Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1724 – Cardiac technical support services provided by industry employed technicians

Applicant:	**Medical Technology Association of Australia (MTAA) Cardiac Forum (MTAA CF)**
Date of MSAC consideration:	**27 July 2023** **30-31 March 2023**

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, visit the MSAC website

1. Purpose of application

An application relating to the cost of cardiac technical support services provided by industry employed cardiac technicians (IECTs) was received by the Department of Health and Aged Care from the Medical Technology Association of Australia Cardiac Forum (MTAA CF). MTAA CF members include the medical device companies Medtronic, Abbott, Biotronik, MicroPort CRM and Boston Scientific. They supply cardiac implantable electronic devices (CIEDs) in Australia and also provide cardiac technical support services via IECTs. CIEDs refer to, permanent pacemakers (PPMs), implanted cardioverter defibrillators (ICDs), implantable loop recorders (ILRs) and cardiac resynchronisation therapy devices (CRTs). The purpose of this application was to determine the reasonable cost of providing follow-up cardiac technical support services for CIEDs.

This application was submitted in the context of the Prostheses List (PL; now known as the Prescribed List of Medical Devices and Human Tissue Products) reforms. The reforms aim to reduce the cost of medical devices used in the private health sector and streamline access to new medical devices. These aims will be achieved through a number of measures including reducing the gap between the prices paid for the same medical devices in the public hospital system and the benefits paid in the private sector through the PL. These measures will be implemented through a series of staged benefit reductions occurring over a four-year period, which commenced in 2022. The MTAA CF companies have contended that reductions to the PL benefits for CIEDs would reduce their ability to continue providing follow-up cardiac technical support services through their IECTs, given the PL benefit is currently used to cover the costs associated with the provision of follow-up services as well as the cost of the device.

This application follows the 14 March 2022 Memorandum of Understanding between the then Minister for Health and Aged Care and the MTAA ("the MoU"). In line with the MoU, the Department deferred applying the PL benefit reductions to CIEDs for 12 months pending the outcome of the current MSAC application, with the view that the amount determined to be the reasonable cost of providing cardiac technical support services will not be subject to the scheduled PL benefit reductions applied to the CIEDs.

2. MSAC's advice to the Minister – July 2023

MSAC considered the focussed evaluation of the updated cost estimates it requested at its meeting in March 2023. MSAC recalled the original ADAR estimated that the total cost of follow-up cardiac technical support services provided by IECTs to be $73.3 million in 2022 and this increased substantially to $91.3 million (revised to $87 million by the applicant after correcting for errors associated with certification costs of technicians) in the updated cost estimates provided by the applicant in February 2023. MSAC recalled that the updated cost estimates were derived from an additional 4-weeks of data collection, provided by the applicant in its February 2023 pre-ESC response (i.e., a total of 8 weeks of data collection).

MSAC noted that the overall number of services provided in the updated data increased only slightly and the substantial increase in estimated costs was associated with an increase in the calculation of overhead costs reported by the MTAA CF members. The MSAC considered the updated overhead costs were overestimated and advised overhead costs should be adjusted to reflect 30% of the reasonable estimate of direct costs, as initially proposed in the ADAR. MSAC also reaffirmed its March 2023 advice that the cost of follow-up services presented in the application were overestimated and considered the average hourly wage of IECTs and IECT onboarding costs should be adjusted in line with this earlier advice.

Based on the data provided by the applicant, the MSAC noted that in addition to the cost of the CIEDs, the current PL benefits for these devices include the following costs:

- Peri-implantation services provided by IECTs;
- Follow-up services provided by IECTs to public patients; and
- Follow-up services provided by IECTs to privately insured patients.

The MSAC considered that a PL benefit for a CIED should be limited to the cost of the principal CIED, and associated peri-implantation costs as these are integral to the functioning of the CIED (and that these components should therefore be subject to the staged PL benefit reductions).

MSAC recalled the cost of follow-up cardiac technical support services provided by IECTs would not be subject to the current staged PL benefit reductions. MSAC considered that ultimately the cost of follow-up cardiac technical support services provided to public or privately insured patients should not be funded via PL benefits for CIEDs. However, in order not to compromise the current care of patients with CIEDs or inadvertently increase any out-of-pocket costs associated with the receipt of these services, the MSAC advised that the costs for these follow-up services be excluded from the current staged PL benefit reductions. MSAC reiterated its earlier advice that further consideration needs to be given to identifying alternative, evidence-based models of care for all patients with CIEDs, how these services are most appropriately funded, and how the funding of these services are transitioned out of the PL benefit amount.

The MSAC advised that the principles articulated above should be used to negotiate appropriate benefit reductions for CIEDs with the MTAA CF member companies.

Consumer summary

The Department of Health and Aged Care (the Department) received an application from the Medical Technology Association of Australia Cardiac Forum (MTAA CF) as part of the ongoing Prostheses List (PL) reform process. The Prostheses List (now known as the Prescribed List of Medical Devices and Human Tissue Products) sets out which prostheses (typically medical devices) and the amount (benefit) that private health insurers must pay for these, for privately insured patients with the appropriate insurance cover. These minimum benefit amounts for many devices are much more expensive than the cost of these devices paid by public hospitals. Private health insurers say these higher device prices lead to higher private health insurance premiums. The Prostheses List reform process is reducing the amount (benefit) that must be paid by private health insurers for a medical device so that it is closer to prices paid by public hospitals. In the 2020-21 financial year, health insurers paid over $199 million in benefits for a group of devices called Cardiac Implantable Electronic Devices (CIEDs). If private health insurers were able to pay the lower prices generally paid by public hospitals (called the weighted average public sector price) for these devices, they would have only paid $80.5 million.

In this application, the Department requested advice from MSAC on the reasonable cost of cardiac technical support services provided by industry-employed cardiac technicians. Medical device companies advise they use the higher prices (Prostheses List benefits) to employ cardiac technicians who make sure CIEDs are working properly and review alerts sent by these devices.

CIEDs are battery-powered electronic devices implanted in the body to manage heart conditions. CIEDs include devices such as:

- pacemakers (to help the heart beat in a regular rhythm)
- implantable cardioverter-defibrillators (to detect and stop irregular heartbeats)
- implantable loop recorders (to record heartbeat and help detect irregular heartbeats)
- cardiac resynchronisation therapy devices (to help the heart pump more efficiently by correcting heartbeats so that both the left and right side of the heart beats at the same time)

To ensure CIEDs work optimally and for as long as possible, they need to be checked regularly by technicians (1–4 times a year) as well as when the person with a CIED has medical issues including possible heart problems. Cardiac technicians may check whether the CIED is working as intended. To do this a cardiac technician may review data recorded by the device, check alerts, check device components (such as batteries and leads), review device settings, adjust how the device works (change device programming) and provide information to the cardiologist. The cardiac technician may be able to check the CIED remotely if the device is transmitting its data. This is called remote monitoring.

Cardiac technicians may work without direct supervision by the cardiologist. In many cases the cardiac technician may be the only point of clinical contact for routine device follow-up. However, the cardiologist is responsible for the decisions of the cardiac technician.

Some technicians are employed by the device companies that sell the CIEDs. In public hospitals, these services are generally provided by technicians employed by the hospital. Cardiac technicians are not formally recognised as health professionals. There are no specific qualifications that are universally required to work as a cardiac technician or specific requirements for ongoing professional development. Therefore, cardiac technicians may have different levels of training, certifications and qualifications. Cardiac technicians are not formally recognised or regulated as health professionals. MSAC considered that it was important that people with CIEDs are informed about the role of their cardiologist and cardiac technician.

Consumer summary

MSAC considered this application at its March 2023 and July 2023 meetings. This was so MSAC could consider additional data that was provided by the applicant too late in the process for consideration at its March 2023 meeting. MSAC provided advice on how to calculate the reasonable cost of cardiac technical support services. Although the PL benefit sets out the amount private health insurers must pay for privately insured patients with the appropriate insurance cover, MSAC advised that it might be reasonable to include the cost of some services provided to public hospitals patients until reforms change how these services are funded.

MSAC considered that funding these services through the PL was not ideal because the PL is designed to pay for devices, not ongoing services for devices. MSAC considered that these services were expensive and inefficient as technicians often travel to attend one patient (instead of a group of patients). MSAC advised that relying on medical device companies to employ cardiac technicians to provide cardiac technical support services to patients was problematic. MSAC considered the funding of these services through the PL results in a lack of transparency in how these services are provided and funded.

MSAC agreed there is an opportunity to reform the way these services are provided, to optimise patient outcomes, efficiency, transparency and value for money. New technologies are developing, which include the ability to monitor and program these devices remotely. MSAC considered that the collection, sharing (use and transmission), and storage of data from CIEDs are important issues for consumers, the public and the Australian health system and should be considered in future reforms. MSAC advised that reforms should include input from people with CIEDs to ensure cardiac technical support services meet their needs and expectations.

MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC provided advice on how to calculate the reasonable cost of cardiac technical support services. MSAC advised that it might be reasonable to include some services provided to public hospitals patients until reforms change how these services are funded. MSAC advised that the current model of care for provision of CIED follow-up services that relies on industry is problematic and that cross-subsidising follow-up services through the Prostheses List benefit has resulted in an opaque mechanism of funding for these services. MSAC advised that further reform should be undertaken to encourage uptake of other ways to provide this care. This may include private cardiologists who employ cardiac technicians directly to provide these services. MSAC advised that this would have to be addressed through longer-term reform.

Summary of consideration and rationale for MSAC's advice – July 2023

The MSAC considered the focussed evaluation of the updated cost estimates provided by the applicant in its February 2023 pre-ESC response. MSAC recalled the updated cost estimates were not independently evaluated prior to its March 2023 consideration of the application due to the late submission of this data by the applicant, outside of the standard MSAC evaluation timeframes. MSAC noted that the original ADAR estimated that the total cost of follow-up cardiac technical support services provided by IECTs to be $73.3 million in Year 1 and this increased to $91.3 million in Year 1 in the updated cost estimates provided by the applicant in February 2023. MSAC recalled that given the magnitude of difference between these two estimates, it requested that the updated *Utilisation and Cost model Workbook* provided by the applicant be independently evaluated and the base case respecified to enable MSAC to advise on a more reliable estimate of the reasonable cost of follow-up services provided by IECTs.

MSAC noted that the updated cost estimates were based on an additional 4 weeks of data collection conducted by the applicant, in addition to the initial 4 weeks of data collection submitted in the ADAR (i.e. a total of 8 weeks of data collection). As well as updating the number and types of services conducted in the additional 4 -week period, the updated cost estimates included revised estimates of overhead costs. MSAC noted that the ADAR (based on the original 4 weeks of data collection) estimated the cost of providing cardiac technical support services in 2022 was $73.3 million (including $16.9 million in overhead costs). The updated cost estimates submitted in February 2023 (based on a total of 8 weeks of data collection), revised this estimated cost to $91.3 million in 2022 (including $31.6 million in overhead costs). In its July 2023 pre-MSAC response, the applicant further revised this estimated cost to $87 million in 2022, after correcting for errors associated with the application of certification costs of technicians, and some overhead costs incorrectly reported by its members. Table MA. 1 summarises the changes the applicant made to the cost estimates over the lifespan of the MSAC application. MSAC recalled that the February 2021 MTAA-commissioned KPMG report on Cardiac Implantable Electronic Device (CIED) service valuation[1] estimated the median cost of follow-up cardiac technical support services provided by IECTs to be $103 million for the 2023-23 financial year (ranging from $85.9 to 125 million).

Table MA. 1 Updated costing estimates with correction to certification rates (July 2023 pre-MSAC response)

Data	2022	2023	2024	2025	Percentage change from ADAR
ADAR base case (considered at March 2023 MSAC) – Round 1 service volumes (4 weeks data) [a] and overhead costs estimated as 30% of direct costs					
Total services	697,258	746,066	798,290	854,170	NA
Total costs	$73,275,912	$79,855,322	$86,933,257	$94,550,963	NA
Round 1 + Round 2 service volumes (8 weeks data) [a] and updated overhead costs [b]					
Total services	761,281	814,571	871,591	932,602	9.2%
Total costs	$91,269,603	$98,579,816	$106,383,556	$114,720,227	24.6%
Round 1 + Round 2 service volumes (8 weeks data) [a] and updated overhead costs corrected (updated base case) [c]					
Updated overhead costs	$31,017,034	$33,802,039	$36,798,066	$40,022,572	NA
Total costs	$90,637,882	$97,891,373	$105,634,093	$113,905,091	23.7%
Updated base case + Only apply certification to 10% per annum (S4)					
Total costs	$87,043,743	$94,077,992	$101,601,470	$109,653,225	18.8%

Source: Applicant's July 2023 Pre-MSAC response
MA= MSAC Advice
[a] Round 1 data collection included 4 weeks data on cardiac technical support services provided from Monday 15 August 2022 and ended on Sunday 11 September 2022.A further 4 weeks data was collected Monday 21 November 2022 to 18 December 2022 (Round 2) and presented in subsequent estimates.
[b] Updated estimates of actual overhead costs provided by the Cardiac Forum member companies.
[c] Correction of an error in the overhead costs.

MSAC noted that the overall estimate of the number of services provided in the updated data increased only slightly and the substantial increase in estimated costs was associated with a substantial increase in overhead costs reported. The additional 4-week data collection (8 weeks in total) increased the total number of services provided by 9.2% compared with the ADAR. This increased the direct costs of providing technical support services from $56.4 million to $59.6 million, however the updated sum of overhead costs provided by the member companies in February 2023 was $32 million in 2022, compared with the previous estimate submitted in the ADAR of less than $17 million. This substantial increase in the overhead costs resulted in the

[1] KPMG report on Cardiac Implantable Electronic Device (CIED) service valuation. Available from: https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/mtaa-submission_pl_reform.pdf

total estimated cost of follow-up cardiac support services provided by IECTs increasing from $73.3 million to $87 million.

MSAC noted that the applicant in its July 2023 pre-MSAC response explained that while the ADAR estimated a nominal overhead cost as being 30% of direct costs, the updated overhead costs provided in February 2023 were calculated by each of the five member companies of the MTAA CF using a generalised list of costing categories to determine actual overhead costs for their business to provide cardiac technical support services. MSAC considered the updated estimate of overhead costs was uncertain and could not be validated. MSAC agreed with the focussed evaluation that the overhead costs may include costs that were not relevant to the provision of technical support services. MSAC queried the appropriateness of including consumables not funded by PL benefits in the overhead costs as PL reforms have aimed to remove general use and consumable items. MSAC noted the applicant's July 2023 pre-MSAC response that the interpretation of what was relevant in each category was left to each of the five MTAA CF companies to independently decide, contributing to the substantial variation in the distribution of costs across the categories. MSAC considered this variability in interpretation and lack of transparency regarding the costs included in each category resulted in the estimation of the overhead costs being unreliable. MSAC also considered the fact that the number of IECTs was not linked to the number or mix of services provided lacked face validity. MSAC agreed with the applicant's July 2023 pre-MSAC response that it is the larger companies who provide the majority of the cardiac services and hence realise economies of scale with this service provision, and that while the direct costs are entirely influenced by the number of services provided, at a unit level, the overhead costs are higher for the smaller companies to resource themselves to provide these services. MSAC considered that it was not reasonable to remove the overhead costs from the two most costly companies as suggested by the focused evaluation, as a means of determining a more reasonable estimate of overhead costs.

MSAC noted the updated overhead costs were approximately 50% of the direct costs and considered they were overestimated. MSAC advised that it would be reasonable to calculate the overhead costs of providing technical support services for CIEDs as 30% of the reasonable estimate of direct costs, as initially proposed in the ADAR. MSAC considered that this would be more consistent with the average value of overhead costs calculated from the last 5 rounds of the National Hospital Cost Data Collection Public Hospitals Report. MSAC advised that the *Utilisation and Cost model Workbook* submitted by the applicant does not appropriately calculate the overhead costs as being 30% of the direct costs and that this requires adjustment.

MSAC advised that the reasonable cost of technical support services for CIEDs should be based on the updated service volumes derived from the 8 weeks of data collection used in the updated cost estimates. In addition to adjusting overhead costs to be 30% of the reasonable cost of direct costs, MSAC reaffirmed that the reasonable cost of technical support services for CIEDs should be calculated based on its March 2023 advice with respect to:

- Reducing the average hourly wage of IECTs to $50 per hour, based on the average salary of $95,000 for a cardiac technician [2]; and
- Reducing onboarding costs to $30,000 per employee.

MSAC noted the applicant's pre-MSAC response which did not agree these changes were reasonable and claimed that industry would not be able to support the current level of cardiac services if funding is reduced from current levels. MSAC noted that the July 2023 pre-MSAC response considered using a wage rate of $50 per hour to be inadequate as IECTs are more highly skilled than public hospital technicians and considered $85 per hour better reflected the

[2] The effective hourly rate equated to $77.50, $96.88, and $108.50 per hour for metropolitan, regional, and remote areas respectively after applying on-demand, rural and remote loadings.

private healthcare sector. MSAC considered $50 per hour remained an appropriate average hourly rate, reflecting the lower wages paid to inexperienced technicians requiring supervision and the higher wages paid to experienced technicians. MSAC reaffirmed its advice that onboarding costs for new IECTs should be $30,000 reflecting 6 months' salary of a junior technician of $60,000 per year. MSAC noted that the July 2023 pre-MSAC response stated that it can take up to 2 years to become an expert across a range of device types for treatment cardiac arrythmias. However, MSAC considered that onboarding costs of over $200,000 were unreasonably high.

MSAC reaffirmed that cardiac technical support services are a necessary and clinically important service for people with CIEDs. MSAC reaffirmed its previous advice that the current model for providing ongoing cardiac technical support services was problematic and was not consistent with clinical guidelines. MSAC advised that further reform should be undertaken to encourage uptake of other models of care, such as the provision of services by private cardiologists who employ cardiac technicians. MSAC noted that in the July 2023 pre-MSAC response, the applicant posited that a fourth model of care exists in Australia, involving independent cardiac technicians providing services to hospitals and cardiology practices with hourly rates starting at $175 per hour. The applicant claimed that in comparison to the fourth model of care, the current model of service provision through IECTs provides excellent value for money. However, MSAC considered the corrected estimates provided by the applicant with higher overhead costs (i.e. $87M) resulted in similar effective hourly rates of approximately $175 per hour for IECTs.[3] (assuming all IECTs work full-time (with 7 billable hours per day) and take a total of 5 weeks of annual leave and public holidays per year).

Based on the service data provided by the applicant, MSAC noted that in addition to the cost of the CIEDs, the current PL benefits for these devices include the following costs:

- Peri-implantation services provided by IECTs;
- Follow-up services provided by IECTs to public patients; and
- Follow-up services provided by IECTs to privately insured patients.

MSAC considered that a PL benefit for a CIED should be limited to the cost of the principal CIED, and associated peri-implantation costs as these are integral to the functioning of the CIED (and that these components should therefore be subject to the staged PL benefit reductions).

MSAC recalled the cost of follow-up cardiac technical support services provided by IECTs would not be subject to the current staged PL benefit reductions. MSAC considered that ultimately the cost of follow-up cardiac technical support services provided to public or privately insured patients should not be funded via PL benefits for CIEDs. MSAC noted the applicant's July 2023 pre-MSAC response which stated that "it is unreasonable to exclude services provided in the public without an alternative funding mechanism to support these services". However, in order not to compromise the current care of patients with CIEDs or inadvertently increase any out-of-pocket costs associated with the receipt of these services, the MSAC advised that the costs for these follow-up services be excluded from the current staged PL benefit reductions. MSAC reiterated its earlier advice that further consideration needs to be given to identifying alternative, evidence-based models of care for all patients with CIEDs, how these services are most appropriately funded, and how the funding of these services are transitioned out of the PL benefit amount.

The MSAC advised that the principles articulated above should be used to negotiate appropriate benefit reductions for CIEDs with the MTAA CF member companies.

[3] $87,043,743/301 full time equivalent IECTs each working 1,645 hours per year

3. MSAC's advice to the Minister – March 2023

MSAC noted that the Department of Health and Aged Care (the Department) received an application from the Medical Technology Association of Australia Cardiac Forum (MTAA CF) as part of the ongoing PL reform process. MSAC noted the purpose of the application was to determine the reasonable cost of the cardiac technical services provided by industry-employed cardiac technicians. The applicant considers that these services are currently cross-subsidised via the higher PL benefits paid for CIEDs by private health insurers, compared to the prices paid for the same devices in the public sector.

MSAC considered that the current model of care for provision of CIED follow-up services that relies on industry is problematic and that cross-subsidising follow-up services through PL benefits has resulted in an opaque mechanism of funding for these services. MSAC advised that further reform should be undertaken to encourage uptake of alternative models of care, such as the provision of services by private cardiologists who employ cardiac technicians, but noted this would have to be addressed through longer-term reform.

MSAC considered that the estimates for the cost of follow-up services provided by the applicant were likely overestimated and were based on an inefficient model of service provision. MSAC noted the applicant did not provide the type or level of data that was requested of them throughout the MSAC process. MSAC noted the applicant instead presented an aggregate cost of providing cardiac technical support services across all device types, which did not allow the cost of follow-up services per device or per patient to be calculated.

