventricular tachycardia or fibrillation, an electrical shock is emitted to arrest the arrhythmia and avoid sudden cardiac death (Stevenson and Voskoboinik, 2018).

CRTs function in a similar manner as a pacemaker but sends small electrical impulses to both lower chambers of the heart to help them beat together in a more synchronised pattern (CRT pacing). There are two types of CRT devices. A CRT-P provides CRT pacing therapy, and a CRT-D provides CRT pacing and includes a built-in ICD. This device is typically indicated as a treatment for patients with moderate-to-severe chronic systolic heart failure and ventricular dyssynchrony (Abraham and Hayes, 2003).

ILRs are subcutaneous, single-lead, electrocardiographic (ECG) monitoring devices used for diagnosis in patients with heart rhythm disorders. The device is typically implanted in the left parasternal region and can store ECG data automatically in response to a significant bradyarrhythmia or tachyarrhythmia event. It is particularly useful either when symptoms are infrequent (and thus not amenable to diagnosis using short-term external ECG recording techniques) or when aggregate long-term data is required (Stevenson and Voskoboinik, 2018).

Clinical trials that have been published in the last 10 years demonstrating the survival benefit of CIED implantation in certain populations with heart disease have contributed to the establishment of numerous clinical guidelines from peak cardiac bodies which support their use (Bardy et al., 2005, Moss et al., 2002, Kirchhof et al., 2016).

22. Specify the characteristics of patients with (or suspected of having) the medical condition, who would be eligible for the proposed medical service/technology (including details on how a patient would be investigated, managed and referred within the Australian health care system, in the lead up to being eligible for the service):

Patients eligible for cardiac technical support services provided by IEAPs include patients implanted with PPMs, ICDs, CRTs and ILRs. Typically, these devices are implanted in patients with bradyarrhythmias, ventricular tachyarrhythmias, and advanced systolic heart failure (Steffen et al., 2019). Although IEAPs provides extensive support in both the public and private healthcare system, the focus of this application is on the private healthcare system where companies supplying CIEDs take on delivery of most cardiac technical support services.

PART 6b – INFORMATION ABOUT THE INTERVENTION

23. Describe the key components and clinical steps involved in delivering the proposed medical service/technology:

To obtain optimal device performance and longevity, CIEDs are serviced on a periodic basis. This regular evaluation is required to assess and optimise CIED performance and safety, identify and correct any device system abnormalities, anticipate the need for elective CIED replacement, monitor cardiac arrhythmias and physiologic parameters, and communicate information related to CIED monitoring to involved physicians and other healthcare providers where appropriate (Wilkoff et al., 2008).

CIED servicing requirements

There are between 1 and 4 scheduled follow-up checks that occur each year for each patient, based on guidelines by the Cardiac Society of Australian and New Zealand (CSANZ)(CSANZ, 2017). This occurs every 3-6 months for both PPMs, ICDs and CRTs, and 6-12 months for ILRs. In addition, there may be unscheduled follow-up checks if the patient develops new symptoms, or an event was detected via remote monitoring. A comprehensive list of all scheduled, unscheduled and remote monitoring services is outlined in Table 4.

The role of supporting staff in the provision of these cardiac services has been previously acknowledged by MSAC in their assessment of remote monitoring of CIEDs where they noted that 'diagnostic testing of the device is likely to be managed by a technician on behalf of the cardiologist' (MSAC, PSD 1197, p2). Similarly, the MBS Review Taskforce Report from the Cardiac Services Clinical Committee noted that "regarding item 11721, the Committee agreed that industry representatives perform many of these tests and then pass the information on to clinicians" (2018 MBS Review Taskforce Report, p226).

IEAPs role in the public healthcare system

In the public healthcare system, cardiac services are performed by the treating physician and supported by hospital-employed cardiac technologists, cardiac physiologists and device nurses. The costs of these services are borne from within the hospital's funding envelope with additional support provided by IEAPs. Public hospital cardiac physiologists provide technical support for all brands of CIEDs and therefore additional specialised support is required from IEAPs for product specific training and assistance with complex servicing tasks (for example, algorithm optimisation can often only be performed by IEAPs due to their product expertise).

IEAPs role in the private healthcare system

In the private healthcare system, most cardiac support services are performed by IEAPs with only a limited number of larger practices employing cardiac physiologists (equivalent to the public sector) who can perform these services. In this setting, IEAPs provide essential equipment required for cardiac servicing, perform the majority of CIED servicing tasks, and collaborate directly with the physician. In larger practices with cardiac physiologists, IEAPs assist with the cardiac physiologists' training and perform CIED servicing tasks with a higher level of complexity that are escalated to them.

IEAP support services are only carried out at the request and under the direction of a qualified physician. Although physician services are subsidised through Medicare for periodic in-office as well as remote examinations of CIED patients, cardiac technical support services provided by IEAPs are unfunded, despite the necessity of the services and the need for a highly trained technician to provide them.

Although IEAPs provide support in both the public and private healthcare system, the focus of this application is on the private healthcare system where companies supplying CIEDs take on delivery of most cardiac technical support services.