MSAC noted that the costs provided by the applicant included the costs associated with providing cardiac technical services to the public sector as well and implantation-related services. MSAC considered it was inappropriate to include the costs associated with providing cardiac technical support services to the public sector in the calculation of the cost of follow-up services paid for by private health insurers through the PL benefit for privately insured patients. MSAC also considered that implantation-related services should not be categorised as follow-up services and should be removed from the calculation of the reasonable cost of cardiac technical services provided by industry-employed cardiac technicians. MSAC considered the costs associated with implantation-related services, including day-1 checks, should already be included in the cost of the device itself, consistent with other PL listed devices. MSAC also considered inputs to the cost of providing follow-up services, such as the average hourly wage of cardiac technicians and onboarding costs were likely overestimated.

MSAC noted that the applicant's pre-MSAC response stated that pacemaker leads were erroneously omitted from the list of CIEDs presented in their application that require ongoing monitoring during patient follow-up. MSAC considered the cost of follow--up services should only be attributed to the principal CIEDs. The reason for this is that the servicing requirement is generally attributable to the use of the principal CIED rather than the ancillary products.

MSAC noted that the applicant initially estimated the cost of follow-up services to be $73.3 million per year, which was subsequently increased to $91.3 million in its pre-ESC response. MSAC requested independent evaluation of the updated cost estimates provided in the pre-ESC response. MSAC considered that this would enable it to advise on a more reliable estimate of the reasonable aggregate cost of follow up cardiac technical support services. MSAC considered this additional analysis could be expedited. MSAC considered the updated estimate of the cost of follow-up services could be considered out-of-session, or by the MSAC Executive.

Summary of consideration and rationale for MSAC's advice – March 2023

The MSAC noted the purpose of the application was for MSAC to provide its advice on the reasonable cost of follow-up cardiac technical support services for CIEDs provided by the IECTs. MSAC noted this amount would not be subject to the staged PL benefit reductions.

MSAC noted that the need to determine funding approaches for CIED technical support services have been discussed by government and medical technology sector since 2017.[4] In the 2021–22 Federal Budget, the Australian Government committed to reduce the cost of medical devices used in the private health sector and streamline access to new medical devices, to improve the affordability and value of private health insurance for Australians. MSAC noted that one of the aims of the PL reforms is to reduce the gap between PL benefits (in the private sector) and the prices paid for prostheses in the public hospital system (referred to as weighted average price [WAP]). MSAC noted that items on the PL will have their benefit levels reference priced by establishing the gap between PL benefits and the prices paid in public hospital system.

MSAC noted that the Department deferred the scheduled 1 July 2022 PL benefit reductions for CIEDs for 12 months in line with the March 2022 Memorandum of Understanding (MoU) between the Minister for Health and Aged Care and the MTAA. This was to ensure continued access for patients to CIEDs and to allow for MSAC deliberations on the value of the technical support services. As part of the MoU, the MTAA agreed to take all reasonable steps to ensure that cardiac companies that produce CIEDs commit to engage with MSAC and provide MSAC with company data relevant to the MSAC process. On 1 July 2023, PL benefits for CIEDs were reduced based on the assumption that the cost of the device has been estimated at approximately 54% of the current CIED PL benefit. Any additional reductions based on MSAC's advice will be applied to the CIED benefit reductions scheduled for 1 July 2024.

MSAC noted technical support services provided to people with CIEDs by IECTs are currently cross subsidised through higher benefit amounts paid by private health insurers for CIEDs listed on the PL. MSAC noted the cost of providing these support services have been claimed by CIED manufacturers to justify the large discrepancy between the PL benefit amount paid for these devices on the PL and the equivalent public sector reference prices. The applicant claims the higher PL benefits amounts are used to fund services for patients whose CIEDs are implanted in both the private and public health services.

MSAC noted that the amount determined to be the reasonable cost of cardiac technical support services will not be subject to the scheduled reductions to the PL benefits which will be applied to the CIEDs. MSAC noted that the intent of the PL is to fund implantable products rather than services and that cross-subsidising the cost of follow-up services through the PL benefit has resulted in a non-transparent mechanism of funding for these services.

MSAC noted that it was estimated that 220,172 Australians were living with a CIED in 2021. MSAC noted that the rates of new CIED implantations per population was increasing.

MSAC considered that cardiac technical support services provided under the supervision of a cardiologist were needed for the safe and effective use of CIEDs. MSAC noted that following CIED implantation, a Day-1 check is performed in-person or remotely. Thereafter, MSAC noted that patients with CIEDs require scheduled and unscheduled cardiac technical support services. MSAC noted that the frequency of scheduled services will vary depending on the CIED, the

[4] Agreement between the Government and the Medical Technology Association of Australia (October 2017). Available from: https://www.health.gov.au/resources/publications/agreement-between-the-government-and-the-medical-technology-association-of-australia

system and clinical alerts from the CIED, and clinical need. MSAC noted that PPMs are reviewed approximately every 12 months whereas ICDs and CRTDs need to be reviewed more frequently. MSAC noted ILRs are reviewed as clinically indicated. In addition, MSAC noted that patients also have clinical cardiology reviews of their condition as indicated.

MSAC recalled that it had previously considered MSAC applications for CIED follow-up (including remote monitoring). This included MSAC Application 1197 and 1197.1 for Remote Monitoring of Patients with Implanted Cardiac Devices and MSAC Application 1443 for ILRs for diagnosis of atrial fibrillation in cryptogenic stroke.

MSAC noted that the applicant had used the term "industry employed allied health professionals" in its application. MSAC considered that while technicians are trained and competent, they are not formally recognised as allied health professionals and the term "industry employed cardiac technicians" (IECTs) is more appropriate. MSAC considered that although IECTs provide a clinically important, quality service, the current model of providing these services through technicians employed by device suppliers is not ideal.

MSAC noted that there are several models for the provision of cardiac technical support services for CIEDs:

- Model 1: Services provided through public hospitals and outreach services that employ cardiac technicians
- Model 2: Services provided through private cardiologists who employ in-house cardiac technicians
- Model 3: Services provided through private cardiologists with only IECT provided technical support

MSAC noted that limited information was provided in relation to the different models of care for providing technical support services for CIEDs. MSAC considered information regarding the use of Model 1 and Model 2 was lacking. MSAC considered that the applicant focussed on Model 3 and noted the applicant's pre-MSAC response considered that there is no alternative model which can provide useful comparative estimates. MSAC considered that it would be possible to cost alternative models of care as they do exist within Australia and overseas, although Model 3 is the predominant model currently in use. MSAC considered alternate models of care that are aligned with the Cardiac Society of Australia and New Zealand (CSANZ) guidelines [5] (such as Model 2) could provide appropriate cardiac technical support services for people with CIEDs.

MSAC considered the ADAR did not adequately address technological improvements that enable remote monitoring and programming of CIEDs. MSAC noted that the CSANZ consider remote monitoring of CIEDs to be the standard of care and that it should be offered to all patients when possible. MSAC noted the remote programming of CIEDs is an emerging development [6,7]. MSAC considered that in-person consultations with cardiac technicians may not be necessary when remote programming is fully implemented in clinical practice. MSAC noted that the Expert Reference Group had advised that it expects up to 90% of services to be provided remotely in the future.

[5] Leitch J *et al.* Cardiac Society of Australia and New Zealand (CSANZ) Position Statement on the Follow-Up of Cardiovascular Implantable Electronic Devices 2022. *Heart Lung Circ*. 2022;31(8):1054-1063.
[6] Xiong S *et al*. Realtime Remote Programming in Patients Carrying Cardiac Implantable Electronic Devices Requiring Emergent Reprogramming. *Front Cardiovasc Med*. 2022;9:871425.
[7] Siddamsetti S *et al*. Remote programming of cardiac implantable electronic devices: A novel approach to program cardiac devices for magnetic resonance imaging. *J Cardiovasc Electrophysiol*. 2022;33(5):1005-1009.

MSAC acknowledged consultation feedback from clinicians and consumers had raised concerns and fears about a potential withdrawal of services provided by IECTs. MSAC considered the phased reductions in PL benefit will not apply to the reasonable cost of services provided by IECTs and this should ensure continuation of services provided by IECTs.

MSAC noted PL benefit reductions for CIEDs and the need to determine funding approaches for CIED technical support services have been discussed by government and industry since 2017.[8]

MSAC noted that that the Department had provided a submission request to the applicant that outlined the data and information required to inform its deliberations on the reasonable cost of cardiac technical support services (Table 2). MSAC considered several aspects of the Department's submission request were not addressed by the applicant. MSAC noted the applicant instead presented an aggregate cost of providing cardiac technical support services across all device types. MSAC noted that this did not allow the cost of follow-up services per device or per patient to be calculated. MSAC noted that the ADAR did not provide actual wage expenses, the number of full-time equivalent (FTE) technicians, or the number of patients seen by each technician per year. MSAC considered that the these were reasonable data requests which could have been provided as part of the ADAR.

MSAC noted that the applicant initially estimated the cost of follow-up services at $73.3 million per year (from the ADAR, which was based on a 4-week data collection period in 2022). MSAC considered the estimates provided should not be considered a costing study for the reasons outlined above.

MSAC noted that the applicant's estimate of costs increased to $91.3 million in its pre-ESC response. The revised costs in the pre-ESC response included data from a further 4-week data collection in late 2022. MSAC noted that that the cost of providing cardiac technical support services had been estimated $78.6 million for 2019-20 using similar data collection methods (KPMG report [9].)

MSAC considered that the estimates provided by the applicant in the ADAR and in its pre-ESC response were likely overestimated. MSAC considered the applicant's estimates were based on an inefficient model of service provision. Furthermore, MSAC considered the costs of providing services should decrease (not increase) over time with wider uptake of remote monitoring and programming and more efficient models of care.

MSAC noted that because the updated figures from the applicant were submitted late in the assessment process (as part of the pre-ESC response) there had been no opportunity for them to be formally evaluated. MSAC considered that it was difficult to elucidate the differences in the costs provided in the ADAR and the pre-ESC response. MSAC considered that evaluation of the estimates provided in the pre-ESC response was needed to for it to provide advice on the reasonable cost of cardiac technical support services which would not be subject to the scheduled PL benefit reductions. MSAC considered the pre-ESC response's claim that the updated figures included overhead costs inappropriately omitted from the ADAR should be assessed.

MSAC noted that ESC advised that the reasonable cost of cardiac technical support services is $44.4 million per year.

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[8] Agreement between the Government and the Medical Technology Association of Australia (October 2017). Available from: https://www.health.gov.au/resources/publications/agreement-between-the-government-and-the-medical-technology-association-of-australia

[9] KPMG report on Cardiac Implantable Electronic Device (CIED) service valuation. Available from: https://www.mtaa.org.au/sites/default/files/uploaded-content/field_f_content_file/mtaa-submission_pl_reform.pdf

MSAC considered that it could provide advice on the principles to be used when considering the reasonable to cardiac technical support services which can then be applied once the formal evaluation of the updated $91.3 million estimate is conducted. MSAC advised that the cost of services provided to the public sector should be removed from the calculation of the reasonable cost of follow-up services. MSAC considered that the purpose of the PL is to set out minimum benefits for prostheses for privately insured patients, and therefore PL benefits should not be used to cross-subsidise public sector activity. MSAC advised that hospital funding from activity-based funding (via the Australian Refined Diagnosis Related Groups and Tier 2 funding) could be explored to ensure that the CIED technical services are sufficiently resourced to allow for in-house provision for public patients in the public hospital setting.

MSAC considered the cost of peri-implantation services should not be included in the estimated cost of cardiac technical support services. MSAC considered implantation-related services to be integral to the functioning of the CIED and should remain in the PL benefit for the CIED (and hence be subject to benefit reductions). This is consistent with other devices on the PL.

MSAC noted that the pre-MSAC response stated that pacemaker leads were incorrectly omitted from the list of current PL items for CIEDs. The pre-MSAC response stated that CIED expenditure included all components of the CIED system (including leads). MSAC considered that it is reasonable to consider pacemaker leads, generators, adaptors and transmitters as essential components of the CIED system (along with the principal CIED). However MSAC considered that for the purpose of applying the PL benefit reductions, the aggregate cost of technical support services provided by the applicant should not be distributed across the ancillary components associated with the CIEDs, only the principal devices.

MSAC noted the pre-MSAC response clarified that PL reimbursement for remote monitors (in Part C of the PL) covers the hardware, telecommunication charges, data hosting and security costs, and updates to software and websites (but not technical support). MSAC considered the applicant's request not to include these Part C remote monitoring items but to include other ancillary products was inconsistent. MSAC considered the cost of follow-up services should only be attributed to the principal CIEDs. The reason for this is that the servicing requirement is generally attributable to the use of the principal CIED rather than the ancillary products.

MSAC advised the cost of technical support services should be calculated using a lower hourly wage of $50, based on a starting salary of approximately $60,000 for a junior technician and $100,000 for a senior technician, as noted in the Commentary. MSAC considered that in the absence of alternative reliable estimates, the regional loading of 25% and travel costs could be retained for the current calculations. MSAC advised that certification costs for the 10% of the workforce undergoing certification each year, and annual training costs for all technicians could be retained. MSAC considered that in the absence of alternative reliable estimates the 1.55 on-demand wage loading could be retained for the current calculations. MSAC advised that onboarding costs should be reduced from $212,000 - 250,000 to $30,000 per employee. MSAC based this revised estimate on the assumption that trainee (junior) technicians may require 6 months of supervision by a senior technician before they are able to perform the services unsupervised. MSAC considered this was a conservative assumption (i.e. it is probably still an over-estimate of the on-boarding costs).

MSAC considered independent evaluation of the updated cost estimates provided in the pre-ESC response would enable it to confidently advise on the reasonable aggregate cost of follow up cardiac technical support services. MSAC considered this additional analysis could be expedited and a final estimate of the cost of follow-up services could be considered by MSAC out-of-session, or by the MSAC Executive.

MSAC considered that Australia is unique in having such a heavy reliance on device suppliers to provide technical support for CIEDs. MSAC advised that the current arrangement of IECTs providing cardiac technical support services (Model 3) entrenched in the health system was problematic. MSAC considered that this model is expensive and inefficient as a substantial proportion of face-to-face services were for a single patient/device check. MSAC considered cross-subsidising cardiac technical support services through higher PL benefits had resulted in a non-transparent funding mechanism for these services. MSAC noted the advice of the CIED Expert Panel and considered that existing Medicare Benefits Schedule (MBS) reimbursement for remote monitoring services (provided under cardiologist supervision) are probably inadequate for the services provided.

MSAC considered that there is an opportunity to phase-in new models of care that will improve access to higher quality care at a lower cost as a part of longer-term reform. MSAC considered the lived experience of people with CIEDs should be central to informing future reforms. MSAC noted that patients receive care in both the public and private sector and considered future reforms need to account for this.

MSAC advised that there is a substantial opportunity to undertake reform to move away from dependence on IECTs (Model 3). MSAC considered that Model 1 should be supported through appropriate hospital funding. MSAC advised that existing MBS items for services associated with CIED follow-up and remote monitoring should be reviewed to better support Model 2. MSAC considered existing MBS items may need to be modified to provide higher reimbursement, remove the need for an annual face-to-face review, and/or increase the fee for remote monitoring. MSAC advised that the alternative models of funding and the potential to develop funding mechanism outside the MBS should also be considered. MSAC noted that the potential for out-of-pocket costs is a significant concern for people with CIEDs. MSAC advised that a reformed approach to providing cardiac technical support services should be adequately funded to ensure patients do not incur out-of-pocket costs.

MSAC considered that people with CIEDs should receive technical support services under the care of a cardiologist with appropriate training in CIED management. MSAC considered this would not require cardiologists to personally undertake all device interrogations. MSAC noted that this may result in patients having more than one cardiologist if their CIED cardiologist does not manage their other cardiac issues.

MSAC considered that a reformed approach should ensure patients are clearly informed about role of their treating clinicians and technicians, remote monitoring, and matters related to data storage, use and security.

MSAC noted advice from the expert panel that private cardiology clinics have implemented Model 2 for providing CIED technical support. MSAC noted that most patients in one clinic were enrolled in remote monitoring. MSAC noted that two private clinics charged an annual fee of $200-400 for remote monitoring which is used to pay for the cardiac technician salary. MSAC noted that these fees cover the provision of remote monitoring, checking of transmission alerts, addressing connection problems and phone calls or letters to patients or their physician by the cardiac technicians and cardiologists in response to these alerts.

MSAC noted using Model 2, one full time technician can provide services for approximately 400-500 patients, resulting in approximately 500 full time equivalent cardiac technicians needed to provide technical support services based on the current number of patients with CIEDs in Australia. MSAC recognised there would still be a need for some IECT involvement under this Model 2 for provision of device-specific knowledge if required.

MSAC considered a national CIED registry should be considered as a part of future reforms. MSAC noted that the applicant was supportive of a national CIED registry to capture patient data. MSAC considered a registry should capture service level data to capture services being provided, capture who is providing the services, and who is involved in clinical decision making.

4. Background

The Medical Technology Association of Australia (MTAA) Cardiac Forum (CF) has a membership of five companies (Medtronic, Abbott, Biotronik, MicroPort CRM and Boston Scientific) that supply CIEDs and their associated cardiac technical support services in Australia. The MTAA Cardiac Forum is representing these companies in discussions with the Australian Government to determine a new framework for setting and reviewing Prostheses List (PL) benefits for CIEDs.

The Department of Health and Aged Care has received an application from the MTAA CF as part of an ongoing Prostheses List reform process. The purpose of the application is to determine the cost of the cardiac technical services provided to support patients with CIEDs with the aim of finding a long-term funding mechanism for these services. For the purpose of this application, CIEDs included pacemakers (PPMs), implanted cardioverter defibrillators (ICDs), implantable loop recorders (ILRs) and cardiac resynchronisation therapy devices (CRTDs).

Under the PL benefits reform of medical devices with a benefit level >7% above the Weighted Average Price (WAP), the benefit was reduced by 40% of the difference between the Prostheses List benefit and the WAP in the first year (on 1 July 2022), a further reduction of 20% of the difference in the second year (on 1 July 2023), and a final 20% reduction of the difference in the final year leaving a 20% difference between the WAP and the PL price.

The MTAA CF has stated that if the planned phased reduction of PL benefits goes ahead for CIEDs, they would be unable to sustain the existing level of CIED implantation and follow-up technical services carried out by IECTs without an alternative reimbursement mechanism for these services.

To ensure continued access to technical services for patients for CIEDs, a Memorandum of Understanding was drawn up with the MTAA CF. The Memorandum of Understanding for the policy parameters of the Prostheses List Reforms (dated 14 March 2022) deferred the commencement of all benefit reductions for the CIEDs on the Prostheses List by one year to 1 July 2023, to allow for MSAC deliberations on the value of the technical support services to ensure continued access for patients for CIEDs. MTAA committed to take all reasonable steps to ensure that cardiac companies that produce CIEDs commit to engage with MSAC (expected no later than March 2022) and provide MSAC during its deliberations with company data relevant to the MSAC process.

The data requests as stated in the Submission Request are included in Table 2. It is shown in the table which data requests were addressed/provided in the ADAR, the limitations of the data provided, and the consequences of the data not provided.

Table 2 Submission Request

The submission should address the following:	Addressed/provided in the ADAR?	Limitations / consequences / discussion
Data requests on models of care		
What models of care for Cardiac Implantable Electronic Device (CIED) follow-up services exist in Australia and what is their relative use? Who provides these services and in what treatment setting?	Partly. One of the models of care (the model where services are provided by IECTs) was provided. Information on the remaining models of care (i.e. services in the public system, or in private clinics with their own technicians) was lacking.	Unable to get a clear view of the overall provision of cardiac services in Australia, as only one model of care was presented in the submission, and it is unknown what proportion of overall services are being provided under this model.
Is remote servicing likely to become more common and how will this impact the cost of providing technical services?	Partly addressed in ADAR.	It was discussed that the proportion of remote monitoring services increased during the global pandemic, but that it was questionable if it will be maintained to the same extent as practice preference is for face-to-face services.
Identify and describe the services IECTs provide in relation to CIEDs i.e. what is the service, what is the role of the IECT in providing the service and in what setting is the service provided. This includes for remote monitoring. Please identify the related MBS item number available for each service.	Yes, this was provided in the ADAR.	
Describe the databases each company holds to manage this aspect of their work	Not addressed in ADAR.	
How many active clients does each company service (an active client is one who requires services and has received at least one service in the past 12 months)?	Not provided in ADAR. See Table 2-3 in ADAR.	The data on how many patients are being serviced is needed to estimate the average annual cost of cardiac services per patient, or the cost of services over the life of a device.
What evidence exists around the frequency and types of CIED checks - referencing clinical data and Australian Guidelines? Does this match the pattern of service provision provided?	Not provided in ADAR. See Table 2-3 in ADAR.	Data on frequency and type of checks per patient is needed to determine whether the Australian Guidelines are being followed, and to see the pattern of service provision in Australia.
Describe and quantify the mix of scheduled versus unscheduled services and face to face versus remote services	Partly. This was provided for one model of care (services provided by IECTs). The mix of services within the public system and with privately employed cardiac technicians remains unclear.	The number and mix of different services in the different models of care would give insight in the total number of services provided in Australia, and would provide information on how service provision differs within the different models of care.
Provide actual data on volume of services, and numbers of patients treated per session or site visit.	Partly. The number of services provided by IECTS within a 4-week period was provided. The number of patients per session or site visit was not provided, although the number of services per site visit was.	Limitations: these data provided were a modified analysis set and were not complete. These data are also limited to services provided by IECTs, and it is unclear whether these data are representative of what occurs yearly (as it is based on a 4-week period).

The submission should address the following:	Addressed/provided in the ADAR?	Limitations / consequences / discussion
Are there efficiency gains that industry could achieve under their current model?	Partly, this was briefly discussed in section 3.7 of the ADAR.	It was discussed that the proportion of remote monitoring services increased during the global pandemic, however that it was questionable if it will be maintained to the same extent as practice preference is for face-to-face services. It should be clarified why this is the case as an increase in remote monitoring could potentially lead to large efficiency gains.
What proportion of services are provided to patients whose device was implanted in a public hospital, but who receive follow up through private practice?	Partly. It was not provided how many patients were serviced, and how many patients had a device implanted in a public or private hospital. It was presented how many services were provided by IECTs to patients who had a device implanted in a public or private hospital.	The number of patients being serviced in public and private practice would be helpful to quantify the services provided in the different models of care. This was subsequently provided in the pre-ESC response.
Cost data requests		
For each of the models of care and services identified above, provide actual cost and activity for each company providing these services *	The total cost of one of the models of care was provided. No costs/models were provided for other models of care. No costs per company were provided. However, some company specific information was provided to the DoHAC by the MTAA regarding number of services provided (after this was requested in an email).	Costs for each model of care are needed to determine where efficiencies can be increased. Likewise, variations in costs between companies may have demonstrated where efficiencies may be possible.
These costs should be at the patient level, or at least split by any variations in service provision that could reasonably be expected to affect the cost, including different types of CIED checks, whether the check is scheduled or unscheduled, whether the check was remote, and whether the device was implanted in a public or private practice.	Partly, costs at the patient level were not provided in the ADAR. Costs were estimated for the private sector and the public sector separately, however this was only done for IECT related costs.	Costs per patient are useful to determine how service provision can be optimised and assist in proposing a more efficient model of care.
Costing data provided should be split by direct and indirect costs associated with various aspects of care (e.g. staffing, travel, consumables), including allocation of costs for different staffing specialities involved, and evidence as to why these costs can be attributed to the cost of providing the CIED follow-up services.	Partly. Split cost data were provided for the IECT model of care (Travel costs, labour costs, training costs, overhead costs). Allocation of costs for different staffing specialties was not provided.	

The submission should address the following:	Addressed/provided in the ADAR?	Limitations / consequences / discussion
Activity data should identify the location of the service provision and location of the patient	Yes. It was reported in the ADAR whether the services provided by IECTs were provided in a private or public hospital, private facilities other than a hospital, or the patient's home. Furthermore, it was shown whether the service was provided in a metro, regional, remote or unknown locality.	These data were not complete as almost a quarter of the total number of services were not included in the ADAR.

*It is acknowledged that the MTAA Cardiac Forum is comprised of several companies. If there are confidentiality concerns associated with providing the actual cost and activity data for CIED follow-up services, it is acceptable for each company to submit this data separately and this should not be considered an impediment to sharing the required information for the purpose of this application.

Additionally, the commentary considered if an alternative care model for CIED technical support services could improve the efficiency and effectiveness of providing these services to patients treated in the private health system (e.g. private hospitals and clinics only) in Australia. This could reduce the cost of providing these services for privately insured patients while maintaining the effectiveness and safety of CIED follow-up.

MSAC has not previously considered funding of cardiac technical support services provided by IECTs.

MBS funding for physician involvement in cardiac technical services during CIED follow-up, including remote monitoring, have been considered recently by MSAC. These applications were1443 (Implantable loop recorders for diagnosis of atrial fibrillation in cryptogenic stroke), and 1197/1197.1 (Remote Monitoring of Patients with Implanted Cardiac Devices).

There are currently no direct funding mechanisms by which cardiac technicians can be reimbursed by the Australian Government.

5. Overview of CIED technical services

Cardiac implantable electronic devices (CIEDs)

Cardiac implantable electronic devices (CIEDs) are implanted for diagnosis, treatment and/or monitoring of cardiovascular conditions. They are battery powered devices and include pacemakers (PPMs), implantable cardioverter-defibrillators (ICDs), cardiac resynchronisation therapy devices (CRTDs) and insertable cardiac monitors like implantable loop recorders (ILRs). Devices are usually implanted under conscious sedation as day case surgery or with an overnight stay.

PPMs are usually implanted in patients for bradyarrhythmia treatment. Some patients are completely dependent upon their PPM while others have their PPM as a back-up with pacing required infrequently. ICDs are used for patients with tachyarrhythmia and risk of sudden cardiac arrest. CRTDs are utilised by patients with congestive heart failure. It can be used for cardiac resynchronisation, bradycardia pacing or defibrillation, depending upon the type of CRTD i.e. CRT-P or CRT-D. Implantable loop recorders (ILRs) are subcutaneous, electrocardiographic monitoring devices used for monitoring for cardiac arrhythmias. They are different from other CIEDs as they are used for diagnostic not therapeutic purposes. They are used for diagnosing heart rhythm disorders when aggregated long-term data, rather than short-term Holter monitoring, is required because arrhythmia is suspected to occur rarely. Data are stored in the ILR when a

bradyarrhythmia or tachyarrhythmia event occurs. CIED therapy for patients with heart failure improves morbidity, mortality and has a positive impact on quality of life.

The number of CIEDs currently implanted in Australia determines the volume of cardiac technical support services required to maintain CIED follow-up in line with published guidance (Leitch, 2022). Registry data for CIEDs in Australia are currently very limited. The companies supplying CIEDs in Australia were unable to provide data for the total number of active CIEDs currently in use.

The "Australian and New Zealand Cardiac Implantable Electronic Device Survey" for 2021 is based on a survey of sales from all CIED manufacturers in Australia with sales of new devices considered to align with the number of new implants[10]. It includes PPM, ICDs and CRTDs. There are currently no data for the newer subcutaneous CIEDs as many have only recently received market authorisation in Australia. All CIED companies participated in the survey. The authors reported that there are approximately 140 Australian centres implanting PPMs and 127 centres implanting ICDs, according to manufacturer-held data. However, the relative proportion of implantations occurring in the public vs private sectors is unknown.

In 2021 there were 25,190 PPMs implanted of which 19,410 were new implants and 5,780 (23%) replacement devices. The number of new PPM implants per million population was 755 in 2021. This was a 1% increase in prevalence when compared to survey data from 2017. For ICDs, there were 6,421 implants in 2021 of which 4,519 were new implants and 1,902 (30%) were replacement ICDs. The number per million population was 187 for Australia. For CRT-P and CRT-D CIEDs, there were 4,382 new implants in Australia, 66% of which were CRT-D devices. For implantable event monitors (equivalent to ILRs), 6,933 monitors were implanted. Overall, there were 42,926 CIEDs implanted (both new and replacement) in 2021. Growth in new implants per million population since 2017 was 1% for PPMs and 6.8% for ICDs. Data were not available from the survey for growth of new ILR implants.

The KPMG report provided an estimated prevalence of CIEDs in the Australian population for the periods 2019/20 to 2022/23 based on projected population growth and the number of new CIED insertions relative to the number of deaths and CIED removals for each type of CIED under consideration.[11] The prevalence of CIEDs was projected to grow by an average of 7% per year over this period. This increase is mainly driven by the increase in the prevalence of ILRs (Figure 1).

[10] Mond HG, Crozier I, Sloman Retired JG. The Australian and New Zealand Cardiac Implantable Electronic Device Survey, Calendar Year 2021: 50-Year Anniversary. Heart Lung Circ. 2022 Nov 10:S1443-9506(22)01129-5. doi: 10.1016/j.hlc.2022.09.016. Epub ahead of print. PMID: 36372717.

[11] KPMG 2021, 'Cardiac Implantable Electronic Device (CIED) service evaluation (on behalf of the Medical Technology Association of Australia)'.

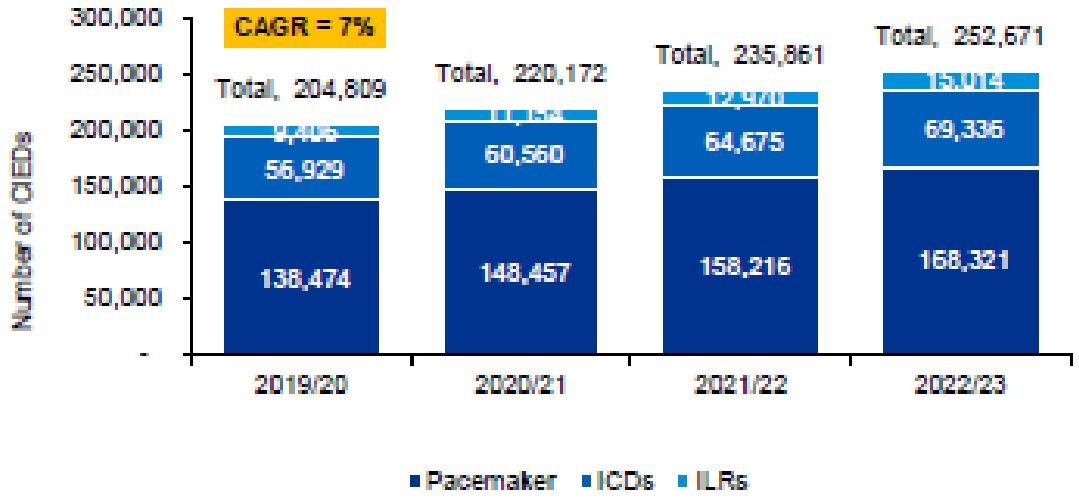


Figure 1 Estimated prevalence of CIED implanted in the Australian population, 2019/20 to 2022/23

Source: KPMG report (2021) Figure 7 page 18.
Data based on estimates from KPMG
Values reported are per financial year
ICD, implantable cardiac defibrillator; ILR, implantable loop recorder

Post-implantation, patients with CIEDs require regular follow-up checks (either in-person as an outpatient and/or remotely) 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. IECTs can be involved in these follow-up checks, "on-demand" at the request of the physician responsible for patient care, providing technical services to optimise the function of the device.

Other healthcare staff (cardiologist, non-industry employed cardiac technician) with appropriate training and knowledge can also carry out some or all of these technical services during follow-up.

Role of healthcare staff in CIED technical support services

A team-based approach is used to deliver CIED technical services. A cardiologist can be supported during CIED implantation and ongoing technical support of CIEDs by cardiac technicians (either industry or clinic/hospital employed) and other health care staff, such as nurses.

Cardiologists

Guidance on physician training in CIED implantation and follow-up is provided by CSANZ.[12] The clinician caring for the individual with a CIED is ultimately responsible for the initiation of any CIED check, interpretation of the resultant data and for any decision concerning CIED reprogramming. CIED interrogation may be performed by the cardiologist but the tasks, including remote transmission assessment or CIED reprogramming, may be delegated to hospital/clinic-

[12] The Cardiac Society of Australia and New Zealand (CSANZ) 2017, 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>.

employed cardiac technicians or IECTs. A physician may be trained to carryout CIED follow-up assessments even if they are not qualified to perform CIED implantations.

Non-industry employed cardiac technicians

Non-industry employed cardiac technicians are employed by either a private clinic/hospital or by a public clinic/hospital to provide technical support services for CIEDs. According to the 2022 CSANZ guidelines on CIED follow-up, "Cardiac device physiologists may perform CIED follow-up and make programming changes without direct medical supervision. In many cases the cardiac device physiologist is the only point of clinical contact for routine device follow-up. Consequently, they provide a central role in the follow-up of cardiac devices and patient care."[13] However, the supervising physician has ultimate responsibility for the decisions of the cardiac technicians. Cardiac technicians support follow-up of CIEDs within their hospital/clinic supplied by any of the CIED companies in Australia. Specialist advice from an IECT either remotely (via email/telephone) or in-person is requested when a clinic/hospital employed cardiac technician or physician does not have sufficient knowledge of an individual company's CIEDs or software algorithms required to resolve a query, troubleshoot, or carry out device reprogramming.

Industry employed cardiac technicians (IECT)

Industry employed cardiac technicians (IECT) are cardiac technicians employed by a CIED manufacturer (industry) to provide implantation support and technical support services only for the manufacturer's CIEDs. According to the 2022 CSANZ guidelines on CIED follow-up, "With increasing complexity of CIEDs it has become difficult for physicians to remain familiar with extensive programmable features and software algorithms across the range of CIED devices. Industry holds an important role in facilitating the optimal device programming for each patient and in troubleshooting device-related issues." The physician can request assistance with technical support services from an IECT on-demand in both the private and public sector. If the physician chooses to have an IECT assist in this process it is considered a private agreement between the physician and the IECT providing the service. Specialist advice from an IECT either remotely (via email/telephone) or in-person may be requested by a physician or cardiac technician when specialist knowledge of an individual company's CIEDs is required to resolve a query, troubleshoot or carry out device reprogramming. While CIEDs provided by each of the five companies supplying Australia may share many similar features, they also have brand-specific characteristics. It may be beneficial for the technical service team to seek advice from IECTs employed by each individual company to support their devices.

Training for CIED technical support services

There is no standardised training and accreditation process for cardiac technicians in Australia. The education and training pathway for cardiac technicians usually involves a tertiary qualification (e.g., a Bachelor of Science (BSc) degree or equivalent) and employment as a cardiac physiologist. Both clinic/hospital-employed cardiac technicians and IECTs currently work towards certification provided by the Allied Professionals Certified Cardiac Device Specialist (CCDS) Exam through the International Board of Heart Rhythm Examiners (IBHRE). The CSANZ

[13] Leitch, J, Asakai, H, Dawson, L, Medi, C, Norman, M, Stevenson, I, Toal, E, Turnbull, S & Young, G 2022, 'Cardiac Society of Australia and New Zealand (CSANZ) Position Statement on the Follow-Up of Cardiovascular Implantable Electronic Devices 2022', Heart Lung Circ, vol. 31, no. 8, 2022-8, pp. 1054-1063.

guidelines recommend development of a co-ordinated national approach to training and credentialing of cardiac technicians in Australia, similar to that available in New Zealand.

IECTs are cardiac technicians but as employees of a single CIED company are trained by their employer to provide technical support for CIEDs supplied by their company.

Non-industry-employed cardiac technicians in a clinic or hospital receive workplace-based training and mentoring from more experienced cardiac technologists. They may also obtain IBHRE certification, as discussed above. Additionally, they receive on-going training/education on an annual basis specific to the individual company CIEDs from IECTs employed by each of the five companies currently providing services active in Australia (Abbott, Biotronik, Boston Scientific, Medtronic, and MicroPort). The extent, time and associated costs of provision of product specific training and educational support for cardiac technicians from industry via IECTs was not included in the ADAR. However, according to the MTAA Cardiac Forum in response to a request for further information, training of clinic staff by IECTs takes the form of both formal education (in-house services) and ad-hoc education, both of which are provided free of charge. Formal education comprises pre-planned in-person (on or off-site) or virtual sessions. Information from a private CIED clinic that employs cardiac technicians to support their cardiologists suggests that approximately 5 product-specific training sessions per annum (one per CIED manufacturer) would be provided to each hospital/clinic team to introduce and discuss any new CIED models or hardware/software/associated technology changes.

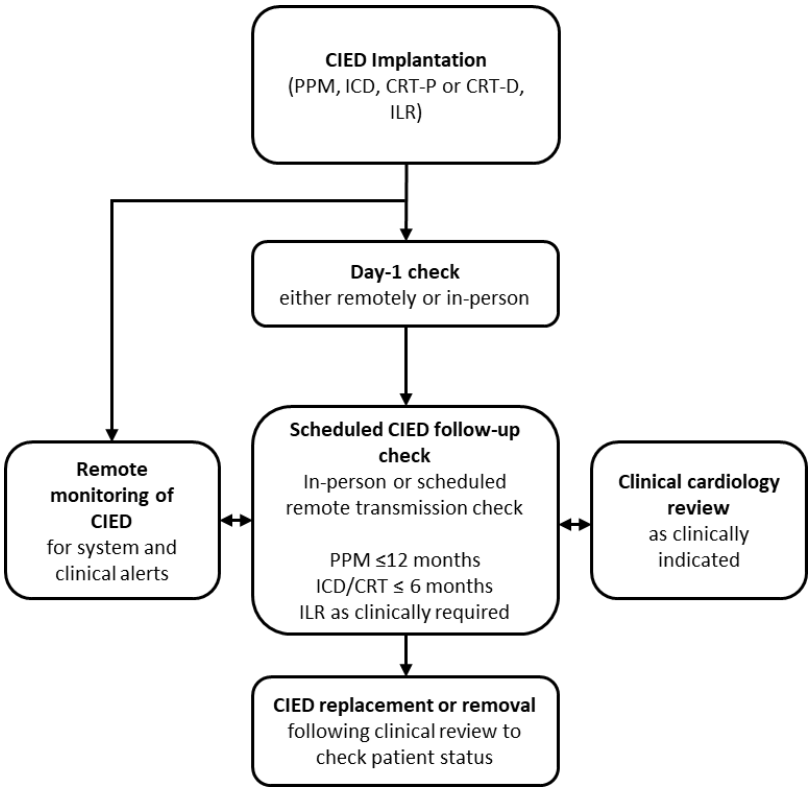
Australian expert consensus recommendations for follow-up of CIED

Expert guidance for follow-up technical services has been published.[14,15] The CSANZ expert consensus schema for CIED follow-up from the 2022 guidelines recommends that scheduled CIED checks, either remote or in-person, should occur at least every 12 months for patients with PPMs, at least every 6 months for patients with ICDs or CRTDs and as clinically indicated for patients with ILRs. There is no recommendation regarding the exact frequency of scheduled checks as these may be influenced by the presence or absence of remote monitoring alerts and changes in the patient's clinical status at review. The frequency of remote monitoring may be changed in response to the outcome of scheduled checks, changes in the patient's clinical status or device reprogramming. Additionally, unscheduled services may be required when patients undergo certain procedures, including MRI scans, radiation oncology, and electrophysiology procedures.

[14] Leitch, J, Asakai, H, Dawson, L, Medi, C, Norman, M, Stevenson, I, Toal, E, Turnbull, S & Young, G 2022, 'Cardiac Society of Australia and New Zealand (CSANZ) Position Statement on the Follow-Up of Cardiovascular Implantable Electronic Devices 2022', Heart Lung Circ, vol. 31, no. 8, 2022-8, pp. 1054-1063.

[15] Slotwiner, D, Varma, N, Akar, JG, Annas, G, Beardsall, M, Fogel, RI, Galizio, NO, Glotzer, TV, Leahy, RA, Love, CJ, McLean, RC, Mittal, S, Morichelli, L, Patton, KK, Raitt, MH, Ricci, RP, Rickard, J, Schoenfeld, MH, Serwer, GA, Shea, J, Varosy, P, Verma, A & Yu, CM 2015, 'HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices', *Heart Rhythm*, vol. 12, no. 7, 2015-7, pp. e69-100.

Figure 2 Schema for CIED follow-up



Adapted from Leitch et al (2022) Figure 1.

CIED = cardiovascular implantable electronic device; ICD = implantable cardioverter-defibrillator; CRT = cardiac resynchronisation therapy; PPM = permanent pacemaker; ILR = implantable loop recorder.

Technical services during CIED implantation and follow-up

IECTs can provide technical support to the clinical team during CIED implantation and post-implantation follow-up. The Heart Rhythm Society policy statement by Haines et al (2022) provides guidance on the role of IECT but it is unclear whether these recommendations are adhered to in Australia. A member of the reference group has advised that these guidelines have not been adhered to in Australia.

CIED services that may require IECT technical support can be divided into the following categories:

- Implantation support
- Scheduled in-person follow-up services
- Unscheduled in-person cardiac technical support services
- Remote monitoring services
- Remote services provided by telephone or email

A description of each type of technical service and the setting it is provided in are shown in Table 3 The role of IECTs in provision of these services is discussed below.