In the private healthcare system, IEAPs are involved in a range of servicing tasks for unscheduled and scheduled cardiac servicing (Table 4) including:

- Data retrieval
- Device interrogation
- Interpretation of interrogation results
- Algorithm optimisation
- Device reprogramming /device reprogramming recommendations to HCPs
- Troubleshooting
- Electrical conduction tests
- Ongoing device education and support to patients
- Documentation and communication with relevant HCPs
- Review diagnostics/EGM
- Remotely monitoring patients (see below)

IEAPs role in remote monitoring

Cardiac services monitor cardiac arrhythmias and physiologic parameters, and communicate information related to CIED monitoring to physicians and other healthcare providers where appropriate. CIED checks have historically been performed by the patient attending a dedicated clinic in the physician's room or hospital. Increasingly, CIED interrogation and data retrieval is performed remotely utilising external transmitter devices carried by the patient (commonly an app on a patient's smartphone) or installed in the patient's home. For safety reasons, remote monitoring does not offer the ability to adjust device settings remotely, however, it allows the clinic to detect anomalies earlier and to react accordingly, for instance by calling the patient into the clinic for an in person check and reprogramming. When employed prudently, remote monitoring can avoid unnecessary clinic visits (those carried out on a calendar basis in the absence of any information about the patient's device status and in hindsight turning out to be unnecessary) and allow focus on actionable events.

Remote monitoring is used for both routine checks/scheduled transmissions or unscheduled transmissions e.g., a check after an alert is received. If action is required, the patient would need to come to a clinic for review and possible CIED programming changes. The majority of remote follow-up for CIED patients have IEAP involvement involving considerable administrative burden taken on by industry. Unlike an in person follow-up, in which the administration tasks are largely managed by the clinic, industry data indicates that 2/3 of IEAP time spent on remote monitoring is administration based, including scheduling follow-up checks and pursuing missed transmissions. Only the final 1/3 of the remote monitoring time involves the technical support required to retrieve the data that is transmitted.

Table 4 Key components of the proposed medical service

Service	Description of service	Tasks performed by IEAPs*	Who typically orders the service?**	Setting
Scheduled				
Planned post implant check	Scheduled follow-up at the hospital within 24 hours post implant	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs	Cardiologist	Inpatient private hospital (admitted patient)
Planned follow-up	Scheduled follow-up. First appointment 1-12 weeks post implant. Follow-up schedules are dependent on the type of implanted device and disease state. There are between 1 and 4 scheduled follow-up checks that occur each year for each patient, based on guidelines by the Cardiac Society of Australian and New Zealand (CSANZ)(CSANZ, 2017).	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs	Cardiologist	Private outpatient clinic
Unscheduled				
Ward check	Device interrogation for patients admitted to a hospital ward where cardiac involvement is suspected	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs	Variable depending on the condition of the patient	Inpatient private hospital (admitted patient)
Emergency department check	Device interrogation for patients in the emergency department where cardiac involvement is suspected	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs	ER registrar, ER intern, ER consultant, nurse, cardiologist	Inpatient private hospital (admitted patient)
MRI check	CIED programming to an 'MRI safe' mode prior to the performance of the MRI scan and reprogramming to original settings following the procedure	Data retrieval, device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, review diagnostics/EGM, ongoing device education and support to patients	Radiologist	Private outpatient clinic, Inpatient private hospital (admitted patient)
Radiation oncology check	Device interrogation to detect/mitigate any radiotherapy induced CIED defects	Data retrieval, device interrogation, interpretation of interrogation results, documentation and communication with relevant HCPs	Oncologist	Private outpatient clinic, inpatient private hospital (admitted patient)

Pre-op/theatre check	Reprogramming to avoid the effects of electromagnetic interference	Device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs	Variable depending on the condition of the patient	Inpatient private hospital (admitted patient) and day surgery (day setting)
ICU reprogramming	Device reprogramming (rate adjustment) to maintain cardiac output	Device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs	Critical Care Medicine Specialists	Inpatient private hospital (admitted patient)
EP procedure reprogramming	Reprogramming to avoid the effects of electromagnetic interference and/or optimise procedural outcomes	Device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs	Electrophysiologist	Inpatient private hospital (admitted patient)
Nursing home check	Routine check/reprogramming for immobile patients	Data retrieval, device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs	Geriatrician, Cardiologist	Residential aged care facility
Palliative reprogramming	The CIED may need to be deactivated in patients with imminent death where the resuscitation is unwanted	Device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting. documentation and communication with relevant HCPs	Hospice and Palliative Medicine Specialists	Inpatient private hospital (admitted patient), private outpatient clinic, residential aged care facility, patient's home
Remote monitoring				
Remote monitoring	Routine checks/scheduled transmissions or check after an alert is received and ad-hoc transmissions as requested by the follow-up doctor for clinical investigation (e.g. symptomatic patient)	If action required: Patient needs to come to clinic for review and possible programming changes. Industry data indicates that 2/3 of IEAP time spend remote monitoring is administration based, including scheduling follow-up checks and chasing missed transmissions. The final 1/3 of the remote monitoring time involves the technical support required to retrieve the data that is transmitted.	Cardiologist	Patient's home, Private outpatient clinic, Inpatient private hospital (admitted patient)

Abbreviations: CIED=cardiac implantable electronic device; ER=emergency room; HCP=health care professional; ICU=intensive care unit; IEAP=industry employed allied health professional; MRI=magnetic resonance imaging

* Level of IEAP involvement is dependent on the experience of the physician and the technical difficulty of the case. Some physicians may choose to perform some of these services based on personal preference or the circumstances prompting the CIED check (device checks at locations away from the physicians' rooms are largely performed by IEAPs)

** A range of HCPs can order a cardiac service. The following list indicates the HCP most likely to order the cardiac service. The HCP ordering the cardiac service will either directly call the device company to request cardiac technical support or contact the cardiac advanced trainee on call who will contact the device company

24. Does the proposed medical service include a registered trademark component with characteristics that distinguishes it from other similar health components?

No

25. If the proposed medical service has a prosthesis or device component to it, does it involve a new approach towards managing a particular sub-group of the population with the specific medical condition?

Cardiac technical support services provided by IEAPs are not new within the Australia healthcare setting, with the provision of these services dating back to the establishment of the PL in 2005. Government has recognised that reimbursement for these services have been bundled into the benefit for the device at implant, however an accurate estimation of the cost of these services has not previously been considered.