Table 3: CIED technical services

Service	Description of service	Setting
Implantation support		
ILR implant support	Implantation of a new ILR or explant of old device and replacement.	Hospital cardiac catheter laboratory/operating suite
Pacemaker implant support	Implant of pacemaker and leads, replacement of device only, replacement of device and leads or addition of new leads.	Hospital cardiac catheter laboratory/operating suite
ICD implant support	Implant of ICD and leads, replacement of device only, replacement of device and leads or addition of new leads.	Hospital cardiac catheter laboratory/operating suite
CRTD implant support	Implant of CRT-D/CRT-P devices and leads, replacement of device only, replacement of device and leads or addition of new leads.	Hospital cardiac catheter laboratory/operating suite
Scheduled in-person follow-up services		
Day-1 post-implant check	Service occurs at the hospital within 24 hours post-implant to ensure appropriate device programming and safe patient outcomes.	Inpatient private hospital (admitted patient)
Routine follow-up	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 the 2022 guidelines by the Cardiac Society of Australian and New Zealand on CIED follow-up. A member of the reference group advised that routine follow-up can be performed remotely or in the cardiologist's office/clinic and most typically as a combination of both these approaches (in-person consultation after scheduled remote interrogation of the CIED).	Private outpatient clinic
Unscheduled in-person cardiac technical support services		
Ward check	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.	Inpatient private hospital (admitted patient)
Emergency department check	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, change CIED therapy where clinically directed and/or check battery in patients lost to follow-up.	Inpatient private hospital (admitted patient)

Service	Description of service	Setting
MRI check	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.	Private outpatient clinic, Inpatient private hospital (admitted patient)
Radiation oncology check	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.	Private outpatient clinic, inpatient private hospital (admitted patient)
Pre-op/theatre check	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.	Inpatient private hospital (admitted patient) and day surgery (day setting)
ICU reprogramming	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.	Inpatient private hospital (admitted patient)
EP procedure reprogramming	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.	Inpatient private hospital (admitted patient)
Nursing home check	Device interrogation/reprogramming for immobile patients.	Residential aged care facility
Palliative reprogramming	Device reprogramming (deactivation) in situations where the resuscitation is unwanted.	Inpatient private hospital (admitted patient), private outpatient clinic, residential aged care facility, patient's home
Remote monitoring services		
Remote monitoring	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 is 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. This service can be performed as a scheduled check or in the event of a device alert (unscheduled).	Patient's home, Private outpatient clinic, Inpatient private hospital (admitted patient)

Source: Adapted from MSAC 1724 ADAR Table 1-1, page 20.
CIED = Cardiac Implantable Electronic Devices; EP = Electrophysiology Procedure; ICD = Implantable cardioverter defibrillators; ICU = intensive care unit; ILR = Implantable loop recorders; MRI = magnetic resonance imaging; PPM = Pacemakers

Implantation support

CIED implantation support and the Day-1 post-implantation check are included in the ADAR as scheduled services. In the 2022 CSANZ guideline schema, they are considered as separate to scheduled services (Figure 2).

IECTs may provide peri-implantation technical support and Day-1 post-implantation device checks at the time of implantation of a CIED. These services can include providing advice to the surgeon about device specifications and features to help the surgeon select the most appropriate device for their patient. It should be noted that IECTs only provide advice about CIEDs manufactured by their company and therefore the advice they provide is not comparative. The IECT can program the newly implanted CIED (provide algorithm optimisation and device reprogramming recommendations to the clinician) under clinical supervision and provide patient education on the new CIED and use of remote monitoring. They often provide administrative support by registering the CIED. Requests for implantation support are often made at short notice (within 24 to 48 hours). A member of the reference group advised that device implantation in the public system are usually done as same day outpatient procedures. In the private system, Day-1 post-implantation services are now mostly performed remotely. They stated that there is currently no longer a need for a routine in-hospital Day-1 IECT visit, however a remote check would be necessary.

Cardiac support services associated with device implantation are not considered to be within the scope of ADAR assessment as it is considered that reimbursement for implantation technical support could be included in the PL benefit of CIEDs. Implantation support and the Day-1 post-implantation check contributes to safe and effective use of the CIED. It may be reasonable to consider that customer service and technical support contributing to safe and effective use of a CIED at the point of implantation would reasonably be included in the cost of the device for both the public and private sector. This type of support service is not reimbursed in Australia for other implanted devices.

Scheduled in-person follow-up services

For the purposes of the ADAR, a scheduled service is a routine service included in clinical guidance on CIED follow-up. Apart from implantation services discussed above, the remaining scheduled services are routine follow-up checks (whether or not they are planned, or requested at short notice). The equipment used to interrogate the CIED during a scheduled follow-up check is specific to each CIED manufacturer so that multiple sets of equipment are required in a clinic/hospital to cover all brands of CIEDs likely to be encountered during consultations.

The involvement of an IECT in scheduled follow-ups may depend upon whether the clinic or hospital employs their own cardiac technicians and whether IECT specialist knowledge of the particular device is required to resolve a clinical or system issue with the patient's CIED. Non-industry employed cardiac technicians are employed in both public and private clinics/hospitals. Although IECTs predominantly support technical services in private clinics/hospitals, they also provide services on-demand to physicians and cardiac technicians working in public clinics/hospitals.

There were 9,776 scheduled services carried out by IECT staff (250 IECTs; 263.6 FTE) in the 4-week MTAA survey period, of which almost three quarters (71.9%; 7,028 services) were routine follow-up checks. This service is usually carried out in-person as an outpatient at a clinic or hospital, however remote scheduled checks can be performed (with follow up in-person consultation is required). A member of the reference group advised that scheduled checks are most typically performed as a combination of an in-person consultation after a scheduled remote interrogation of the CIED. Furthermore, it was stated by another member of the reference group that the average number of scheduled checks per FTE IECT (9.3 per week) was considered a low workload for one FTE.

The CIED most frequently serviced by IECTs in-person was PPM (63.4%, 6,794 services), followed by ICD (16.2%, 1,733 services), CRT-D or CRT-P (13.1%, 1,403 services), and ILR (6.6%, 704

services). The median time to carry out a scheduled follow-up check was 15 minutes with a range of 5 minutes to 4 hours.

Unscheduled in-person cardiac technical support services

Unscheduled services may require support from an IECT or cardiac technician without prior notice at a clinic or hospital. They are carried out in either outpatient or inpatient settings depending upon the type of service required. Although these services form a small proportion of overall technical services, the burden of providing them is high in terms of availability of staff at short notice as these services can occur at any time of the day or night and costs of in-person attendance 24 hours/7 days per week to carry out the required service.

In total, there were 935 unscheduled services completed by IECTs during the data collection period according to the MTAA survey reported in the ADAR. The most common unscheduled services were ward checks (37.5%, 351 services), outpatient MRI checks (21.1%, 197 services) and pre-op/theatre checks (10.5%, 98 services). It should be noted that 77 services (8.2% of unscheduled services) were cancelled after being requested. A reference group member advised that most devices do not need IECT review before or after surgery, and therefore pre-op/theatre checks are only a small component of the unscheduled workload.

Because they are unscheduled requiring attendance often at short notice, only one technical service is likely to be required at a single location per trip. These services are therefore likely to be associated with higher costs than routine scheduled services where multiple patients may be seen at a single location. The median time required to complete these services, excluding travel was variable, at 15 to 45 minutes.

A member of the reference group has highlighted that many of the unscheduled checks described by the applicant can now be streamlined using remote monitoring technology. Remote monitors are now available from several CIED manufacturers and are able to interrogate all models of a specific manufacturer's CIED. The placement of these monitors in cardiac wards, emergency departments and radiation oncology centres can remove the need for an IECT perform these checks in-person. They advised that this process is well established in South Australia (reference group member's personal experience) and potentially in other Australian states. The reference group member considers that this process is likely to continue to proliferate, significantly reducing the need for IECTs to attend some of these unscheduled requests in person. This statement regarding unscheduled checks was confirmed by another reference group member. They stated that radiation oncology checks are almost entirely carried out via remote monitoring providing that the patient is enrolled in the remote monitoring service. In cases where they are not, either industry has been helpful in providing a monitor for use or the treating cardiologist has been able to arrange access via remote monitor or smartphone app.

Remote monitoring services

Remote monitoring of CIEDs is considered the new standard of care and CSANZ guidance is that it should be offered to patients wherever possible. CSANZ guidance recommends a hybrid of scheduled in-person checks and remote monitoring of CIEDS individualised according to patient and device circumstances.

Remote monitoring of CIEDS involves remote device interrogation and regular device monitoring (for alerts). Remote device interrogation can be either scheduled by the physician or may be triggered by a patient who believes they are experiencing cardiac-related symptoms. During daily remote monitoring, an alert transmission may be triggered by either a cardiac event, such as arrythmias, or a system-related issue, such as abnormal lead parameters or battery depletion.

Data from the CIED is transferred to either a transmitter carried by the patient, usually a mobile phone app, or to a transmitter installed in the patient's home, often located in the bedroom. Patient consent is required to participate in remote monitoring in order to allow their personal data to be collected and stored on servers belonging to the manufacturer of their CIED. Data collected on the servers from remote transmissions can be accessed via a web interface by physicians or technicians. Each CIED manufacturer uses different hardware (transmitter) and software for remote monitoring of their CIEDs.

Patients are offered access to home/remote monitoring and the equipment required at the time of CIED implantation, however not all patients take up remote monitoring. The company-specific equipment and infrastructure (servers and patient transmission database managed by each CIED company) are funded by PL benefits. The benefit paid per remote monitoring system is currently set at $1,448.57 in 2022. The item was billed 17,725 times in 2020-2021.

Remote monitoring may reduce the number of scheduled in-person checks and therefore may provide greater convenience for patients living in regional and remote communities and for frail patients with limited mobility. A reduction of in-person visits also reduces travel required by physicians, cardiac technicians, nurses and IECTs to regional and remote areas. Systematic reviews of the evidence have reported that use of remote monitoring is non-inferior to standard in-person assessment for the outcomes assessed in the studies.[16,17,18]

The proportion of patients enrolled in remote monitoring services has increased during the coronavirus pandemic due to limited availability of in-person CIED interrogations and consultations at clinics and hospitals. Remote monitoring requires physicians or technicians to review device alerts and may therefore require more resources than an in-person only model, however may also reduce the use of scheduled services. An Australian study (O'Shea et al 2021[19]) reported that remote monitoring resulted in approximately 2 alerts per annum per PPM and ICD, and 4 alerts per annum for ILRs. However, it was also reported that 95.2% of alerts were non-urgent.

However, ILRs were associated with a high false-positive alert rate in a study by O'Shea et al (2021) which included 1470 patients with ILRs remote monitored over six months. They transmitted 14,086 alerts (median 3 [interquartile range, 1–10)] alerts per patient). Of these alerts, 40% were true-positives (clinical or system failure events) and 60% were false-positive events. There were 387 (26.3%) patients who only had false-positive alerts (median of 2 [IQR, 1–7] false-positive alerts per device). At least 1 false-positive alert was transmitted by 56% of patients, who had an average false-positive alert rate of 75.8%.[20]

Papavasileiou et al (2013) evaluated the burden on clinicians of the management of ICD-implanted patients enrolled in remote monitoring. A total of 14.9 hours per month were spent on the remote monitoring of 154 patients which is equivalent to 9.7 hours for every 100 patients

[16] Alotaibi, S, Hern, ez-Montfort, J, Ali, OE, El-Chilali, K & Perez, BA 2020, 'Remote monitoring of implantable cardiac devices in heart failure patients: a systematic review and meta-analysis of randomized controlled trials', *Heart Fail Rev*, vol. 25, no. 3, 2020-5, pp. 469-479.
[17] Hajduczok, AG, Muallem, SN, Nudy, MS, DeWaters, AL & Boehmer, JP 2022, 'Remote monitoring for heart failure using implantable devices: a systematic review, meta-analysis, and meta-regression of randomized controlled trials', *Heart Fail Rev*, vol. 27, no. 4, Jul, pp. 1281-1300.
[18] Parthiban, N, Esterman, A, Mahajan, R, Twomey, DJ, Pathak, RK, Lau, DH, Roberts-Thomson, KC, Young, GD, Sanders, P & Ganesan, AN 2015, 'Remote Monitoring of Implantable Cardioverter-Defibrillators: A Systematic Review and Meta-Analysis of Clinical Outcomes', *J Am Coll Cardiol*, vol. 65, no. 24, Jun 23, pp. 2591-2600.
[19] O'Shea, CJ, Middeldorp, ME, Hendriks, JM, Brooks, AG, Lau, DH, Emami, M, Mishima, R, Thiyagarajah, A, Feigofsky, S, Gopinathannair, R, Varma, N, Campbell, K & ers, P 2021, 'Remote Monitoring Alert Burden: An Analysis of Transmission in >26,000 Patients', *JACC Clin Electrophysiol*, vol. 7, no. 2, 2021-2, pp. 226-234.
[20] O'Shea, CJ, Middeldorp, ME, Hendriks, JM, Brooks, AG, Harper, C, Thomas, G, Emami, M, Thiyagarajah, A, Feigofsky, S, Gopinathannair, R, Varma, N, Campbell, K, Lau, DH & ers, P 2021, 'Remote Monitoring of Implantable Loop Recorders: False-Positive Alert Episode Burden', *Circ Arrhythm Electrophysiol*, vol. 14, no. 11, 2021-11, p. e009635.

being monitored (or about 6 minutes per patient per month). Optimal programming and setting of alert thresholds which may require IECT input could reduce the number of false positive results received.

6. Models of care

In Australia, cardiac technical support services are currently provided through three different care models. These models are described below.

Model 1: Services provided through public hospitals and outreach services that employ cardiac technicians

A proportion of patients will have a CIED implanted in the public system. Patients may be followed-up after implantation in the public system or may choose to be followed-up in the private system.

Cardiac technical support services for patients in the public system are mostly funded by the States and Territories. These services are usually provided by a cardiologist supported by hospital-employed cardiac technicians, cardiac physiologists and device nurses. Occasionally an IECT is asked to provide support services in the public system. This usually occurs when product specific training is required, or when more complex servicing tasks are needed. As in private clinics/hospitals, IECTs are not reimbursed for providing these services in the public system.

A member of the reference group stated that the range of support from IECTs varies quite significantly in the public system (between hospitals). Some public hospitals rely heavily in IECT support (particularly for unscheduled checks, more complex CRTD implants, and on weekends and out-of-hours, but even for Day-1 checks). They indicated that the issue is magnified in smaller health services and regional centres with fewer expert non-industry cardiac technicians available. This reference group member raised that as the role of industry in the public system is quite varied, any alternate model of care would need to support the public services to varying degrees until the model is fully implemented.

The data presented by the ADAR showed that 17.6% of all in-person support services provided by IECTs were done in a public hospital (1,886 of 10,711 services).

The total number of cardiac technical support services provided in public hospitals is unknown. Data from the National Hospital Morbidity Database provided the total number of implantations and included both public and private Australian hospitals. Furthermore, Mond et al. (2022) presented data on all sold PPMs and ICDs in Australia in 2021 (implanted in both the public and private system). The Hospital Casemix Protocol has data of CIEDs inserted in the private system. It was recognised that the data from the National Hospital Morbidity Database was unlikely to be complete, and it was estimated that it contained data of 90% of the total number of procedures provided (expert opinion). However, data from Mond et al. (2022) should represent all PPMs and ICDs implanted in Australia. Using these data sources allows us to provide a rough estimate of the number of CIEDs implanted in the public system per year (Table 4).

The data indicate that 49.2% of PPM implantations, 56.5% of ICD implantations and 49.0% of ILR implantations occur in the public system. The KPMG report into cardiac services assumed that approximately 44% of CIED services are provided in a public health care setting, which is a slightly lower estimate when compared to the estimate of CIEDs publicly implanted in Table 4 (based on data from Mond et al (2022) and the Prostheses List). This difference may reflect patients that have had their CIED implanted in the public system but have chosen to receive CIED follow-up checks in the private system.

Table 4 Estimates for number of CIEDs implanted per year

Source and year	Public or private	PPM, n (%)	ICD, n (%)	ILR / Cardiac event recorder, n (%)	Total n (%)
National Hospital Morbidity database 2020/2021	Public and Private	90%: 19,897 100% estimate: 22,108	90%: 4,029 100% estimate: 4,477	90%: 7,148 100% estimate: 7,942	90%: 31,074 100% estimate: 34,527
Mond et al. (2022) 2021	Public and Private	25,190	6,421	6,933	38,544
Hospital Casemix Protocol 1 / Prostheses list 2020/2021	Private	12,800	2,795	4,069	19,664
Data from National Hospital Morbidity database minus Prostheses List data	Public	9,308 (42.1%)	1,234 (27.6%)	3,873 (48.7%)	14,863 (43.0%)
Data from Mond et al. (2022) minus Prostheses List data	Public	12,390 (49.2%)	3,626 (56.5%)	2,864 (41.3%)	18,880 (49.0%)

ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = pacemaker

Model 2: Services provided through private cardiologists who employ cardiac technicians

Some private clinics employ their own cardiac technicians to provide cardiac technical services to their patients. The cardiologist claims an MBS fee for the patient consultation which includes CIED interrogation, and often the patient attending the private clinic will have an out-of-pocket gap payment. MBS items for services used with different CIEDs are shown below in Table 5.

Most technical support services in this model of care will be provided by the non-industry-employed cardiac technician in collaboration with the cardiologist. However, varying levels of support are also provided by IECTs in this model of care. IECT support in these private clinics can range from responding to a request for advice over the telephone or email to providing in-person support at the clinic during a scheduled in-person check (e.g. in-person device interrogation and reprogramming). One of the private clinics which uses this model of care stated that less than 10% of in-person checks would involve an IECT mainly via advice provided by email or telephone.

IECTs also provide formal and ad-hoc education to cardiac staff (cardiologist, cardiac technicians and nurses) employed by private clinics about the devices supplied by their company.

It is unclear how many non-industry cardiac technicians are employed by private clinics, or how many cardiac support services are provided by cardiologists and nurses instead. Therefore, it is extremely difficult to estimate the total cost of cardiac technical support services provided via this model of care.

Remote monitoring is encouraged in the CSANZ guidelines and considered the new standard of care. A private clinic which uses this model of care runs a fully independent remote monitoring

service staffed by their own cardiac technicians. It was estimated that 80-90% of ICD patients and 60-70% of the pacemaker patients attending this private CIED clinic are currently enrolled in remote monitoring, and this proportion is increasing each year. Patients are charged $200 for a PPM and $300 for an ICD (MBS rebate + out-of-pocket expense for a patient) per year for enrolment in the remote monitoring service. These fees are used to pay the cardiac technician's salary. It was estimated that one full time cardiac technician (1FTE) can provide services for 400-500 patients. Similarly, another cardiology clinic charges similar annual fees ($300 for a PPM and $400 for an ICD; fees are in addition to the MBS benefit rebate provided to specialists for this service) for its remote monitoring service. These fees are reduced by $100 for pensioners and are free for Veterans with a Gold Card.

In both clinics, the fees cover the provision of remote monitoring, checking of transmission alerts, sorting out monitor connection problems and phone calls or letters to patients or their physician by the cardiac technicians and cardiologists in response to these alerts. If a patient requires an in-person follow-up check in response to an alert, there are MBS item numbers for a rebate of the fee charged according to the CIED type, although the patient may also be charged a gap fee for their in-person consultation (Table 5).

Table 5 MBS items relevant to cardiac technical support services provided by cardiologists/specialists

Device category	Item	Fee	Description	Date listed
PPM	11719	$70.60	Implanted pacemaker (including cardiac resynchronisation pacemaker) remote monitoring involving reviews (without patient attendance) or arrhythmias, lead and device parameters, if at least one remote review is provided in a 12-month period. Payable only once in any 12-month period.	01 Sep 2015
	11720	$70.60	Implanted pacemaker testing, with patient attendance, following detection of abnormality by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus including reprogramming when required, not being a service associated with a service to which item 11721 applies.	01 Sep 2015
	11721	$73.70	Implanted pacemaker testing of atrioventricular (AV) sequential, rate responsive, or anti-tachycardia pacemakers, including reprogramming when required, not being a service associated with a service to which item 11704 11719, 11720, 11725 or 11726 applies.	31 Oct 1992
ICD	11725	$200.35	Implanted defibrillator (including Cardiac Resynchronisation Defibrillator) remote monitoring involving reviews (without patient attendance) of arrhythmias, lead and device parameters, if at least 2 remote reviews are provided in a 12-month period. Payable only once in any 12-month period.	01 Sep 2015
	11726	$100.20	Implanted defibrillator testing with patient attendance following detection of abnormality by remote monitoring involving electrocardiography, measurement of rate, width and amplitude of stimulus, not being a service associated with a service to which item 11727 applies.	01 Sep 2015
	11727	$100.20	Implanted defibrillator testing involving electrocardiography, assessment of pacing and sensing thresholds for pacing and defibrillation electrodes, download and interpretation of stored events and electrograms, including programming when required, not being a service associated with a service to which item 11719, 11720, 11721, 11725 or 11726 applies.	01 Nov 2006
	38213	$432.10	Cardiac electrophysiological study, performed either: (a) during insertion of implantable defibrillator; or (b) for defibrillation threshold testing at a different time to implantation; other than a service	01 Nov 1996

Device category	Item	Fee	Description	Date listed
			associated with a service to which item 38209 or 38212 applies	
ILR	11728	$36.75	Implanted loop recording for the investigation of atrial fibrillation if the patient to whom the service is provided has been diagnosed as having had an embolic stroke of undetermined source, including reprogramming when required, retrieval of stored data, analysis, interpretation and report, other than a service to which item 38288 applies. For any particular patient—applicable not more than 4 times in any 12 months.	01 May 2018
	11731	$36.75	Implanted electrocardiogram loop recording, by a medical practitioner, including reprogramming (if required), retrieval of stored data, analysis, interpretation and report, if the service is: (a) an investigation for a patient with: (i) cryptogenic stroke; or (ii) recurrent unexplained syncope; and (b) not a service to which item 38285 applies. Applicable only once in any 4-week period.	01 Mar 2021
	11736	$36.75	Implanted loop recording via remote monitoring (including reprogramming (if required), retrieval of stored data, analysis, interpretation and report), for the investigation of atrial fibrillation, if the service: (a) is provided to a patient who has been diagnosed as having had an embolic stroke of undetermined source; and (b) is not a service to which item 38288 applies. Applicable not more than 4 times in any 12 month period.	01 Nov 2022
	11737	$36.75	Implanted electrocardiogram loop recording via remote monitoring (including reprogramming (if required), retrieval of stored data, analysis, interpretation and report), by a medical practitioner, if the service is: (a) an investigation for a patient with: (i) cryptogenic stroke; or (ii) recurrent unexplained syncope; and (b) not a service to which item 38285 applies. Applicable only once in any 4 week period	01 Nov 2022

Source: MSAC 1724 ADAR; Table 1-5, page 34, but item descriptors and fees have been updated.
Please note that the MBS fees for 2022 have been added to update this table from MSAC 1724 ADAR; Table 1-5. The MBS item descriptors for MBS items 11721 and 11727 have also been updated.

Model 3: Services provided through private cardiologists with only IECT technical support

In this model of care (the main focus of the ADAR), the treating physician can claim the MBS fees if they have an in-person consultation with the patient (Table 5) and they rely on support from IECTs to deliver services in their clinic. IECTs will travel to the cardiologist's practice to perform technical services on-demand at the request of the physician or can supply advice remotely via email or telephone.

In this model of care, IECTs costs are considered by industry to be funded through an up-front payment included in the Prostheses List (PL) benefit that a CIED company receives when the device is being implanted (Table 6), and through any private arrangement made between the individual IECT and the treating physician who requested IECT technical support. The cost of remote monitoring equipment (transmitter or smartphone app) and monitoring infrastructure (company-owned and maintained secure servers to store patients remote monitoring data either located in Australia or offshore) are also funded through a separate PL benefit; it is unclear whether this PL benefit for remote monitoring equipment includes an allowance for funding of technical support services (transmission review and associated administration activities) for remote monitoring services as considered by industry for CIED follow-up technical support services funded by CIED PL benefits.

Table 6 Prostheses list items

Device category	Product group	Benefit	Last updated
PPM	08.04 - Single Chamber Pacemakers	$3,948-$5,398	May 2018-July 2021
	08.05 - Dual Chamber Pacemakers	$4,502-$9,296	May 2018-July 2021
	08.09 - Pacemaker/ICD Adaptors	$333	May 2018- March 2021
	08.10 - Pacemaker/ICD Extenders	$353	May 2018- March 2021
	08.11 - Pacemaker/Lead Accessories	$54-$867	May 2018- March 2021
	08.16 - Remote Monitoring System	$1,450	July 2019- March 2021
ICD	08.01 - Single Chamber ICDs	$28,398 -$31,200	May 2018-November 2020
	08.02 - Dual Chamber ICDs	$31,389-$33,338	July 2019-November 2020
	08.07 - ICD Leads	$1,559-$5,994	May 2018- November 2020
	08.09 - Pacemaker/ICD Adaptors	$333	May 2018- March 2021
	08.10 - Pacemaker/ICD Extenders	$353	May 2018- March 2021
	08.16 - Remote Monitoring System	$1,450	July 2019- March 2021
CRTD	08.03 - ICDs with CRT	$34,632-$36,582	July 2019-November 2020
	08.06 - CRTD Pacemakers	$9,004-$10,454	May 2018-July 2021
	08.16 - Remote Monitoring System	$1,450	July 2019- March 2021
ILR	08.14 - Implantable Cardiac Event Recorder	$2,886	May 2018-March 2021
	08.16 - Remote Monitoring System	$1,450	July 2019- March 2021

Source: MSAC 1724 ADAR; Table 1-6, page 35
CRTD = cardiac resynchronisation therapy device; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = pacemaker

The model presented with the ADAR reported that the total annual number of services provided by IECTs is estimated to be 697,258 in 2022. The model estimates 286.6 full time equivalent IECTs provide these services, which is equivalent to each IECT (1.0 FTE) providing 2,433 services (comprised of comprised of 409 in-person scheduled follow up services, 210 implantation services and 1,814 remote services per year).

The ADAR did not estimate the costs of services per device or per patient. It did however present the estimated total costs of services and a breakdown of these costs over 4 years (to 2025, (Table 7). The total costs of cardiac services by IECTs consisted of travel costs (8% of total costs), training costs for IECTs (21% of total costs), labour costs (48% of total costs), and overhead costs (23% of total costs).

Table 7 Total cost of cardiac services by IECTs

	2022	2023	2024	2025
Private	$53,478,816	$58,273,421	$63,432,283	$68,985,517
Public	$19,797,096	$21,581,901	$23,500,974	$25,565,446
Travel cost	$5,964,370	$6,771,171	$7,661,698	$8,643,720
Training cost	$15,175,253	$16,100,943	$17,026,634	$17,952,324
Labour cost	$35,226,463	$37,702,355	$40,352,262	$43,188,415
Overhead cost	$16,909,826	$19,280,853	$21,892,664	$24,766,504
Total cost	**$73,275,613**	**$79,855,322**	**$86,933,257**	**$94,550,963**

Source: MSAC 1724 ADAR, Table 4-17, page 69.
Note: Cost inflated using annual CPI in June 2022 quarter (6%)

Travel costs

The travel costs for in-person services assume an average travel time of at least one hour per service location (Table 8). The costs for travel are shown in Table 9.

Table 8 Total travel time to provide cardiac services

Time	Number of services (%)	Average time (hr:mins)
Travel to metro area	8,811 (82.7)	1:03
Travel to regional area	1,810 (17.0)	1:58
Travel to remote area	34 (0.3)	2:55
Weighted average	10,655 (100)	1:10

Abbreviations: hr=hour; MAS=modified analysis set; mins=minutes

Table 9 Travel costs

		2022	2023	2024	2025
A	Total number of in-person services (scheduled or unscheduled)[a]	177,388	189,805	203,091	217,307
B	Travel time for in-patient services (A × [redacted] hours per service)	[redacted]			
C	Average cost per hour of travel [b]				
D	Average cost of tolls/flights per service [c]				
E	Average cost of parking per service				
F	Average cost of additional travel per service				
	Travel cost (B × C + A × (D + E + F))	**$5,964,370**	**$6,771,171**	**$7,661,698**	**$8,643,720**

[a] No. services reported in tables used to estimate the labour cost of in-person services.
[b] Travel costs varied by area (due to more KMs travelled) (i.e. metro, regional or remote), which varied across cardiac device type
[c] Tolls/flight costs varied by area (i.e. metro, regional or remote), which varied across cardiac device type

Training costs

For each new staff member, the on-boarding costs were assumed to $212,278 (with 10% staff turnover), in addition to certification costing $13,267, and annual updating of training for all IECTs. These costs were insufficiently justified.

Table 10 Training costs

		2022	2023	2024	2025
A	No. IECT	301	301	301	301
B	Training cost per IECT [a]	$15,921	$16,892	$17,863	$18,834
C	Total training cost (A × B)	$4,792,185	$5,084,508	$5,376,831	$5,669,155
D	Certification cost per IECT [a]	$13,267	$14,077	$14,886	$15,695
E	Total certification cost (A × D)	$3,993,487	$4,237,090	$4,480,693	$4,724,296
F	IECT turnover	10.0%	10.0%	10.0%	10.0%
G	Onboarding cost per IECT [a]	$212,278	$225,227	$238,176	$251,125
H	Total onboarding cost (A × F × G)	$6,389,581	$6,779,345	$7,169,110	$7,558,874
	Total training cost (C + E + H)	**$15,175,253**	**$16,100,943**	**$17,026,634**	**$17,952,324**

[a] Costs have been inflated each year by 6.1%, relative to the base year (e.g. training cost in 2024 is equivalent to the training cost in 2022 [$15,291] multiplied by 112.2% [i.e. 1 + 6.1% annual inflation × 2 years])

Labour costs

Labour costs included not only the time spent in-person with a patient, or the time spent reviewing transmissions or alerts for remote monitoring, but also elements such as waiting time (an average of [redacted] minutes per service location), and loadings. There was a 25% regional loading to account for setting up local support networks in regional areas, a 40% remote loading, and an on-demand loading of 1.55, to allow for coverage of peak demand times. It is suggested that the regional loading and on-demand loading are higher than required. The base wage ($85/hr) is also higher than several websites suggest is likely for cardiac technologists (~$49/hr), and higher than the salary for cardiac technicians employed by private clinics.

Table 11 Labour costs, scheduled in-person services

		2022	2023	2024	2025
A	No. implantation support services	32,895	35,198	37,662	40,298
B	Hours related to implantation support services (A × [redacted] hours per service)[a]	[redacted]			
C	No. day 1 post-implantation checks				
D	Hours related to day 1 post-implantation checks (C × [redacted] hours per service) [b]				
E	No. routine follow-up services				
F	Hours related to routine follow-up services (E × [redacted] hours per service) [c]				
G	Total hours related to scheduled in-person services (B + D + F)				
H	Average cost per hour [d]				
	Labour cost of scheduled in-person services (G × H)	**$24,896,510**	**$26,646,251**	**$28,518,962**	**$30,523,286**

[a] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[b] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[c] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[d] Wages ranged from [redacted] in metro areas to [redacted] in remote. The average wage was weighted by the location of the service, which varied by cardiac device type. Inflation (6.1% each year, relative to the base year) was only applied on remote wages.

Table 12 Labour costs, unscheduled in-person services

		2022	2023	2024	2025
A	No. ward checks	5,855	6,265	6,703	7,173
B	Hours related to ward checks (A × [redacted] hours per service) [a]	[redacted]			
C	No. emergency department checks	1,234	1,321	1,413	1,512
D	Hours related to emergency department checks (C × [redacted] hours per service) [b]	[redacted]			
E	No. MRI checks (inpatient)	834	892	955	1,022
F	Hours related to MRI checks (inpatient) (E × [redacted] hours per service) [c]	[redacted]			
G	No. MRI checks (outpatient)	3,286	3,516	3,762	4,026
H	Hours related to MRI checks (outpatient) (G [redacted] hours per service) [d]	[redacted]			
I	No. radiation oncology checks (inpatient)	67	71	76	82
J	Hours related to radiation oncology checks (inpatient) (I × [redacted] hours per service) [e]	[redacted]			
K	No. radiation oncology checks (outpatient)	250	268	286	307
L	Hours related to radiation oncology checks (outpatient) (K × [redacted] hours per service) [f]	[redacted]			
M	No. pre-op/theatre checks	1,635	1,749	1,872	2,003
N	Hours related to pre-op/theatre checks (N × [redacted] hours per service) [g]	[redacted]			
O	No. ICU reprogramming services	701	750	802	858
P	Hours related to ICU reprogramming services (O × [redacted] hours per service) [h]	[redacted]			
Q	No. EP procedure reprogramming services	0	0	0	0
R	Hours related to EP procedure reprogramming services (Q × [redacted] hours per service) [i]	[redacted]			
S	No. nursing home checks	217	232	248	266
T	Hours related to nursing home checks (S × [redacted] hours per service) [j]	[redacted]			
U	No. palliative reprogramming inpatient services	200	214	229	245
V	Hours related to palliative reprogramming inpatient services (U × [redacted] hours per service) [k]	[redacted]			
W	No. palliative reprogramming outpatient services	33	36	38	41
X	Hours related to palliative reprogramming outpatient services (W × [redacted] hours per service) [l]	[redacted]			
Y	Total hours related to unscheduled in-person services (B + D + F + H + J + L + N + P + R + T + V + X)	[redacted]			
Z	Average cost per hour [m]	[redacted]			
	Labour cost of unscheduled in-person services (Y × Z)	[redacted]			

[a] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[b] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[c] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[d] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting

[e] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[f] Comprised [redacted] hours labour [redacted] hours travel and [redacted] hours waiting
[g] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[h] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[i] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[j] Comprised of [redacted] hours labour, [redacted] hours travel [redacted] hours waiting
[k] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[l] Comprised of [redacted] hours labour, [redacted] hours travel and [redacted] hours waiting
[m] Wages ranged from [redacted] in metro areas to [redacted] in remote. The average wage was weighted by the location of the service, which varied by cardiac device type. Inflation (6.1% each year, relative to the base year) was only applied on remote wages.

Table 13 Labour costs, remote services

		2022	2023	2024	2025
A	No. remote services	519,870	556,261	595,199	636,863
B	Hours related to remote services (A × 0.11 hours per service)	[redacted]			
C	Average cost per hour [a]				
	Labour cost of remote services (B × C)				

[a] Wages ranged from $[redacted] in metro areas to $[redacted] in remote. The average wage was weighted by the location of the service, which varied by cardiac device type. Inflation (6.1% each year, relative to the base year) was only applied on remote wages.

Table 14 Total labour costs

	2022	2023	2024	2025
Labour cost of scheduled in-person services (G × H)	[redacted]			
Labour cost of unscheduled in-person services (Y × Z)				
Labour cost of remote services (B × C)				
Total labour costs	**$35,226,463**	**$37,702,355**	**$40,352,262**	**$43,188,415**

Implantation-related services were included in the total costs, however, it may be reasonable to exclude these services from the current review. It may be reasonable to expect costs associated with the attendance of an IECT at implantation for initial programming, and at a Day 1 check, to be included in the cost of a device. This would be reflected in the cost of the device in both public and private settings. When implantation-related services are removed from the total costs (as these could be included in the cost of the device), the total costs of cardiac services provided by IECTs are estimated to be $57,781,365 in 2022. This is a reduction of 21.1% of the total costs. Other univariate sensitivity analyses are included in Table 15 below.

The total cost and cost per scheduled/unscheduled/remote service as per the model in the ADAR are shown in Table 16 and Table 17.

Table 15 Sensitivity analyses

Alternative scenarios	2022	2023	2024	2025	Percent change from base case in 2022
ADAR base case					
Total Services	697,258	746,066	798,290	854,170	
Total Costs	$73,275,912	$79,855,322	$86,933,257	$94,550,963	NA

Alternative scenarios	2022	2023	2024	2025	Percent change from base case in 2022
SA1: Change average hourly wage to $50 (base case: $85.03)					
Total Services	As per base case				
Total Costs	$54,409,287	$59,378,407	$64,712,894	$70,443,233	-25.7%
SA2: Remove Loadings					
Total Services	As per base case				
Total Costs					
SA3: Remove ILRs [a]					
Total Services	520,876	557,337	596,351	638,095	
Total Costs					
SA4: Remove admin costs					
Total Services	As per base case				
Total Costs					
SA5: Costs of in-person services only[a]					
Total Services	177,388	189,805	203,091	217,307	
Total Costs					
SA6: Remove Onboarding costs					
Total Services	As per base case				
Total Costs					
SA7: Change in annual update costs					
Total Services	As per base case				
Total Costs without annual update costs					
Total Costs with annual update at $5,000					
Total Costs with annual update at $10,000					
SA8: Remove certification costs					
Total Services	As per base case				
Total Costs					
SA9: Remove all training and onboarding costs					
Total Services	As per base case				
Total Costs					
SA10: Exclude implantation related services [b]					
Total Services	651,418	697,017	745,808	798,015	
Total Costs	$59,122,961	$64,529,953	$70,344,708	$76,601,254	-21.1%

Source: generated during the evaluation from the utilisation and cost spreadsheet.

[a]Presenting costs for individual categories (ie, excluding ILRs or reporting for only Scheduled Services) reduces the onboarding, training and certification costs relative to the reduction of overall services. This results in an approximate cost that may not be accurate if the excluded services require a different duration of effort to those that are retained in the model. For example, excluding ILRs from the model removes 150,455 services, however 94.5% of these are remote services that will require less effort than in-person services. Therefore, while this approach would result in a reduction of 21.6% of all training costs, the removal of these services would not result in a reduction of 21.6% in IECTs.

[b]Training and overhead costs are separated by year and type of CIED, but not by type of service (ie, routine follow up, implantation support etc). Therefore, excluding implantation related services – called "implantation support service" and "Day 1 post implantation check" – requires that a proportion of training and overhead costs are also excluded. This has been done by reducing these costs proportionally by the reduction in services associated with the exclusion of implantation related services. Across both public and private settings, the overall reduction in services differs for each type of device, ranging from a reduction of 9.59% for CRTDs to 2.34% for ILRs.

Table 16 Unscheduled, scheduled and remote services. Cost per service and sensitivity analysis of total costs

	Multivariate sensitivity analysis	2022	2023	2024	2025	Cost per service (2022)
Total unscheduled services (n)		14,312	15,314	16,386	17,533	
Total cost	**Unscheduled services**	[redacted]				
	Unscheduled services and no onboarding costs					
	Unscheduled services with no onboarding, annual update or training costs					
	Unscheduled services with no onboarding, annual update, training or loadings					
Total scheduled services (routine follow-up only, n)[a]		117,235	125,442	134,223	143,618	
Total cost	**Scheduled services**	[redacted]				
	Scheduled services and no onboarding costs					
	Scheduled services with no onboarding, annual update or training costs					
	Scheduled services with no onboarding, annual update, training or loadings					
Total remote services (remote monitoring, n)		519,870	556,261	595,199	636,863	
Total cost	**Remote monitoring services**	[redacted]				
	Remote monitoring services and no onboarding costs					
	Remote monitoring services with no onboarding, annual update or training costs					
	Remote monitoring services with no onboarding, annual update, training or loadings					

Source: generated during the evaluation from the Utilisation and Cost spreadsheet.

[a]Training and overhead costs are not separated by type of service (ie, the component of the cost cannot be isolated for routine follow up scheduled services). However, routing follow up services are 71.9% of all scheduled services. Therefore the cost of training and overheads has been reduced for scheduled services by 28.1%.

Table 17 Cost per scheduled/unscheduled/remote service, per type of CIED

	PPM	ICD	ILR	CRTDs
Scheduled services (routine follow-up)				
Number of services	74,632	20,618	7,206	14,780
Total cost				
Cost per service (only labour and travel costs, 2022)				
Cost per service including average training and overhead costs (2022)				
Unscheduled services				
Number of services	9,291	2,836	417	1,768
Total cost				
Cost per service (only labour and travel costs, 2022)				
Cost per service including average training and overhead costs (2022)				
Remote services				
Number of services	235,329	71,784	164,638	48,119
Total cost				
Cost per service (only labour and travel costs, 2022				
Cost per service including average training and overhead costs (2022)				

Source: generated during the evaluation from the Utilisation and Cost spreadsheet.
CRTD = cardiac resynchronisation therapy device; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = permanent pacemaker

In Table 17 above, the training and overhead costs were calculated by taking the total training and overhead costs from the Utilisation and Cost spreadsheet (Table 18).

Table 18 Average training and overhead costs per service

	PPM	ICD	ILR	CRTD
Total services	348,661	100,693	176,382	71,522
Total training and overhead costs				
Average training and overhead costs per service				

Source: generated during the evaluation from the Utilisation and Cost spreadsheet.
CRTD = cardiac resynchronisation therapy device; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = permanent pacemaker

7. Summary of public consultation input

Consultation input was received from seven (7) organisations and three (3) individual health professionals. There was a broad response from organisations representing consumers, medical and health professionals, private health industry, and private hospitals:

- Hearts4Hearts
- The Australian Medical Association (AMA)
- Professionals in Cardiac Sciences Australia (PiCSA)
- Private Healthcare Australia
- Representatives of private health insurers
- Ramsay Health Care Australia
- Australian Private Hospitals Association

Support for the service was mixed. The medical association and consumer group raised concerns with the potential rising of out-of-pocket costs for consumers for cardiac services. The representatives of private health industry were not supportive of this application.

The consumer organisation were not supportive of any reforms that would increase the risk of out-of-pocket costs to the patient.

The AMA did not support funding this service via the MBS, believing this will lead to patients bearing large out of pocket expenses. Instead, the AMA supported a system where private health insurers reimburse these services or via a revised prostheses list benefit.

PiCSA acknowledged the complexity with the current funding arrangements for follow-up to patients and agreed that it was not appropriate for allied health staff who are providing follow-up care to patients to be industry employed. They supported the effort to uncouple the cost of follow-up from the cost of the prosthesis and to fund the labour of follow-up care more appropriately. However, PiCSA opposed any model that would make it cheaper or easier for cardiologists to utilise IEAPs versus non-industry cardiac physiologists.

The representatives of private health insurers and private hospitals were not supportive of this application.

8. Updated Cost and Utilisation data

MSAC requested an independent evaluation of the updated cost estimates provided in the pre-ESC response in February 2023. The updated cost estimates included data from a second period of data collection by the applicant, which resulted in an increase to the estimated cost of providing cardiac technical support services in 2022 from $73.3 million to $91 million.