In the upcoming revisions to the PL, it is proposed that the cost of CIEDs servicing is calculated separately, but paid for through the device on the PL. This approach achieves efficient pricing on the PL without removing the unique characteristics of the private healthcare market.

26. If applicable, are there any limitations on the provision of the proposed medical service delivered to the patient (i.e. accessibility, dosage, quantity, duration or frequency)?

There are between 1 and 4 scheduled follow-up checks that occur each year for each patient, based on guidelines by the CSANZ (CSANZ, 2017). This occurs every 3-6 months for both PPMs, ICDs and CRTs, and 6-12 months for ILRs. In addition to scheduled follow-up checks, unexpected onset of symptoms may prompt unscheduled follow-ups. Similarly, information transmitted via a home monitoring system (remote monitoring) may give cause for a review in an unscheduled follow-up. The aggregated industry data collected over the six-week period in 2019 suggest that there are 0.087 unscheduled checks and 0.77 remote monitoring services required for every scheduled service. As the frequency of unscheduled and remote monitoring services are dependent on the clinical condition of the patient, it would not be appropriate to place an annual restriction on cardiac services.

27. If applicable, identify any healthcare resources or other medical services that would need to be delivered <u>at the same time</u> as the proposed medical service:

IEAP provided cardiac technical support services are performed in collaboration with treating physicians. Treating physicians are ultimately responsible for any patient related clinical decision including programming changes, whilst IEAPs provide essential equipment and are tasked with the majority of physical performance of CIED servicing. Although physicians are subsidised through Medicare for periodic in-office as well as remote examinations of CIED patients (MBS items 11719, 11720, 11721, 11725, 11726, 11727, 38213, 11728, 11731), the support services performed by IEAPs are not, despite the necessity of the services and the need for a highly trained technician to provide them.

Although aggregated industry data collected over a six-week period in 2019 demonstrated the significant service burden for clinically necessary support services provided by IEAPs, additional healthcare resources or other medical services was not captured. Given the clinical necessity of these services, it is proposed that a transitional funding arrangement is established during which the CF will commit to a robust data collection process to accurately measure the number, type, duration, and cost for each service (additional healthcare resources or other medical services delivered at the same time as the proposed medical service). After this transitional period, it is proposed that the value of cardiac technical support services provided by IEAPs is reassessed.

Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of PPI (*6CPA PPI Final MSAC minutes, p4*).

28. If applicable, advise which health professionals will primarily deliver the proposed service:

IEAPs

29. If applicable, advise whether the proposed medical service could be delegated or referred to another professional for delivery:

A limited number of larger private practices employ cardiac physiologists who can perform these services.

30. If applicable, specify any proposed limitations on who might deliver the proposed medical service, or who might provide a referral for it:

IEAPs should provide clinical assistance only at the request of a treating physician. All servicing activities should be overseen by an appropriately trained or experienced physician (defined by CSANZ as a physician adequately trained in the management of patients with CIEDs) who is ultimately responsible for making any decisions related to clinical management of the patient including programming changes (CSANZ, 2017).

31. If applicable, advise what type of training or qualifications would be required to perform the proposed service, as well as any accreditation requirements to support service delivery:

IEAPs are widely considered to be highly trained in the provision of cardiac technical support services, with rigorous company specific training processes for an individual to be considered competent. Although there is no standardised training and accreditation process, IEAPs are all tertiary qualified, and many companies currently use an additional accreditation process provided by International Board of Heart Rhythm Examiners (IBHRE).

Similarly, CSANZ provide guidelines for the training and competency of physicians involved with CIED implantation and follow-up, however, there is no formal/mandatory accreditation process for practitioners claiming MBS rebates for cardiac services.

To increase certainty of the high-quality and standardised level of care that IEAPs are delivering to patients, CF will commit to developing a compulsory industry wide accreditation process for IEAPs. Given the clinical necessity of IEAP provided services, it is proposed that a transitional funding arrangement is established whilst this program is being developed and implemented.

32. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select <u>ALL</u> relevant settings):

Although IEAPs provide support in both systems, the focus of this application is on reimbursement for cardiac technical support services provided by IEAPs in the private healthcare system where companies supplying CIEDs take on delivery of most cardiac technical support services.

☒ Inpatient private hospital (admitted patient)
☐ Inpatient public hospital (admitted patient)
☒ Private outpatient clinic
☐ Public outpatient clinic
☒ Emergency Department
☐ Private consulting rooms - GP
☐ Private consulting rooms – specialist
☐ Private consulting rooms – other health practitioner (nurse or allied health)
☒ Private day surgery clinic (admitted patient)
☐ Private day surgery clinic (non-admitted patient)
☐ Public day surgery clinic (admitted patient)
☐ Public day surgery clinic (non-admitted patient)
☒ Residential aged care facility
☒ Patient's home
☐ Laboratory
☐ Other – please specify below

(b) Where the proposed medical service is provided in more than one setting, please describe the rationale related to each:

Table 5 Rationale for each proposed medical service

Service	Setting	Rationale
Planned post implant check	Inpatient private hospital (admitted patient)	Service occurs at the hospital within 24 hours post implant to ensure appropriate device programming and safe patient outcomes.
Planned follow-up	Private outpatient clinic	To obtain optimal device performance and longevity, CIEDs are checked on a periodic basis. Typically, this service occurs in physicians private rooms. Follow-up schedules are dependent on the type of implanted device and disease state. There are between 1 and 4 scheduled follow-up checks that occur each year for each patient, based on guidelines by the Cardiac Society of Australian and New Zealand (CSANZ)(CSANZ, 2017).
Ward check	Inpatient private hospital (admitted patient)	Device interrogation for patients admitted to a hospital ward where cardiac involvement is suspected. This allows treating physicians to find the source of device malfunction, investigate patient cardiac abnormalities and/or check battery in patients lost to follow-up.
Emergency department check	Inpatient private hospital (admitted patient)	Device interrogation for patients in the emergency department where cardiac involvement is suspected. This allows treating physicians to find the source of device malfunction, investigate patient cardiac abnormalities and/or check battery in patients lost to follow-up.
MRI check	Private outpatient clinic, Inpatient private hospital (admitted patient)	Device reprogramming to an 'MRI safe' mode prior to the performance of the MRI scan in hospital. Program device to MRI conditional mode/settings to avoid patient injury caused by MRI environment. Typically, this service occurs on site and an MRI facility, however, some occur in the hospital setting.
Radiation oncology check	Private outpatient clinic, inpatient private hospital (admitted patient)	Device interrogation to detect permanent damage to a cardiac device and assess for device interference caused by radiation therapy. Typically, this service occurs on site at the Radiation Oncology facility or in the hospital setting.
Pre-op/theatre check	Inpatient private hospital (admitted patient) and day surgery (day setting)	Device reprogramming to reduce/eliminate risk of electromagnetic interference on the patient or the implanted device and associated outcomes (e.g. inappropriate shock, asystole) for patient admitted to hospital or day surgery.
ICU reprogramming	Inpatient private hospital (admitted patient)	Device reprogramming (rate adjustment) to maintain cardiac output for patients admitted to the ICU. These alterations to device function are performed to improve patient outcomes.
EP procedure reprogramming	Inpatient private hospital (admitted patient)	Device reprogramming to reduce/eliminate risk of electromagnetic interference on the patient or the implanted device and associated outcomes (e.g. inappropriate shock, asystole) for patient admitted to hospital.
Nursing home check	Residential aged care facility	Device interrogation/reprogramming for immobile patients.
Palliative reprogramming	Inpatient private hospital (admitted patient), private outpatient clinic, residential aged care facility, patient's home	Device reprogramming (deactivation) in situations where the resuscitation is unwanted.
Remote monitoring	Patient's home, Private outpatient clinic, Inpatient private hospital (admitted patient)	Device interrogation and data retrieval is performed remotely utilising external transmitter devices carried by the patient or installed in the patient's home. If action required, the patient needs to come to clinic for review and possible programming changes. This could occur in the physician's private rooms or in the hospital setting.

Abbreviations: CIED=cardiac implantable electronic device; EP=electrophysiology; ER=emergency room; HCP=health care professional; ICU=intensive care unit; IEAP=industry employed allied health professional; MRI=magnetic resonance imaging

33. Is the proposed medical service intended to be entirely rendered in Australia?

☒ Yes
☐ No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

34. Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service):

IEAP provided cardiac technical support services are performed in collaboration with treating physicians. Treating physicians are ultimately responsible for any patient related clinical decision including programming changes, whilst IEAPs provide essential equipment and are tasked with majority of physical performance of CIED servicing. Although physicians are subsidised through Medicare for periodic in-office as well as remote examinations of CIED patients (MBS items 11719, 11720, 11721, 11725, 11726, 11727, 38213, 11728, 11731), the support services performed by IEAPs are not, despite the necessity of the services and the need for a highly trained technician to provide them.

In the absence of cardiac technical support services provided by IEAPs, CIED servicing would not be able to be performed and therefore there is no appropriate comparator for the proposed medical service.

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35. Does the medical service (that has been nominated as the comparator) have an existing MBS item number(s)?

☐ Yes (please list all relevant MBS item numbers below)
☐ No
NA. There is no appropriate comparator for the proposed medical service.

36. (a) Will the proposed medical service/technology be used in addition to, or instead of, the nominated comparator(s)?

☐ In addition to (i.e. it is an add-on service)
☐ Instead of (i.e. it is a replacement or alternative)
NA. There is no appropriate comparator for the proposed medical service.

(b) If yes, please outline the extent to which the current service/comparator is expected to be substituted

N/A. There is no appropriate comparator for the proposed medical service.

PART 6c CONTINUED – INFORMATION ABOUT ALGORITHMS (CLINICAL MANAGEMENT PATHWAYS)

37. Define and summarise the CURRENT clinical management pathway (algorithm) that patients follow when they receive the COMPARATOR service (i.e. the landscape before the proposed service is introduced). An easy-to-follow flowchart is preferred, depicting the current clinical management pathway), but dot-points would be acceptable. Please include health care resources used in the current landscape (e.g. pharmaceuticals, diagnostics and investigative services, etc.).

Current standard of care for cardiac services within the Australian private healthcare setting involves IEAP technical support. In the absence of cardiac technical support services provided by IEAPs, CIED servicing would not be able to be performed and therefore there is no appropriate comparator for the proposed medical service.

38. Define and summarise the PROPOSED clinical management pathway (algorithm) that patients would follow <u>after</u> the proposed service/technology is introduced, including variation in health care resources.

IEAP provided cardiac technical support services are performed in collaboration with treating physicians. Treating physicians are ultimately responsible for making any related clinical decisions including programming changes, whilst IEAPs provide essential equipment and are tasked with the majority of the physical performance of CIED servicing. A summary of the clinical management of patients eligible for CIED servicing is outlined in Table 6. As current standard of care for cardiac services within the Australian healthcare setting involves IEAP technical support no variation in health care resources is expected.