The round 2 data collection reports the total numbers of in-person services and remote transmission services over 4 weeks, but not for particular devices (i.e. PPM, ICD, ILR or CRT) or type of follow up (e.g., implantation support service, routine follow up, ward check). To distribute the round 2 services across devices and service type, the model simply multiplied the previous distribution (derived in Round 1) by the percent change in total services from Round 1 to Round 2. For in-person services, Round 2 reported an increase in 13% of total scheduled or non-scheduled services. For remote transmission services, Round 2 reported an increase in 20% of

total services. The focussed evaluation considered that this approach is approximate and does not capture any changes in the distribution of services across devices or service type from Round 1 to Round 2.

Across all services, there was a 9.2% increase associated with the incorporation of Round 2 data. This has had a variable impact on cost components. The largest increase in costs is attributed to the increase in the estimate of overhead costs.

Table 19 Summary of the changes in services and costs with the incorporation of Round 2 data

2022	Services	Labour	Travel	Training	Overhead	Total
Previous	697,258	$35,226,463	$5,964,370	$15,175,253	$16,909,826	$73,275,912
Updated	761,281	$37,955,527	$6,490,068	$15,175,253	$31,648,755	$91,269,603
Percent change	9.2%	7.7%	8.8%	0.0%	87.2%	24.6%

Source: derived from the updated Utilisation and Cost Model spreadsheet.

The applicant has provided a summary of the characteristics of the services from Round 1 (used to inform the initial ADAR) and Round 2 (additional 4 weeks of data collection). The results indicate that the number of services was slightly higher, with an increase in the proportion of phone/email troubleshooting services. There were more regional services provided in Round 2.

The focussed evaluation considered the differences between Round 1 and Round 2, in terms of the number and type of services provided to be relatively minor and likely associated with a difference in the proportion of services provided across the companies included in the data collection.

Table 20 Summary of results from round 1 and round 2 of the prospective data collection exercise

	Round 1, FAS	Round 2 *
Service type		
In-person	13,744 (25.4%)**	15,476 (24.3%)**
Remote transmission review	31,276 (58.3%)	36,548 (57.5%)
Phone/email troubleshooting support	8,714 (16.3%)	11,571 (18.2%)
Locality classification		
Metro	11,311 (82.3%)	11,843 (76.5%)
Regional	2,323 (17.0%)	3,299 (21.3%)
Remote	41 (0.3%)	24 (0.2%)
Unknown	69 (0.5%)	310 (2.0%)
Company providing the service* **		
Company 1	[redacted]	
Company 2		
Company 3		
Company 4		
Company 5		
Total		
Total	53,734 (100%)	63,595 (100%)

*The data collection period for round 2 started on Monday 21 November 2022 and ended on 18 December 2022 for a total of 4 weeks or 27 days. Responders were asked if they conducted an in-person, remote transmission review or phone/email troubleshooting and how many patients they serviced. For in-person services, responders were asked to enter the postcode for each site visit. Postcodes were classified as metro, regional or remote post-hoc based off the Modified Monash Model (MMM). Note that a Modified Analysis Set (MAS) was not considered for this data collection given that all companies supplied data which did not contain any missing fields.
**In both data collection exercises 0.7% of the in-person services were cancelled
*** This information has been redacted from the interim report as it contains commercially confidential information which can not be shared between CF member companies. An unredacted version will be supplied to the Department within the pre-ESC commentary response.
Source: Table 1, 1724 – Attachment A – Additional Data Collection (Interim Report); FAS = full analysis set

Structure and parameters of the model

The structure of the updated *Utilisation and Cost Model workbook* remains unchanged from Round 1. Briefly, most direct costs (with the exception of the number of IECTs) are linked to the number of services provided and costs change proportionally as the number of services is changed in the model.

Two key costs are largely unaffected by the number of services provided:

- Training costs
- Overhead costs

Training costs

Unchanged from the ADAR, training costs are static in the model, and do not vary by the number of services provided. This is because the estimated number of IECTs (301 in the base case) does not vary with other parameters in the model (such as the number of services provided). The number of IECTs is derived from the applicant's Round 1 data collection. The focussed evaluation considered that this approach may not be reasonable if the number or type of services provided by IECTs changes into the future. As highlighted in MSAC's March 2023 consideration, the proportion of patients enrolled in remote monitoring is increasing each year, and this may reduce the need for unscheduled checks. Additionally, MSAC noted (in March 2023) that it may be

reasonable to assume a 90%+ uptake of remote monitoring within 3-5 years. The focussed evaluation considered this change may reduce the number of required IECTs.

The model assumes $15,175,253 attributed to training costs in the first year (this is unchanged from the initial ADAR based on Round 1 data). This cost is comprised of training an estimated 301 industry IECTs.

In March 2023, MSAC advised that annual training costs for all technicians could be retained, and that certification costs could be retained but would only be applied to 10% of the workforce undergoing certification each year. MSAC advised that onboarding costs should be reduced from $212,000 - $250,000 to $30,000 per employee. MSAC based this revised estimate on the assumption that trainee (junior) technicians may require 6 months of supervision by a senior technician before they are able to perform the services unsupervised. MSAC considered this was a conservative assumption and may still represent an overestimate of true onboarding costs. The training related cost inputs for the applicant's model and the revised estimates based on the MSAC PSD are presented in Table 21.

Table 21 Costs included in training IECTs

Cost component	Cost	Revised based on MSAC PSD
IBHRE certification	$13,267.40	Retain – applied to 10% of workforce
Annual training (update)	$15,920.88	Retain
Onboarding costs	$212,278.43 (applied to 10% turnover)	$30,000
Turnover for on-boarding costs	10%	10%
Total cost per IECT per year (in 2022)[a]	$50,416.12	$20,248
Total cost in the model (in 2022)[b]	$15,175,253	$6,094,534

Source: derived from the updated utilisation and cost model spreadsheet and March 2023 MSAC PSD

[a]Total cost per IECT is estimated as certification costs plus training costs plus 10% x onboarding costs

[b]Total cost in the model is estimated as total cost per IECT x 301 IECTs

The revised certification costs assumes that only new staff require certification, and that there is a 10% turnover of staff each year. Staff turnover is sourced from the applicant's model. The focussed evaluation considered that if certification is required of all staff on a regular basis (such as every 10 years), then the estimation of certification costs would be slightly higher. Based on an annual 10% rate of turnover, most staff would not practice as an IECT for the full 10 years and therefore would not require re-certification, however a proportion would.

Overhead costs

The ADAR stated that overhead costs (provided in Round 1) were a collection of costs that are not directly related to the provision of cardiac technical support services but which are required for the provision of services and therefore need to be factored into the total resourcing requirement (IHPA Australian Hospital Patient Costing Standards 4.1, 2021). In the case of IECT-provided cardiac services, the following overhead or indirect costs are included:

- Annual cost of equipment such as programmers and consumables needed for service delivery, including stock write-offs
- Cost of remote monitoring network maintenance
- Administrative costs around maintaining labour force (Finance, HR, Supply Chains etc)

The ADAR (Round 1) estimated the overhead costs at 30% of direct costs. Direct costs were estimated as the sum total of labour costs, training costs and travel costs. The use of 30% is in line with the average value of overhead costs in last five rounds of National Hospital Cost Data Collection (NHCDC) Public Hospitals Report.

The updated utilisation estimates also included updated overhead costs from a survey of 5 participating companies. The focussed evaluation considered the estimate of the overhead costs and the way in which they are applied in the model is uncertain. The updated estimate of overhead costs was approximately $32 million in 2022. This updated estimate was reported is approximately 53.1% of the amount of non-overhead costs. This is a substantial increase from the estimate of 30% of non-overhead costs previously applied in the ADAR.

Table 22 Recorded overhead costs for 2022, and method of deriving overhead costs across the subsequent 3 years

		2022	2023	2024	2025
#1	Total cost of services[a]	$73,275,912	$79,855,322	$86,933,257	$94,550,963
#2	Total cost of services w/o overhead	$56,366,086	$61,427,171	$66,871,736	$72,731,510
#3	Estimate of overhead costs[b]	$16,909,826		Calculated (#2 x #4)	
#4	Overhead costs (as a proportion of non-overhead costs) (#3 / #2)	30%		Assumed to be constant (30%)	
#5	Revised 2022 Estimate of Overhead costs[c]	$31,648,755			
#6	Overhead costs divided by non-overhead costs (#5 / #2)	56%		Assumed to be constant (56%)	
#7	Forecast overhead costs (#2 x #6)		$34,490,482	$37,547,528	$40,837,708
#8	Overhead costs in private[d]	$23,036,089	$25,111,996	$27,344,391	$29,746,277

Source: derived from the updated utilisation and cost model spreadsheet.

[a]Total cost of services estimated in the previous ADAR base case, presented in Table 3 of Attachment A (Additional Data Collection) report.

[b]Overhead costs as estimated in the previous ADAR base case, presented in Table 3 of Attachment A (Additional Data Collection) report.

[c]Annual overhead costs as collected from companies during the Round 2 data collection.

[d]Approximately 72.8% of total overhead costs are ascribed to the private system in the applicant's model.

The focussed evaluation considered the revised estimate of overhead costs is uncertain (see Table 24 for the components included in overhead costs). Furthermore, overhead costs do not change in the model in response to changes in the number or type of services provided. However, the proportion of overhead costs applied to services provided in the public system can be removed from the estimates.

Table 23 Comparison of overhead costs applied in the ADAR with the updated estimates

	ADAR (Round 1)	Updated data (Round 2)		
	Total	Total	Private	Public
Services (in 2022)	697,258	761,281	627,887	133,394
Total costs	$73,275,912	$91,269,603	$66,611,116	$24,658,486
Non-overhead costs	$56,366,086	$59,620,848	$43,575,027	$16,045,921
Overhead costs	$16,909,826	$31,648,755	$23,036,089	$8,612,666
Overhead as a percent of direct costs	30%	53.1%	52.9%	53.7%

Source: generated from the updated Utilisation and Cost Model spreadsheet.

The updated overhead costs were derived from data provided by companies during the Round 2 data collection. The applicant has provided a summary of the cost components, reproduced in Table 24. The focussed evaluation considered that it is difficult to interpret the components of the overhead costs, or understand how some of the costs could have been derived. In many cases, there are considerable variations across companies in the categories of overhead costs, which may reflect the difficulties in ascribing costs to particular categories or to the cardiac technical support services component of the business. The focussed evaluation considered that it was not clear whether the sole purpose of the included companies is to provide cardiac technician support for implantable cardiac devices, however it is unlikely. Therefore, many overhead costs would need to be derived from the total business overhead costs and apportioned appropriately to the cardiac technician component of the business.

Table 24 Overhead costing estimates

Cost	Company					Total
	1	2	3	4	5	
Capital equipment + accessories [a]	[redacted]					[redacted]
Maintenance & repairs costs [b]						
Consumables - used not charged [c]						
Consumables - discarded [d]						
Remote monitoring network maintenance [e]						
Service support staff salaries [f]						
Property rent or lease [g]						
Utilities [h]						
IT & comms costs [i]						
Office equipment & supplies [j]						
Insurances [k]						
Administration [l]						
Legal, regulatory and consultancy costs [m]						
Security [n]						
Freight & shipping [o]						
Finance costs [p]						
External Service costs [q]						
Total						$31,648,755

a = Programmers, accessories, cables, test, demo equipment etc. Costs may include lease charges, interest and depreciation charges.
b = Capital Equipment, infrastructure (office building), motor vehicles, etc.
c = Consumables not covered by PL benefits used in supporting implantation processes, clinics etc.
d = Opened not used (e.g. intra-operative need changed after opening package) or expired on consignment.
e = Only those costs not explicitly covered by PL benefit - data charges, server or cloud costs, algorithm maintenance etc.
f = Salary of HR, Payroll, Marketing, Supply Chain, Customer Service, Regulatory and Finance staff, General Management.
g = Facility charges for Warehouse, storage locations, offices etc.
h = Electricity, gas, Phone & Internet, cleaning services, sterilisation; hazardous waste etc. The pre-MSAC response stated hazardous waste costs include disposal of explanted material, items consumed in implantation- sheaths/catheters which may be collected time to time, items returned for quality assurance inspection and reporting, sterile covers for theatre.
i = Hardware, firmware, mobile network etc.
j = Supporting administration, finance, regulatory etc.
k = Public/ product/ professional/ cyber security/ workers comp etc.
l = Business-specific charges.
m = ARTG registration, legal advice, supporting market regulation consultations (MSAC application costs), ASIC, ATO, Audit Fees etc. The pre-MSAC response stated ARTG registration includes software and hardware service equipment required to have ARTG's approval. n = Expenses to maintain asset and data security.
o = Local & O/S in moving stock & equipment.
p = Interest, leasing, finance charge, FX losses.
q = Cost to engage external company providing remote monitoring. The pre-MSAC response stated use of external contractors for providing remote monitoring would be as per any other service industry and should be offset by internal labour hours consumed. This includes peak load coverage, after hours, coverage during training/ leave etc.
r = The pre-MSAC response advised that that inbound freight and duties was incorrectly incorporated into this figure and correct figure should be $[redacted].
Abbreviations: ARTG= Australian Register of Therapeutic Goods, ASIC= Australian Securities & Investments Commission, ATO=Australian Taxation Office, FAS = full analysis set; HR=human resources, IT = information technology; MSAC=Medical Services Advisory Committee, NP=none provided, PL=Prothesis List
Source: Table 2, 1724 – Attachment A – Additional Data Collection (Interim Report)

The largest costs included in the calculation of the overhead costs were:

- Service support staff salaries – 30%
- Capital equipment – 12%
- Consumables used not charged – 12%
- Remote network maintenance – 10%

The focussed evaluation considered that some of the included costs appear unreasonable. Company 3 has reported an annual rent of almost [redacted] dollars. A crude estimate of the number of IECTs that would be employed by Company 3 is [redacted], based on a total of [redacted] IECTs and the proportion of services provided by Company 3 (approximately [redacted]%). Company 4 has reported [redacted] in freight and shipping costs, although it is unclear what equipment is being freighted. The pre-MSAC response stated that this figure incorrectly included inbound freight and duties and advised that the figure for local shipping costs was $[redacted]. This reduced the total overhead costs for 2022 for all companies to $[redacted].

The service support staff salaries are stated to be, "Salary of HR, Payroll, Marketing, Supply Chain, Customer Service, Regulatory and Finance staff, General Management". This accounts for $[redacted] dollars in 2022 (or roughly 10% of the total costs of providing all services in public and private in the applicant's revised model).

The focussed evaluation considered that it may be informative to consider the proposed overhead costs in relation to the number of employed IECTs. Excluding training and certification, travel, wages and on-costs, the estimated overhead costs for each employed cardiac technician is $[redacted]. On the assumption that Company 2 employs approximately [redacted]% of all IECTs (proportional to the number of services provided), the estimated overhead costs per IECT for Company 2 would be [redacted].

The applicant has provided descriptions of what might be captured in the overhead cost categories in table notes to the overhead costing estimates (see table notes to Table 24). The focussed evaluation considered that it was unclear whether these descriptions indicate costs that have been included in the estimate of overhead costs, or are a general description of costs that *might* be associated with the overhead cost category. If the descriptions are costs that have been included, there are several costs that are clearly inappropriate (for example, hazardous waste, ARTG registration and external contractors for providing remote monitoring). If, on the other hand, the descriptions are general, then the basis on which the overhead costs have been generated and distributed across the IECT services is not transparent.

Table 25 Descriptions of overhead costs

Overhead cost	Details	Cost (% of overhead / % of total)[a]
Capital equipment + accessories	Programmers, accessories, cables, test, demo equipment etc. Costs may include lease charges, interest and depreciation charges.	[redacted]
Maintenance & repairs costs	Capital Equipment, infrastructure (office building), motor vehicles, etc.	
Consumables - used not charged	Consumables not covered by PL benefits used in supporting implantation processes, clinics etc.	
Consumables – discarded	Opened not used (e.g. intra-operative need changed after opening package) or expired on consignment.	
Remote monitoring network maintenance	Only those costs not explicitly covered by PL benefit - data charges, server or cloud costs, algorithm maintenance etc.	
Service support staff salaries	Salary of HR, Payroll, Marketing, Supply Chain, Customer Service, Regulatory and Finance staff, General Management.	
Property rent or lease	Facility charges for Warehouse, storage locations, offices etc.	
Utilities	Electricity, gas, Phone & Internet, cleaning services, sterilisation; hazardous waste etc.	
IT & comms costs	Hardware, firmware, mobile network etc.	
Office equipment & supplies	Supporting administration, finance, regulatory etc.	
Insurances	Public/ product/ professional/ cyber security/ workers comp etc.	
Administration	Business-specific charges.	
Legal, regulatory and consultancy costs	ARTG registration, legal advice, supporting market regulation consultations (MSAC application costs), ASIC, ATO, Audit Fees etc.	
Security	Expenses to maintain asset and data security.	
Freight & shipping	Local & O/S in moving stock & equipment.	
Finance costs	Interest, leasing, finance charge, FX losses.	
External Service costs	Cost to engage external company providing remote monitoring.	

[a] Percentage of total overhead costs in updated estimates ($31,648,755), and percentage of total costs of providing cardiac services ($91,269,603)

The focussed evaluation considered the variation in costs for individual items and for total costs is very large across companies. When estimated as a percentage of non-overhead costs, overhead costs range from under [redacted]% up to [redacted]% across the companies. This means that overhead costs, adjusted for the number of services provided, is almost [redacted] times more costly in one company compared to the company with the lowest estimate of overhead costs.

Table 26 Overhead costs reported by each company as a percentage of estimated non-overhead costs in the private and public sector (applicant's revised model)

Company	Total services (Round 2)	Non-overhead costs[a]	Overhead costs[b]	Overhead costs as a percentage of non-overhead costs
1	[redacted]			
2				
3				
4				
5				
Total	63595	$59,620,848	$31,648,755	53.1%

Source: Table 2, 1724 – Attachment A – Additional Data Collection (Interim Report)
aApplied to each company on the basis of the proportion of services provided during the Round 2 data collection period.
bAnnual overhead costs as reported by each company

The focussed evaluation queried whether the updated overhead costs were reasonable, reliable or adequately transparent to include in the Utilisation and Cost Model spreadsheet estimates. Key concerns include: a lack of explanation of the components included in the overhead costs; a lack of explanation for the considerable variability across companies in both the allocation of overhead costs to individual categories and in terms of the overall estimates of overhead costs; and, the reasonableness of some of the included items (such as, but not limited to, costs associated with external remote monitoring).

The focussed evaluation considered that an alternative estimate of overhead costs may be more reasonable, such as an estimate of 30% of non-overhead costs, as was provided in the 1724 ADAR considered by MSAC in March 2023.

Several estimates of overhead costs were included in sensitivity analyses.

Results

ADAR Base Case (Round 1)

Table 27 presents the applicants estimate of the cost of providing cardiac technical support services based on Round 1 data collection, as presented in the ADAR (considered by MSAC in March 2023).

Table 27 The estimated cost of providing cardiac technical support services presented in the ADAR, disaggregated by direct and overhead costs

Data	2022	2023	2024	2025
ADAR base case				
Total services	697,258	746,066	798,290	854,170
Total costs	$73,275,912	$79,855,322	$86,933,257	$94,550,963
corrected	*$73,275,912*	*$78,746,810*	*$84,552,771*	*$90,719,797*
Labour costs	$35,226,463	$37,702,355	$40,352,262	$43,188,415
Travel costs	$5,964,370	$6,771,171	$7,661,698	$8,643,720
Training costs	$15,175,253	$16,100,943	$17,026,634	$17,952,324
Overhead costs[a]	$16,909,826	$19,280,853	$21,892,664	$24,766,504
corrected	*$16,909,826*	*$18,172,341*	*$19,512,178*	*$20,935,338*

Source: Table 3, 1724 – Attachment A – Additional Data Collection (Interim Report); ADAR = Applicant developed assessment report
[a]Overhead costs are estimated as 30% of non-overhead costs. These costs are inflated by 6% in 2023, 12% in 2024 and 18% in 2025. As the non-overhead costs are also inflated by CPI, this represents double-counting. This is corrected in the table.

The updated Utilisation and Cost Model spreadsheet estimates services based on an average of the services from Round 1 and Round 2. There is no option provided in the model to isolate Round 1 data and replicate the ADAR base case.

Updated patient numbers (Round 1 and Round 2)

The applicant has provided an updated estimate of the cost of providing cardiac technical support services based on patient numbers from Round 1 and Round 2 (**Table 28**). Overhead costs have been estimated as 30% of non-overhead costs (as per the approach taken in the ADAR considered by MSAC in March 2023).

Table 28 The estimated cost of providing cardiac technical support services presented in the ADAR, incorporating patient numbers from Round 1 and Round 2, disaggregated by direct and overhead costs

Data	2022	2023	2024	2025	Percentage change from ADAR[b]
Updated model with Round 1 and Round 2 patient numbers					
Total services	761,281	814,571	871,591	932,602	9.2%
Total costs	$77,507,102	$84,488,969	$92,006,235	$100,103,426	5.8%
corrected	*$77,507,102*	*$83,316,134*	*$89,486,836*	*$96,047,275*	*5.8%*
Labour costs	$37,955,527	$40,620,411	$43,472,397	$46,524,621	7.7%
Travel costs	$6,490,068	$7,367,979	$8,336,997	$9,405,574	8.8%
Training costs	$15,175,253	$16,100,943	$17,026,634	$17,952,324	No change
Overhead costs [c]	$17,886,254	$20,399,635	$23,170,207	$26,220,906	5.8%
Corrected [c]	*$17,886,254*	*$19,226,800*	*$20,650,808*	*$22,164,756*	*5.8%*

Source: Table 3, 1724 – Attachment A – Additional Data Collection (Interim Report)
[a]Overhead costs are estimated as 30% of non-overhead costs. These costs are inflated by 6% in 2023, 12% in 2024 and 18% in 2025. As the non-overhead costs are also inflated by CPI, this represents double-counting. This is corrected in the table.
[b]Percent change for 2022 costs.
[c] Calculated as 30% of direct costs (labour, travel and training).

Updated patient numbers with MSAC requested changes (MSAC updated model)

Following the previous MSAC consideration of cardiac technical support services, the following changes were requested.

- Exclude services provided to public patients (S1)
- Exclude peri-implantation services (defined as services at the time of implantation and the day one post-implantation check) (S2)
- Reduce onboarding costs to $30,000 per technician (S3)
- Only apply certification costs to the 10% of technicians being certified each year (S4)
- Reduce the wage rate to $50 per hour (S5)

Parameters that were requested to be preserved:

- Retain services for Implantable Loop Recorders (ILRs)
- Retain regional wage loading of 25%
- Retain on-demand wage loading of 1.55
- Retain the travel, parking and total costs presented in the ADAR
- Retain training costs of $15,921 per annum
- Retain certification costs of $13,267

For this analysis, overhead costs are estimated as 30% of non-overhead costs in the updated model (based on Round 1 and Round 2 data), as presented in Table 28.

Table 29 Stepwise implementation of changes to generate the MSAC updated model

Data	2022	2023	2024	2025	Percentage change from ADAR[b]
Updated model with Round 1 and Round 2 patient numbers					
Total services	761,281	814,571	871,591	932,602	9.2%
Total costs	$77,507,102	$83,316,134	$89,486,836	$96,047,275	5.8%
Exclude services provided to public patients (S1)					
Total services	627,887	671,839	718,868	769,189	-9.9%
Total costs	$61,461,281	$66,061,119	$70,948,121	$76,144,519	-16.1%
S1 + Exclude peri-implantation services (S2)					
Total services	593,409	634,948	679,394	726,952	-14.9%
Total costs	$52,428,467	$56,316,940	$60,437,247	$64,807,361	-28.5%
***S1* + *S2* + Reduce onboarding costs to $30,000 (S3)**					
Total costs	$48,546,590	$52,198,269	$56,081,782	$60,215,101	*-33.7%*
***S1* + *S2* + *S3* + Only apply certification to 10% per annum (S4)**					
Total costs	$46,003,658	$49,500,218	$53,228,612	$57,206,812	*-37.2%*
***S1* + *S2* + *S3*+ *S4* + Reduce the wage to $50 per hour (S5)**					
Total costs	$37,599,148	$40,505,607	$43,602,466	$46,904,791	*-48.7%*

Source: generated from the Utilisation and Cost Model Spreadsheet.

The increased number of services following Round 2 data collection resulted in a 9.2% increase in services. If overhead costs are assumed to be 30% of non-overhead costs, as was presented in the ADAR, the total costs associated with the increase in services was estimated to be 5.8% from the ADAR estimates.

Following the changes requested after MSAC consideration, the total number of services was 14.9% lower than the ADAR (representing a 22% reduction from the revised Round 2 estimates). Total costs were 48.7% lower than presented in the ADAR.

Disaggregated costs of the revised model excluding services to public patients, peri-implantation services, reduced onboarding costs, certification costs applied to 10% of staff per annum, and reduced IECT wages are presented in Table 30.

Table 30 Disaggregated costs for the MSAC updated model

Data	2022	2023	2024	2025
S1 + S2 + S3+ S4 + S5 (MSAC Updated Model) [a]				
Total services	593,409	634,948	679,394	726,952
Total costs	$37,599,148	$40,505,607	$43,602,466	$46,904,791
Labour costs	$11,995,510	$12,837,745	$13,739,115	$14,703,772
Travel costs	$3,405,368	$3,866,012	$4,374,460	$4,935,147
Training costs	$4,312,017	$4,575,050	$4,838,083	$5,101,116
Overhead costs [b]	$17,886,254	$19,226,800	$20,650,808	$22,164,756
Proportion of overhead costs to non-overhead costs	90.7%	90.4%	90.0%	89.6%
Proportion of overhead costs to total costs	47.6%	47.5%	47.4%	47.3%

Source: generated from the Utilisation and Cost Model Spreadsheet.

[a] Updated model with Round 1 and Round 2 patient numbers, excluding peri-implantation services and public hospital services, reduced onboarding and certification costs and reduced IECT wage.

[b] Calculated as 30% of direct costs (labour, travel and training) based on total direct costs in the updated estimates ($59,620,848 in 2022).

Alternative estimates of overhead costs

The largest cost associated with cardiac services in the revised model is overhead costs. These estimates have been kept at 30% of the non-overhead costs presented in the applicant's updated model (including Round 1 and Round 2). As overhead costs have not been permitted to vary by costs or service volumes, the overhead costs account for almost 50% of all costs in the MSAC revised model.

The focussed evaluation considered the estimate of overhead costs represents a key uncertainty in the Utilisation and Cost Model spreadsheet. To address this uncertainty, multiple approaches have been applied to vary the estimate of overhead costs. These were:

- Reducing the overhead costs from the ADAR estimates proportionally by the reduction in services;
- Reducing the overhead costs from the ADAR estimates to be equivalent to 30% of non-overhead costs;
- Increase the overhead costs to match the costs derived by the applicant from the data collection from 5 companies (restricted to the proportion allocated to the provision of private services);
- Adjust the overhead costs to match the costs derived from companies, restricted to overhead costs allocated to the provision of private services, excluding the 2 most costly companies.

The proportion of services provided by Company [redacted] and Company [redacted] as a percentage of the total services captured in the Round 2 data collection was about [redacted]% ([redacted] / 63595 services). Despite this, the companies accounted for more than [redacted]% of the total overhead costs. If these companies are removed from the analysis, and the overhead costs of the remaining 3 companies were inflated to achieve the same number of services, the estimated cost would be approximately $[redacted] lower. The focussed evaluation considered this approach may be reasonable as these companies report overhead costs that are approximately [redacted]% of the non-overhead costs, compared to less than [redacted]% for the remaining three companies.

To exclude the two most costly companies from the estimate of overhead costs, the costs from the remaining 3 companies have been inflated to account for the loss in service provision from the two excluded companies (see Table 31).

Table 31 Excluding the two most costly companies in terms of overhead costs (only private services)[a]

	Services	Proportion	O/H costs	Alternative proportion	O/H costs
Company 1					
Company 2					
Company 3					
Company 4					
Company 5					
Total	**63595**	**100.0%**	**$26,103,153**	**100.0%**	**$17,276,984**

Source: generated during the evaluation based on Table 20 and Table 26. *See updated spreadsheet.*

[a]Private services account for 82.5% of all services in the Utilisation and Cost Model spreadsheet. The O/H costs have been multiplied by 0.825 to remove O/H costs associated with the provision of services in the public sector. This adjustment may result in higher O/H costs than applying the applicant's estimate of the distribution of O/H costs by sector, which assumes that 72.8% of O/H costs are attributed to the private sector.

O/H = overhead

The alternative overhead costs by year are presented in Table 32.

Table 32 Alternative options for calculating overhead costs used in the estimate of costs for providing cardiac technical support services

Option	Description	2022	2023	2024	2025
A	30% of non-OH costs in updated ADAR	$17,886,254	$19,226,800	$20,650,808	$22,164,756
B	Reduced proportionally by services				
C	Set as 30% of non-OH costs				
D	Applicant estimated costs				
E	Removing 2 most costly companies				

Source: generated from the Utilisation and Cost Model Spreadsheet. *See Support!B254:F266 of the updated spreadsheet.*

Description of derivation of overhead costs:

A This estimate (presented in Table 30) is based on 30% of the non-overhead costs after the incorporation of Round 2 data. This estimate is not varied with subsequent changes to costs or services.

B This estimate represents (A) reduced by 22.1% to account for the loss of services provided in the public sector and peri-implantation services

C This estimate represents 30% of non-overhead costs after reductions in services and reductions in wages, training and onboarding costs are applied

D This estimate represents the applicant's estimate of overhead costs derived from the survey of 5 companies. The initial estimate is $31,648,755 across both public and private sectors in 2022. The estimate used in this analysis is $, which is the amount that the Utilisation and Cost Model spreadsheet allocates to the private sector (approximately 72.8%)

E This estimate removes the two most costly companies, as per Table 31. This estimate represents 87.6% of the non-overhead costs of the MSAC revised estimates (after removing public services, peri-implantation services, reducing onboarding costs, reducing certification frequency and reducing IECT wages). This proportion has been used to generate an estimate of overhead costs for 2023-2025.

The MSAC updated model results in a total cost of $37,599,148 for providing cardiac technical support services in 2022. The impact of using alternative estimates for overhead costs on total cost of providing services is presented in Table 33.

Table 33 Sensitivity analyses applying alternative estimates of overhead costs

Data	2022	2023	2024	2025
Updated model with Round 1 and Round 2 patient numbers				
Total costs	$77,507,102	$84,488,969	$92,006,235	$100,103,426
Overhead costs (A)	$17,886,254	$19,226,800	$20,650,808	$22,164,756
MSAC updated model (remove public and peri-implantation services, reduce onboarding costs, reduce certification frequency and reduce IECT wages)				
Total costs	$37,599,148	$40,505,607	$43,602,466	$46,904,791
Overhead costs (A)	$17,886,254	$19,226,800	$20,650,808	$22,164,756
Overhead costs reduced proportionally with services (-22.1%)				
Total costs	[redacted]			
Overhead costs (B)				
Overhead costs set to 30% of updated non-overhead costs (C)				
Total costs	[redacted]			
Overhead costs (C)				
Applicant company survey data for overhead costs (restricted to the private sector)				
Total costs	[redacted]			
Overhead costs (D)				
Overhead costs recalculated removing the 2 most costly companies				
Total costs	[redacted]			
Overhead costs (E)				

Source: generated from the Utilisation and Cost Model Spreadsheet.
Note: letters appearing next to "Overhead costs" in the table refer to the approaches described in Table 32.

Overhead costs in the MSAC updated model are estimated as 30% of the non-overhead costs in the applicant's model incorporating Round 2 data (e.g. $17,886,254 in 2022) and includes overhead costs for direct costs that were removed (public patients, peri-implantation services) or recalculated (onboarding costs, wages, certifications costs). These overhead costs are applied in the MSAC updated model. However, the MSAC updated model involved changes to the number of services, and to parameters that reduced non-overhead costs. The focussed evaluation considered that it may be reasonable to consider that the estimate of overhead costs would vary if the estimate of services is lower, or the estimate of non-overhead costs is lower.

Compared with the MSAC updated model estimates, the total cost of providing cardiac technical support services reduces by approximately 10% if the estimate of overhead costs were revised down proportionally with the reduction of services (associated with the removal of public sector and peri-implantation services).

Applying the applicant's estimate of overhead costs (for the private sector only) derived from the company survey results in a [redacted]% increase in total costs, and if the two most costly companies are removed from the analysis, it results in a [redacted]% reduction in total costs.

The pre-MSAC response provided an updated costs that corrected errors in the overhead costs and applied certification costs to only 10% of technicians per year (Table 34).

Table 34: Updated costs in the pre-MSAC response

Data	2022	2023	2024	2025
Round 1 + Round 2 patient numbers and revised real-world overhead cost (updated base case)				
Total costs	$90,637,882	$97,891,373	$105,634,093	$113,905,091
Overhead costs	$31,017,034	$33,802,039	$36,798,066	$40,022,572
Updated base case + Only apply certification to 10% per annum				
Total costs	$87,043,743	$94,077,992	$101,601,470	$109,653,225

Source: Table 1, pre-MSAC response.

9. Estimated total number of devices being serviced

One of the aims of the request for the application was to determine the total number of active CIEDs in Australia (i.e. how many devices are currently in use and in need of services on a regular basis). However, this number is difficult to determine due to an absence of reporting this data by the MTAA CF members.

The total number of active CIEDs in the KPMG report was estimated to be 252,671 in 2022/2023.

Based on the number of PPMs and ICDs sold in Australia (with the assumption that all of these devices will be implanted), and the average length of time a device is in use (although it is recognised that some of these sources are possibly out-of-date), the average number or range of active devices in Australia was estimated (Table 35). It should be noted that these numbers are uncertain. Based on these estimates, there would be 226,947 – 247,756 active CIEDs in Australia. This estimate is slightly lower than KPMG's estimate.

The MBS item for remote monitoring for a PPM was claimed 34,463 times in the 2021-2022 financial year. This item is payable only once in a 12-month period, which means it was claimed for only 34,463 patients. Not all patients with a PPM will currently have a remote monitoring option, and a proportion of patients will receive monitoring through the public health system and therefore would not be claiming the MBS item. If the estimated number of active PPMs is accurate (n=181,368) this would mean only 19.0% of patients with a PPM had remote monitoring in the private system.

A member of the reference group stated that of all replacement and new implants in 2021, around 70% of individuals were billed for the provision of remote monitoring. This is a higher percentage than the percentage suggested above. Presumably a proportion of the patients are being supplied with the infrastructure for remote monitoring (a monitor or app), without implementing the remote monitoring. More details surrounding this issue should be provided.

ICD/CRT-D remote monitoring was claimed for 13,026 patients in the 2021-2022 financial year. If there are between 31,463 and 45,589 patients with ICDs and CRT-Ds in Australia, only between 28.6% and 41.4% of patients with an ICD or CRT-D would currently have remote monitoring in the private system. Claim data for remote monitoring of ILRs was not available as the MBS item has only recently been introduced.

Table 35 data to work out the estimated number of devices (prevalent) and total time required for providing services

	PPMs	ICDs	CRTDs	ILRs
Devices sold per year (2021)[21] (assumed to be the number of implanted devices)	25,190	6,421	Not reported	6,933
Average length of time the devices are in use	7.2[22] years	4.923 - 7.1[24] years	CRT- D: 4.5 – 6.0 years[6,25,26,27] CRT-P: 8.4 – 10.4 years[6,7]	2-3 years[28]
Estimated number of active devices in Australia	181,368	31,463 – 45,589	Unknown	13,866 – 20,799

CRTD = cardiac resynchronisation therapy device; ICD = implantable cardioverter-defibrillator; ILR = implantable loop recorder; PPM = permanent pacemaker

10. Advantages and disadvantages of the different care models

Currently within the private health system there are two models of care in operation (Model 2 and Model 3); each model has advantages and disadvantages. Some of these advantages and disadvantages are outlined in Table 36.

[21] Mond HG, Crozier I, Sloman Retired JG. The Australian and New Zealand Cardiac Implantable Electronic Device Survey, Calendar Year 2021: 50-Year Anniversary. Heart Lung Circ. 2022 Nov 10:S1443-9506(22)01129-5. doi: 10.1016/j.hlc.2022.09.016. Epub ahead of print. PMID: 36372717.

[22] Katz, D. & Akiyama, T. 2007. Pacemaker longevity: the world's longest-lasting VVI pacemaker. *Ann Noninvasive Electrocardiol,* 12**,** 223-6

[23] Manolis AS, Maounis T, Koulouris S, Vassilikos V. "Real life" longevity of implantable cardioverter-defibrillator devices. *Clin Cardiol.* 2017 Sep;40(9):759-764.

[24] NICE. 2014. Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. Technology appraisal guidance [TA314]

[25] Hadwiger, M., Dagres, N., Hindricks, G., et al. 2022. Device runtime and costs of cardiac resynchronization therapy pacemakers - a health claims data analysis. Ger Med Sci, 20, Doc02

[26] Bossard, M., Sticherling, C., Kühne, M., et al. 2014. Outcome of patients with cardiac resynchronisation defibrillator therapy and a follow-up of at least five years after implant. Swiss Med Wkly, 144, w13938.

[27] Zanon, F., Martignani, C., Ammendola, E., et al. 2016. Device Longevity in a Contemporary Cohort of ICD/CRT-D Patients Undergoing Device Replacement. *J Cardiovasc Electrophysiol,* 27**,** 840-5

[28] Mofrad, P. S. 2012. Implantable Loop Monitors. Circulation, 126, e472-e474.

Table 36 Advantages and disadvantages of Model 2 and Model 3

	Model 2: clinic employs cardiac technicians with occasional IECT technical support	Model 3: clinic relying on IECTs for all services
Advantages	• The patient sees the same technician for each scheduled service (continuity of care) • Technicians provide most services in the clinic (more centralised care, less travel costs and wait times for technicians) • More efficient scheduling of services possible (cost saving)	• No out-of-pocket expenses for patients • IECTs have more knowledge about CIEDs manufactured by their company than a clinic-employed technician • No need to employ/train clinic-employed cardiac technicians if IECTs provide all services
Disadvantages	• Patients currently have an out-of-pocket fee for accessing technical support services • Still need to rely on IECTs for: o Some after-hours unscheduled service support o implantation support and Day-1 checks o complex/advanced reprogramming o training new technicians o technical advice o Updated information on the device • Potential conflict of interest, confidentiality and ethical issues.	• An IECT is trained in providing services for only one brand of CIED, whereas cardiac technicians employed by private clinics will provide services for a range of brands. Therefore, multiple IECTs may be required to attend a single clinic or hospital to service the different implanted CIED brands • IECTs don't provide many services per location visit because they only service their own company CIEDs, which means there are significant travel costs and wait times (inefficient provision of services). • Potential conflict of interest, confidentiality and ethical issues.

CIED, cardiac implantable electronic device; IECT, industry employed cardiac technician

11. Alternative models of care

International reimbursement models

Information was sought on what models of care are used internationally to provide support for CIEDs, and how they are reimbursed. An overview of European reimbursement was reported by Boriani et al. (2022) (Table 37), with further details on three European countries and the United States shown in Table 38.

Insufficient detail was found on the profession that provides the services, or who is able to access reimbursement. However, different types of reimbursement models are fee for service (as is available for in-person services in France, and available in Germany with a maximum of 5 per year); a subscription model (set fee for all services within a certain time-period; as per remote monitoring in France, and for both in-person and remote monitoring in the United States); or a combination of both (one fee for 1-2 services, and another fee for ≥3 services, as per the Netherlands).

Table 37 Reimbursement for in-person and remote monitoring in Europe

Country	Reimbursement tariff for in-person device check	Reimbursement tariff for remote monitoring	Reimbursement specific for hardware and service remote monitoring	Reimbursement tariff for HF disease management
Austria	Yes	No	No	Yes, from 2022
Belgium	Yes	No	No	No
Bulgaria	No	No	No	No
Czech Republic	Yes	Yes	Yes	No
Denmark	Yes	Yes	Yes	No
Finland	Yes	Yes	Yes	No
France	Yes	Yes	Yes for some health insurance	No
Hungary	Yes	Yes	No	No
Italy	Yes	Yes (in 10/20 regional health services)	No	No
Norway	Yes	Yes	No	No
Poland	No	No	No	No
Portugal	Yes	Yes	No	Yes
Russia	No	No	No	No
Slovakia	No	No	No	No
Spain	Funded, no tariff	Funded, no tariff	N/A	No
Sweden	Yes	Yes	No	No
Switzerland	Yes	Yes	Yes	Yes
The Netherlands	Yes	Yes	No	Yes
UK	Yes	Not at a national level	Ordered by NHS Trusts	No

Source: Boriani, G, Burri, H, Svennberg, E, Imberti, JF, Merino, JL & Leclercq, C 2022, 'Current status of reimbursement practices for remote monitoring of cardiac implantable electrical devices across Europe', *Europace*, Jul 29.