Table 6 Summary of the current clinical management of patients eligible for CIED servicing

Service	Description of service	Who typically orders the service?*	Setting	Tasks performed by physicians	Tasks performed by IEAPs**
	Scheduled				
Planned post implant check	Scheduled follow-up at the hospital within 24 hours post implant	Cardiologist	Inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs
Planned follow-up	Scheduled follow-up. First appointment 1-12 weeks post implant. Follow-up schedules are dependent on the type of implanted device and disease state. There are between 1 and 4 scheduled follow-up checks that occur each year for each patient, based on guidelines by the CSANZ (CSANZ, 2017)	Cardiologist	Private outpatient clinic	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs.
	Unscheduled				
Ward check	Device interrogation for patients admitted to a hospital ward where cardiac involvement is suspected	Variable depending on the condition of the patient	Inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs, troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs.
Emergency department check	Device interrogation for patients in the emergency department where cardiac involvement is suspected	ER registrar, ER intern, ER consultant, nurse	Inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, algorithm optimisation, device reprogramming /device reprogramming recommendations to HCPs,

					troubleshooting, ongoing device education and support to patients, documentation and communication with relevant HCPs.
MRI check	CIED programming to an 'MRI safe' mode prior to the performance of the MRI scan	Radiologist	Private outpatient clinic, Inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, review diagnostics/EGM, ongoing device education and support to patients.
Radiation oncology check	Device interrogation to detect any radiotherapy induced CIED defects	Oncologist	Private outpatient clinic, inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, documentation and communication with relevant HCPs.
Pre-op/theatre check	Reprogramming to avoid the effects of electromagnetic interference	Variable depending on the condition of the patient	Inpatient private hospital (admitted patient) and day surgery (day setting)	Responsible for any clinical decisions relating to the patient	Device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs.
ICU reprogramming	Device reprogramming (rate adjustment) to maintain cardiac output	Critical Care Medicine Specialists	Inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs.
EP procedure reprogramming	Reprogramming to avoid the effects of electromagnetic interference and/or optimise procedural outcomes	Electrophysiologist	Inpatient private hospital (admitted patient)	Responsible for any clinical decisions relating to the patient	Device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs.
Nursing home check	Routine check/reprogramming for immobile patients	Geriatrician	Residential aged care facility	Responsible for any clinical decisions relating to the patient	Data retrieval, device interrogation, interpretation of interrogation results, device reprogramming /device reprogramming recommendations to

					HCPs, algorithm optimisation, troubleshooting, documentation and communication with relevant HCPs.
Palliative reprogramming	The CIED may need to be deactivated in patients with imminent death where the resuscitation is unwanted (Stevenson and Voskoboinik, 2018)	Hospice and Palliative Medicine Specialists	Inpatient private hospital (admitted patient), private outpatient clinic, residential aged care facility, patient's home	Responsible for any clinical decisions relating to the patient	Device reprogramming /device reprogramming recommendations to HCPs, algorithm optimisation, troubleshooting. documentation and communication with relevant HCPs.
	Remote monitoring				
Remote monitoring	Routine checks/scheduled transmissions or check after an alert is received	Cardiologist	Patient's home, Private outpatient clinic, Inpatient private hospital (admitted patient)	Responsible for managing remote monitoring and any clinical decisions relating to the patient	If action required: Patient needs to come to clinic for review and possible programming changes. Industry data suggests that 2/3 of IEAP time spend remote monitoring is administration based, including scheduling follow-up checks and chasing missed transmissions. The final 1/3 of the remote monitoring time involves the technical support required to retrieve the data that is transmitted.

Abbreviations: CIED=cardiac implantable electronic device; EP=electrophysiology; ER=emergency room; HCP=health care professional; ICU=intensive care unit; IEAP=industry employed allied health professional; MRI=magnetic resonance imaging

* A range of HCPs can order a cardiac service. The following list indicates the HCP most likely to order the cardiac service. The HCP ordering the cardiac service will either directly call the device company to request cardiac technical support or contact the cardiac advanced trainee on call who will contact the device company

** Level of IEAP involvement is dependent on the experience of the physicians and the technical difficulty of the case. Some physicians may choose to perform some of these services based on personal preference or the circumstances prompting the CIED check (device checks at locations away from the physicians' rooms are largely performed by IEAPs)

PART 6d – INFORMATION ABOUT CLINICAL OUTCOMES

39. Summarise the clinical claims for the proposed medical service against the appropriate comparator(s), in terms of consequences for health outcomes (comparative benefits and harms):

Currently, in the private healthcare sector, IEAPs provide essential equipment required for CIED servicing and are tasked with the majority of the physical performance of CIED servicing. Consequently, cardiac services cannot largely be provided in this setting without the support of IEAPs. Therefore, clinical claims for the proposed medical service have been linked to the outcomes of not servicing CIEDs.

This application is claiming superiority (in terms of safety and effectiveness) of performing cardiac services over the comparator, in which cardiac services are unable to be performed. Cardiac services prevent CIED battery depletion and inappropriate CIED therapy along with facilitating the treatment, monitoring and optimisation of therapy in patients with a range of cardiovascular conditions including bradyarrhythmias, ventricular tachyarrhythmias, atrial fibrillation and advanced systolic heart failure.

Avoid battery depletion

International clinical guidelines have endorsed CIED follow-up procedures for monitoring battery status, used to predict end-of-life of the device to permit timely elective replacement (BHRS, 2020). Therefore, a consequence of not servicing cardiac devices is battery depletion which can result in numerous adverse clinical events and, in some cases, sudden death for patients with CIEDs (Tseng et al., 2015, Bhargava et al., 2016, Liu et al., 2020, Sinha et al., 2017, Sinha et al., 2018). Notably, Sinha et al. (2018) surveyed the adverse clinical events of 266 patients with pacemaker battery depletion and showed that 83 patients (31.2%) had symptoms and 28 patients (10.5%) had clinical events associated with heart failure (32%), chest infection (21%), pacemaker syndrome (18%), pre-syncope (14%), and palpitations (11%).

Additionally, clinical guidelines and recent evidence from a randomised controlled trial show that pacemaker reprogramming (which occurs during CIED servicing) preserves battery longevity (Paton et al., 2021, BHRS, 2020). Prolonged longevity of CIEDs not only avoids the adverse clinical repercussions of battery depletion (as discussed above) but also improves patient health outcomes by avoiding/ deferring the risks (and costs) associated with device replacement (Schmier et al., 2017). Key risk associated device replacement include infection (Uslan et al., 2012, Borleffs et al., 2010, Klug et al., 2007), lead failure (Nichols et al., 2016), and increased patient mortality (Sohail et al., 2011, Tarakji et al., 2014).

Avoid inappropriate CIED therapy

Lead fracture and electromagnetic interference are among the most common reasons for inappropriate ICD shocks, both of which can be mitigated by surveillance and device reprogramming during CIED servicing (Koneru et al., 2011). Inappropriate ICD shock therapy can have a number of negative effects including psychological morbidity and reduced quality of life (Schron et al., 2002, Perini et al., 2017) and potentially increased mortality (Daubert et al., 2008).

Additionally, inappropriate ICD shocks may be delivered in palliative care if CIED devices are not deactivated during a service. According to the NSW guidelines for deactivation of implantable cardioverter defibrillators, when an adult patient with an ICD is in the terminal stages of their life, it may no longer be appropriate for the device to remain active and deliver shocks to the heart (Agency of Clinical Innovation, 2014).

CIED therapy

Given that appropriately servicing CIEDs is a product requirement, it is reasonable to assume that in the absence of servicing these devices they will not operate in the manner to which they were assessed and approved by TGA, MSAC and PLAC. Clinical trials that have been published in the last 10 years demonstrating the survival benefit of CIED implantation in certain populations with heart disease have contributed to the establishment of numerous clinical guidelines from peak cardiac bodies which support their use (Bardy et al., 2005, Moss et al., 2002, Kirchhof et al., 2016). Consequently, a lack of CIED therapy would likely lead to an increase in overall patient mortality.

CIED monitoring capabilities

Cardiac services monitor cardiac arrhythmias and physiologic parameters, and communicate information related to CIED monitoring to involved physicians and other healthcare providers where appropriate. Without ongoing monitoring, diagnosis delays occurring from lapses in providing medical assistance may increase risks of adverse outcomes such as heart failure, stroke or sudden cardiac death among people with certain arrhythmias. This is particularly relevant among high-risk patients, such as those with structural heart disease, in whom early detection of arrhythmia is important to enable interventions to decrease risks of adverse outcomes (Slotwiner et al., 2015).

Optimisation of CIED therapy

Clinical studies show that regular assessment and optimisation of CRT and PPM device parameters is an important factor to increase response rates and subsequent improvement in cardiac function (Varma et al., 2018, Daubert et al., 2017, Martinelli et al., 2001). These parameter changes are individualised to each patient and include optimisation of timing cycles and advanced algorithms with a goal of maximally effective contraction. Observational studies have identified suboptimal programming as a determinant factor of a poor response and changes in device settings may be associated with fewer adverse events. (Mullens et al., 2009).

The availability of cardiac services from IEAPs also improves the quality of life for patients. Patients can experience anxiety and worry over the implantation of CIED or potential for malfunction. One of the cardiac services tasks performed by the IEAPs is ongoing device education and support to patients. Provision of cardiac services provides patients with reassurance that their device is being taken care of and providing optimal level of essential therapy.

40. Please state what the overall clinical claim is:

This application is claiming superiority (in terms of safety and effectiveness) of performing cardiac services over the comparator, in which cardiac services are unable to be performed.

41. List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator):

Based on the consequences of not servicing cardiac devices (discussed above) this application is claiming superiority in terms of effectiveness and safety based on superior patient outcomes including

- Increased survival (mortality) – major outcome
- Decreased clinical events (heart failure, stroke, chest infection, pacemaker syndrome, pre-syncope) – minor outcome
- Improved patient reported outcomes (quality of life) – minor outcome
- Reduced adverse events (infection, death) – minor outcome
- Costs associated with device replacement – minor outcome

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

The estimates presented in Part 7 and Part 8 are based on the KPMG CIED service valuation report which was largely informed by industry data collected over a six-week period in 2019 (KPMG, 2021). Although this report demonstrated the frequency and cost of services provided by IEAPs, CF acknowledge that a more comprehensive data collection process will increase the certainty of estimates relating to the frequency and cost of the individual services. Given the clinical necessity of IEAP provided cardiac services, it is proposed that a transitional funding arrangement is established during which CF will commit to a robust data collection process to accurately measure the number, type, duration, and cost for each service. After this transitional period, it is proposed that the value of IEAP provided CIED support servicing is reassessed.

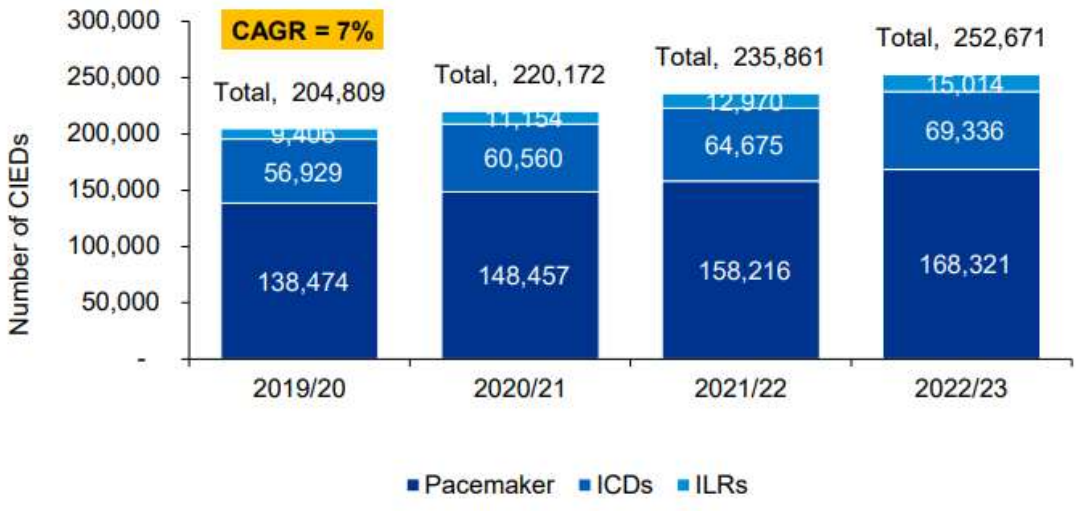
Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of PPI. In the meeting minutes "MSAC suggested that funding for the current PPI programs (SS, DAAs and CIs) could continue while […] protocols for novel ways to enhance services were developed by the pharmacy sector" (*6CPA PPI Final MSAC minutes, p4*).

42. Estimate the prevalence and/or incidence of the condition in the proposed population:

Based the KPMG CIED service valuation report, it was estimated that there are 204,809 CIEDs in use in 2019/20 (KPMG, 2021). This calculation accounts for new insertions of CIEDs, deaths of individuals with CIEDs and removal of CIEDs. This is expected to increase to 252,671 by 2022/23, following an average annual growth rate of 7%. This growth is mainly driven by the increase in the prevalence of ILRs. Figure 1 summarises the estimated prevalence by device type for 2019/20 through to 2022/23.

Details on the assumptions and data sources used to inform these estimates are outlined on p12-18 of the KPMG CIED service valuation report. CRT devices were not captured in this report.

Figure 1 Estimated prevalence of devices implanted in the population, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis
Abbreviations: CAGR=compound annual growth rate; CIED=Cardiac Implantable Electronic Device; ICD=implantable cardiac defibrillators; ILR=implantable loop recorders

43. Estimate the number of times the proposed medical service/technology would be delivered to a patient per year:

Based the KPMG CIED service valuation report (KPMG, 2021), the estimated number of times cardiac support services were being performed by IEAPs were

- On average 2 scheduled services per device year,
- For every scheduled service, each device will require on average, 0.087 unscheduled services and 0.77 remote monitoring services.

This estimate was based on aggregated industry data collected over a six-week period in 2019. It was also estimated that 56% of all services were performed in the private healthcare system, based on a Productivity Commission (2009) report. Further details on the assumptions and data sources used to inform these estimates are outlined on p19-22 of the KPMG CIED service valuation report.

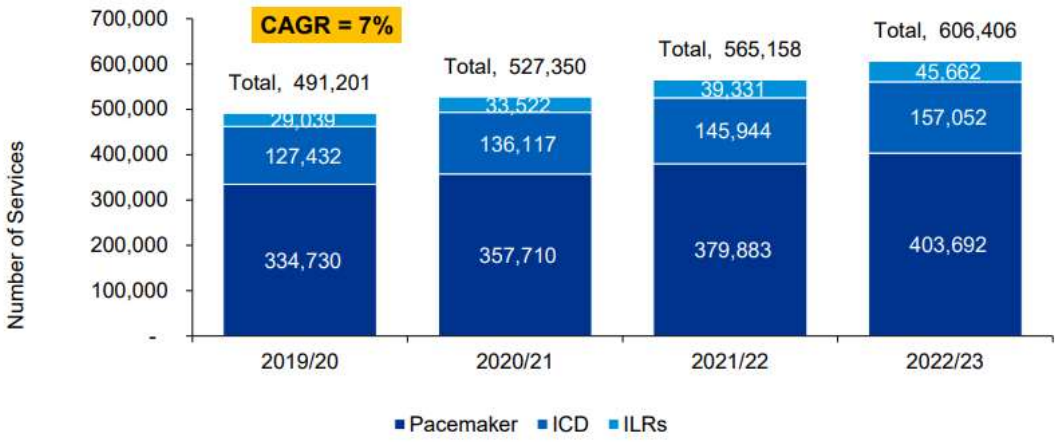
44. How many years would the proposed medical service/technology be required for the patient?

Cardiac technical support services provided by IEAPs are required for the full life of the CIED device or the patient.

45. Estimate the projected number of patients who will utilise the proposed medical service(s) for the first full year:

Based the KPMG CIED service valuation report, the number of scheduled, unscheduled and remote monitoring-based cardiac services provided in a private healthcare system was estimated to be 491,201 in 2019/20 (KPMG, 2021). This number is estimated from a bottom-up approach based on the estimated number of devices in the population and includes the number of insertion support services for 2019. The volume of these services was estimated to grow at the same rate as the number of individuals with CIEDs (7%), estimated at 606,406 by 2022/23 (year 1).

Figure 2 Number of cardiac services provided in a private healthcare system, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis
Abbreviations: CAGR=compound annual growth rate; CIED=Cardiac Implantable Electronic Device; ICD=implantable cardiac defibrillators; ILR=implantable loop recorders

46. Estimate the anticipated uptake of the proposed medical service/technology over the next three years, factoring in any constraints in the health system in meeting the needs of the proposed population (such as supply and demand factors), as well as provide commentary on risk of 'leakage' to populations not targeted by the service.

Using the compound annual growth rate outlined in Figure 2, the estimated number of cardiac support services provided by IEAPs over the next three years are;

- Year 1 (2022/23): 606,406
- Year 2 (2023/24): 648,854
- Year 3 (2024/25): 694,274

PART 8 – COST INFORMATION

47. Indicate the likely cost of providing the proposed medical service. Where possible, please provide overall cost and breakdown:

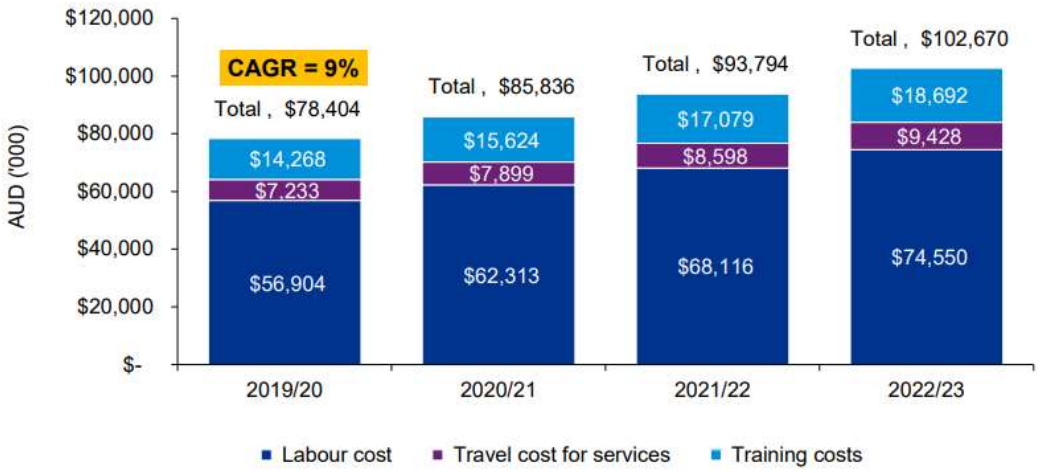
Based the KPMG CIED service valuation report (KPMG, 2021), there are three main components that make up the resource requirements to provide cardiac technical support services;

- Labour cost: $56.9m in 2019/20, $74.5m by 2022/23
- Travel cost: $7.2m in 2019/20, $9.4m by 2022/23
- Training cost: $14.3m in 2019/20, $18.7m in 2022/23

The assumptions underpinning each of these costs are outlined in Appendix A of the KPMG CIED service valuation report (KPMG, 2021).

The cost of cardiac technical support services in 2019/20 is estimated to be over $78 million, increasing at an average growth rate of 9% annually, to reach about $103 million by 2022/23. Figure 3 presents a breakdown of the components that make up the total cost of services. CRT devices were not captured in this report.

Figure 3 Total cost of services provided by companies supplying CIEDs, 2019/20 – 2022/23



Source: KPMG estimates
Note: all values are reported on a financial year basis
Abbreviations: CAGR=compound annual growth rate; CIED=Cardiac Implantable Electronic Device; ICD=implantable cardiac defibrillators; ILR=implantable loop recorders

Using the compound annual growth rate outlined in Figure 3, the estimated cost of cardiac support services provided by IEAPs over the next three years are;

- Year 1 (2022/23): $102,670 million
- Year 2 (2023/24): $111,910 million
- Year 3 (2024/25): $121,982 million

48. Specify how long the proposed medical service/technology typically takes to perform:

Table 7 outlines the estimated time required for each service based the KPMG CIED service valuation report (KPMG, 2021). In addition to the time taken to perform each service, there is also a significant travel time for IEAPs. This was estimated to be 0.5 hour for metro trips, 0.75 hours for regional trips and 1-hour remote trips, according to the NDIS Price Guide 2020-2116.

Table 7 Time required for each service in hours

Service	Time (hours)
Scheduled services	
Planned post implant check	1.00
Planned follow-up	0.50
Unscheduled check	
Ward check	1.00
Emergency department check	1.00
MRI check	2.00
Radiation oncology check	2.00
Pre-op/theatre check	2.00
ICU reprogramming	1.50
EP procedure reprogramming	3.00
Nursing home check	1.00
Palliative reprogramming	1.00
Remote monitoring	
Remote monitoring	0.25

49. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and usage characteristics that defines eligibility for the medical service/technology.

N/A. This application is the continuation of an ongoing reform process to ensure long-term efficient pricing of medical devices. As requested by the Department of Health, this application will present potential funding mechanisms for cardiac support services provided by IEAPs (discussed below).

50. If public funding is sought through an alternative (non-MBS) funding arrangement, please draft a service description to define the population and usage characteristics that defines eligibility for the service/technology.

An outline of potential funding mechanisms has been presented in Table 1. Although all funding mechanisms have limitations, modifying the revised Prostheses List approach is the most appropriate method to achieve efficient pricing on the PL without removing the unique characteristics of the private market. This approach would require an accurate estimation of the cost of CIEDs calculated separately, but paid for through the device on the PL.

Given the clinical necessity of cardiac technical support services provided by IEAPs, it is proposed that a transitional funding arrangement is established during which CF will commit to;

- ***Develop and transition to a compulsory industry wide accreditation process for IEAPs.***
- ***Further data collection to accurately measure the number, type and duration of cardiac technical support services provided.***
- ***Further data collection relating to clinical benefit of cardiac services.***

Following a transitional period of 3 years, CF will commit to reassessment by the Department of Health where data from above list will be provided and a longer-term funding mechanism can be proposed and decided.

Transitional funding with commitment to further data collection has previously been recommended for services which are standard of care by MSAC in its evaluation of PPI. In the meeting minutes "MSAC suggested that funding for the current PPI programs (SS, DAAs and CIs) could continue while […] protocols for novel ways to enhance services were developed by the pharmacy sector" (*6CPA PPI Final MSAC minutes, p4*).

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