Table 38 Details of reimbursement models

Component	France[a]	The Netherlands[a]	Germany[a]	United States[b]
Service costs	*Remote:* ICDs and PPMs: twice per year lump sum of €65 per patient (€130 per year) to cover remote data interrogation and management of alerts ILR: not currently reimbursed *In-person:* ICDs: €70.48 FFS PPMs: €60.41 FFS	Whole care episode covered by "Diagnose Behandeling Combinatie". Same tariffs applied whether in-person or remote. ICDs: mean 2019 price €175 if 1-2 (e)visits, and €365 if >2 (e)visits PPMs: mean 2019 price €170 if 1-2 (e)visits, and €300 if >2 (e)visits ILRs: mean 2019 price €190 if 1-2 (e)visits, and €390 if >2 (e)visits for impulse and conduction disorders	ICD, CRT-P, CRT-D: same fee for in-person and remote ICD: €44.5 FFS (maximum 5x/year) CRT-P, CRT-D: €54.73 FFS (maximum 5x/year) PPM (single and double chambers): RM not reimbursed ILR: RM not reimbursed	For both in-person and RM: *For interrogation:* PPMs, ICDs, CRTDs: services billable every 90 days ILRs: services billable every 30 days *For programming:* Can bill in addition in same period If IECT involved in performing technical service, physician may not bill for the service, and may only bill for services performed by physician
System costs	ICD: RM system included in list of reimbursed products separate from implant. €864 for RM system of single or double chambers €972 for RM systems of triple chambers PPM: No separate tariff but higher tariffs for some implants with a RM system. Additional €500 for rate-adaptive single or double chambers PPMs if >50% of patients are under RM Additional €700 for triple chamber and resynchronisation PPMs if >50% of patients are under RM ILRs: no separate tariff	Covered by DBC system (no separate tariff)	RM infrastructure and support services not usually reimbursed (only selective contracts with health insurance) but under discussion	

Source: [a]KCE report 345: remote monitoring of patients with cardiovascular implantable electronic devices
[b] Medtronic reimbursement guide
DBC = Diagnose Behandeling Combinatie; FFS = fee for service; RM = remote monitorin

12. Proposed model of care in private clinics/hospitals

The current models of care in private clinics/hospitals (Models 2 and 3) rely to a greater or lesser extent on IECTs for technical support where specialist knowledge of a CIED supplied by their company is required. The role of IECTs is acknowledged in the CSANZ guidelines for CIED follow-up in Australia.

IECTs rarely provide any support for CIEDs supplied by other companies. Use of only IECT support in a clinic (Model 3) without an obligation to pay for services supplied by the IECT rather than directly employing a cardiac technician may have benefits for the cardiologist as no investment in staff employment and training is required and costs to the private clinic or cardiologist are lower. However, reliance on IECTs is associated with published concerns around potential conflicts of interest, confidentiality and ethical issues particularly as they interact directly with patients (under the supervision of a cardiologist/physician) as part of the clinic technical services team.

The case for specific reimbursement of IECTs providing CIED technical services rather than for all similarly qualified cardiac technicians involved in CIED follow-up, whether in the public or private sector, is unclear based on information in the ADAR. IECTs may advocate for their company and its products when attending a clinic or hospital providing customer support. Their role has benefits to the company, such as: developing relationships with their customer-base (clinicians and hospitals/clinics), and this may benefit or maintain company market share in Australia; obtaining feedback directly from product users (clinic staff and patients); and, having direct access to patient data/information through follow-up checks or remote monitoring that may benefit ongoing CIED product development. Reliance on IECT specialist support within a clinic/hospital has benefits but could negatively impact on upskilling and further training of clinic/hospital employed cardiac technicians. While there are overheads and costs to industry of providing services via IECTs, there are obvious benefits highlighted above that are not discussed in the ADAR.

Moving towards Model 2 where a clinic or hospital employs their own cardiac technicians reduces reliance on IECTs for services that do not require specialist input and increases flexibility for the cardiologist and clinic staff when scheduling CIED follow-up appointments. It may also increase the role of cardiac technicians employed in a private hospital setting in unscheduled services and support during CIED implantation. Investment in accredited training in combination with hands-on training at clinics/hospitals for graduates or healthcare staff wishing to become cardiac technicians, and development of specialist programs for upskilling of current cardiac technicians, could potentially lead to an increase in the overall number of cardiac technicians in Australia, providing a skilled workforce that benefits both the public and private healthcare sectors. Industry could potentially have a role in both the development and delivery of accredited training. The current lack of accredited training and trained cardiac technicians may be a barrier to the adoption of Model 2 in private clinics/hospitals.

The ADAR discusses efficiencies that could potentially reduce costs associated with the provision of CIED follow-up services. These efficiencies and potential approaches to reimbursement of technical services are included below for each of the services provided by IECTs and, in some cases, by clinic/hospital employed cardiac technicians.

CIED implantation support and Day-1 post-implantation check

As for other implanted devices, it would be reasonable to consider that reimbursement for CIED implantation technical support is included in the device cost for CIEDs. Services provided by IECTs may be considered as “customer support activities”, ensuring that the implanted CIED is working safely and effectively, and consistent with the implanting cardiologist’s expectations. In many cases, CIED implantation is carried out as day surgery and the Day-1 check may be achieved through remote interrogation of the CIED rather than as an in-person consultation with the cardiologist and IECT.

Scheduled in-person follow-up services

The degree of IECT involvement in scheduled follow-ups may depend upon whether the clinic or hospital employs their own cardiac technicians, the training of the cardiologist and whether the service requires IECT specialist knowledge of the particular CIED to resolve a clinical or system issue. For scheduled in-person follow-ups, IECTs currently only deliver 1 or 2 services per visit to a clinic located in metropolitan areas. The overheads and cost of transportation associated with the provision of a small number of services is high under these circumstances. A greater number of services are carried out at each regional and remote clinic which is more efficient. The ADAR states that industry is responding to these acknowledged inefficiencies in service delivery by reducing a requirement for attendance to deliver some technical services.

A member of the reference group considered that the average number of scheduled checks per FTE IECT (9.3 per week) was a low workload for one FTE. Another member of the reference group stated that in private CIED follow-up clinics, an employed cardiac technician will see 15-20 patients per half day for scheduled checks.

Funding could be provided on a fee per service basis to the clinic to provide reimbursement for technical support to either an IECT or non-industry cardiac technician depending upon the service required. The physician can already claim MBS reimbursement for CIED follow-up patient consultations, either scheduled or in response to remote monitoring alerts.

Unscheduled in-person cardiac technical support services

Unscheduled services form a small proportion of overall CIED technical services. However, the burden of providing them is high in terms of availability of IECT or cardiac technicians at short notice and costs of in-person attendance 24 hours/7 days per week to carry out the required service. Because these are often arranged at short notice, only one unscheduled technical service is likely to be required at a single location per trip. These services are therefore likely to be associated with higher overheads and costs (increased time, travel and salary costs) than routine scheduled services where multiple patients can be seen and services carried out at a single location.

Reimbursement on a fee per service basis may be most appropriate for unscheduled services as the costs vary according to the service provided. A review of the proportion of unscheduled services that would require in-person IECT assistance is required. Many unscheduled services occur in hospitals (that may employ cardiac technicians) or, with the development of new technology, could be performed remotely in the future to reduce the need for in-person attendance.

Members of the reference group have highlighted that many of the unscheduled checks described by the applicant can now be streamlined using remote monitoring technology provided by industry. It is considered that this process is likely to increase, significantly reducing the need for IECTs to attend some of these unscheduled requests in person.

Remote monitoring services

Remote monitoring of CIEDs is considered the new standard of care and CSANZ guidance is that it should be offered to patients wherever possible.

IECTs or non-industry employed cardiac technicians may be involved in reviewing and triaging remote transmissions to determine if a clinically actionable event has been identified. IECTs involved in reviewing of remote transmissions are based at remote monitoring centres (sometimes located overseas) rather than in a clinic or hospital. In some countries, such as in the

UK and US, reviewing transmissions from remote monitoring services has been contracted out to third-party providers.

CIED remote monitoring infrastructure (monitor/smartphone app and servers for data storage) is currently funded by the PL at the time of device implantation. A reference group member highlighted that not all individuals billed for the provision of remote monitoring infrastructure had their remote monitoring activated and enrolled in the remote monitoring service.

Funding for review of remote monitoring clinical or system alerts is currently provided by an item for each CIED type via the MBS. Additionally, some private clinics providing their own remote monitoring service are charging an annual fee to the patient for review of remote transmission and associated administrative tasks. Whether the MBS item and these fees are adequate to cover the cost of providing the service or represent an acceptable cost to the patient is currently unclear and was not informed by the ADAR.

To assess the cost and value of remote monitoring services, an accurate costing review of providing these services is required to inform an appropriate funding model, noting that the burden of remote monitoring likely differs across different CIED types. Alternative options for providing these services may have vastly differing costs (from the use of individual technicians employed by private clinics that monitor a few hundred patients, to large third-party providers that monitor thousands of patients), and several options could be considered during the review.

13. Discussion

From the data supplied in the ADAR by the applicant, the commentary considered that it was not possible to confidently estimate the number of active CIEDs in Australia. The commentary considered that it was also unclear what proportion of technical services were provided by IECT or, alternatively, cardiac technicians who are not industry-employed. As a result, an estimate of the cost of technical support per device lifetime could not be calculated. The commentary considered that similar limitations applied to estimates of annual costs per device and cost per patient. The commentary considered that establishing a national register of implanted CIEDs would be a valuable resource for assessing service provision for these devices.

The ADAR estimated that 697,258 cardiac services could be provided by IECTs in 2022, at an estimated cost of $73 million. The commentary noted that costs for services associated with the implantation of CIEDs were also included in the total cost. Without implantation services (as they may reasonably be included in the price of the CIED), the overall costs would be reduced by 21.1% to $59.1 million.

To inform the costing and design of alternative models of care (and funding), the commentary considered a robust costing study of each of the services currently provided by cardiac technicians is required. The commentary considered consideration should be given to which costs should be included in the cost of the device, and those that could be reimbursed by fee for service or subscription methods. A member of the reference group indicated that uptake of remote monitoring for newly implanted devices is expected to approach 100%, but the speed with which this will be achieved will be influenced by economic levers exercised by Government. They stated that for cost modelling purposes, it would be reasonable to assume a ≥90% uptake of remote monitoring within 3-5 years. An overall estimate of the financial impact of providing cardiac support services in Australia is required.

The commentary considered alternative models of care that are adequately reimbursed and encourage clinics/hospitals to employ their own cardiac technicians with increasingly limited support by IECTs may have additional benefits for society, such as greater flexibility, efficiency

and effectiveness, plus a reduction in potential conflict of interest associated with IECTs providing advice and services to clinicians. A member of the reference group indicated that this could be an opportunity to move towards a more sustainable yet improved model of patient care for CIED follow-up in Australia. They stated that concerns regarding the smaller public and private services require careful consideration and flexibility with introduction of change. Apart from a change in funding structures, remote monitoring and cardiac physiologists will be the key to implementation success.

12. Key issues from ESC to MSAC

Main issues for MSAC consideration

The purpose of the application to estimate the reasonable cost of cardiac technical support services provided by industry-employed technicians for implanted Cardiac Implantable Electronic Devices (CIEDs). It is claimed by the applicant that the delivery of these services in the public sector is currently cross-subsidised via the Prostheses List (PL) benefits paid for CIEDs by private health insurers, which are higher than the prices paid for the same CIEDs in the public sector. ESC noted that the amount agreed for these cardiac technical support services will be quarantined from the scheduled reduction in PL benefits for CIEDs. ESC considered the clinical value and need for these services was not being queried in this application.

The applicant did not provide information on possible alternative models of care. The current model is inefficient (53% of industry-employed cardiac technicians visits are for a single patient) and problematic. The current model of care promotes the provision of CIED care by cardiologists without adequate experience in CIED patient management, by enabling reliance on industry-employed cardiac technicians for support. This model of care also results in a lack of transparency with industry arrangements and that reform in this space should clarify the role of industry as providers of the CIED who also provide device specific software and support as needed rather than being the primary provider of cardiac technical services. The funding arrangements for the current model are not transparent and appear to have driven higher prices for devices for privately insured patients. ESC advised that future reforms should aim to move away from the current model of care being the primary model of care used in Australia. ESC noted that current Medicare Benefits Schedule (MBS) reimbursement for remote monitoring of CIEDs may be insufficient. Consideration could be given to increasing the rebate for remote monitoring under the supervision of cardiologists with CIED expertise, to incentivise the provision of remote monitoring, which is increasingly being used.

ESC considered the cost of cardiac technical support services to be quarantined from PL benefit reductions should exclude peri-implantation services provided to the private sector, and other services provided to the public sector. ESC considered the reasonable cost of cardiac technical support services to be $44.4 million per year.

ESC noted that there are no reliable sources of the current number of patients with active CIEDs, and that the applicant did not provide data on the cardiac technical services per CIED type, as requested by The Department. Therefore it was not possible to estimate the cost of cardiac technical services on a per device or per patient basis.

ESC Discussion

The ESC noted the Department of Health and Aged Care (Department) received an application from the Medical Technology Association of Australia Cardiac Forum (MTAA CF) as part of the ongoing Prostheses List (PL) reform process. ESC noted the MTAA CF members include Medtronic, Abbott, Biotronik, MicroPort CRM and Boston Scientific, who are suppliers of cardiac

implantable electronic devices (CIEDs) in Australia and the providers of cardiac technical support services via industry-employed cardiac technicians.

ESC noted the purpose of the application is to determine the reasonable cost of the cardiac technical services provided by industry-employed cardiac technicians. These services are provided by the technician on behalf of the cardiologist. The applicant states that these services are currently cross-subsidised via the higher Prostheses List (PL) benefits paid for Cardiac Implantable Electronic Devices (CIEDs) by private health insurers. In the context of this application, CIEDs included pacemakers (PPMs), implanted cardioverter defibrillators (ICDs), implantable loop recorders (ILRs) and cardiac resynchronisation therapy devices (CRTDs).

The PL sets out prostheses that private health insurers must pay benefits for (for privately insured patients with appropriate cover) and the PL benefit amount. ESC noted the Department is undertaking PL reform activity to reduce the complexity of the PL, reduce differences in private and public sector prices for medical devices, and streamline assessment pathways for access to new medical devices. The pricing reforms include better aligning the cost of prostheses to the public system and comparable to those in international markets. This will be achieved through scheduled reductions to the PL benefits, based on the 'gap' between the weighted average public sector price (WAP) and the PL benefit amount ("the gap"), as follows:

- 1 July 2022 a 40% reduction of the gap
- 1 July 2023 a 20% reduction of the gap
- 1 July 2024 a final 20% reduction of the gap

ESC noted the Department deferred the scheduled 1 July 2022 PL benefit reductions for CIEDs for 12 months pending the outcome of the current MSAC application, in line with the March 2022 Memorandum of Understanding (MoU) between the Minister for Health and Aged Care and the MTAA. This was due to concerns raised by the MTAA CF members that the reductions in PL benefits for CIEDs will reduce the ability of the MTAA CF members to provide CIED technical support services via industry-employed cardiac technicians on the basis that these services are currently funded through the PL benefits paid by health insurers for the devices. The MoU allows for MSAC deliberations on the cost of the cardiac technical support services.

ESC noted that the PL benefit typically relates to the price of devices, not the services associated with them. However, ESC recognised that, in the case of CIEDs, a component of the current PL benefits is attributable to the provision of cardiac technical support services by industry-employed cardiac technicians. ESC noted that following MSAC's consideration of this application, the reasonable cost of the cardiac technical services provided by industry-employed cardiac technicians will be quarantined from the scheduled reductions to the PL benefits. In practical terms, the PL benefits attributed to the provision of cardiac technical support services will be removed from the gap calculation between private and public sector prices, therefore reducing the gap on which the scheduled reductions will apply.

While ESC recognised the immediate need to provide advice to MSAC regarding the amount of the PL benefits that should be attributable to the devices compared to that reasonably attributable to the associated follow-up services, ESC also considered there is a significant need for wider reforms of how cardiac technical services are provided. ESC considered a wider system-level review of models of care that do not rely on an industry-centric model of cardiac service provision should be the subject of future, longer term reforms.

ESC noted the ADAR referred to industry-employed cardiac technicians as "Industry Employed Allied Health Professionals (IEAHPs)". ESC further noted that cardiac technicians are not currently recognised as allied health professionals through the Australian Health Practitioner Regulatory

Agency (AHPRA) or self-regulated through a relevant professional organisation. ESC considered for the purpose of this application the term IEAHPs should be replaced with industry-employed cardiac technicians (IECTs).

ESC noted MSAC had not considered applications related to the funding of cardiac support services provided by industry-employed cardiac technicians, however MSAC had previously considered applications in relation to remote monitoring of patients with implanted cardiac devices (MSAC Applications 1197, 1197.1) and ILRs (Application 1443).

ESC noted that the 2021 MTAA-commissioned KPMG report on CIED service valuation estimated 220,172 Australians are living with a CIED. ESC was concerned that there is no way of verifying this number or determining the actual number of Australians living with functional CIEDs, highlighting the need for better data collection through a national CIED registry.

ESC noted the submission request made by the Department and the data subsequently provided by the MTAA CF in the ADAR (refer to Table 2). ESC noted that although this application arose due to industry's concerns with the scheduled PL benefit reductions, ESC considered the applicant did not provide sufficient data in their ADAR to answer the key questions posed in the submission request. Further, ESC considered the applicant had not provided an adequate rationale for not doing so. ESC noted that given the reductions to the PL benefits for CIEDs are scheduled to proceed in July 2023, its advice to MSAC will be based on the level of data provided by the applicant in the ADAR. That is, MSAC will advise the Department on the reasonable cost of cardiac support services at the aggregate level across all CIEDs and not on a per device or per patient basis.

ESC noted the current clinical management algorithm for follow-up of patients implanted with CIEDs (Figure 2). ESC considered that efficiencies can be gained in the follow-up of patients with CIEDs by maximising the use of remote monitoring, which could be used to conduct day-1 checks, scheduled remote transition checks, as well as clinical cardiology reviews. ESC noted that in the next 3-5 years, 90% of people with CIEDs could be monitored remotely[29]. ESC agreed with the applicant's pre-ESC response that there are several studies which have established the safety and effectiveness of remote monitoring of patients with CIEDs. ESC noted the clinical need for these services is established and the clinical value of these services was not being queried in the MSAC process. ESC also noted the Heart Rhythm Society has recommended that ILR patients with wireless transmission capabilities could be remotely monitored.

ESC noted that a clinical expert reference group was consulted during the evaluation of the ADAR. ESC noted the reference group were supportive of initiatives to increase uptake of remote monitoring of CIEDs, noting that the experts expressed the view that the current MBS fees for remote monitoring are too low, presenting a potential barrier to uptake. ESC also noted the input provided by the reference group that in the private clinic setting (which employs its own cardiac technicians), approximately one full-time cardiac technician (1 FTE) is able to provide services for 400-500 patients. ESC also noted that remote programming of CIEDs is on the horizon, however this aspect of care is not expected to be part of routine practice for several years.

ESC noted the different categories of technical service associated with CIEDs and the settings in which they are provided (Table 3). ESC again highlighted the opportunity which exists for most services to be provided through remote monitoring.

In relation to the models of care associated with the provision of cardiac services in Australia, ESC noted the 3 main models outlined in the commentary were:

[29] Kelly, Shannon E., et al. "Virtual follow-up and care for patients with cardiac electronic implantable devices: protocol for a systematic review." *Systematic Reviews* 9 (2020): 1-10.

1. Services provided through public hospitals and outreach services that employ cardiac technicians;
2. Services provided through private cardiologists who employ cardiac technicians; and
3. Services provided through private cardiologists relying only on industry-employed cardiac technician support

ESC noted that the applicant did not provide information on alternative models of care. In the pre-ESC response (p2), the applicant expressed the view that this was out of scope of the current application given "the purpose of this application is to value cardiac technical support services provided by IECTs with the main aim of finding a long-term funding mechanism for these services." ESC did not agree, considering that alternative models of care should be examined as part of this application given the purpose of the application is to determine the *reasonable* cost of cardiac support services.

ESC advised that future reforms should aim to move away from the third model of care being the primary model of care used for private patients in Australia. ESC considered this model of care perpetuates dynamics that work against solutions to address fundamental problems that reduce quality of care provided to patients, and increases costs (53% of industry-employed cardiac technicians visits are for a single patient). ESC was concerned that the current model of care promotes the provision of CIED care by cardiologists without adequate experience in CIED patient management, by enabling reliance on industry-employed cardiac technicians for total support. Further, ESC considered this model of care results in a lack of transparency with industry arrangements and that reform in this space should clarify the role of industry as providers of the CIED who also provide device specific software and support as needed rather than being the primary provider of cardiac technical services through a non-transparent funding arrangement. ESC noted the current Medical Research Future Fund research grant opportunity for the assessment of Digital Health Interventions that includes a stream for an implementation trial of remote monitoring of some CIEDs.[30]

ESC recognised there are many stakeholders in this space with varied perspectives and interests. ESC highlighted the importance of keeping the patient interests at the forefront of these issues. ESC noted that industry and some consultation input received expressed strong concern that with inadequate reimbursement, industry's ability to sustain provision of cardiac technical support services will be significantly compromised, potentially resulting in extra costs being passed on to patients.

From the consumers' perspective, ESC noted that if private health insurance premiums remain the same, then out-of-pocket costs could increase to cover the cardiac technical services. This might result in patients avoiding device checks in order to avoid out-of-pocket costs. ESC considered greater transparency on how device manufacturers handle patient data from CIEDs was important to consumers.

ESC noted that the ADAR focuses on justifying the current PL benefits for CIEDs. The ADAR states the following with respect to services delivered by industry-employed cardiac technicians:

- *Provide up-to-date, highly specialised knowledge of specific devices.*

  ESC considered the claim that industry-employed cardiac technicians provide up-to-date, highly specialised knowledge of specific devices is not disputed, however it would be reasonable to conclude that public sector employed cardiac technicians have broad

[30] Assessment of High-Cost Gene Treatments and Digital Health Interventions Grant Opportunity. Accessed from: https://www.grants.gov.au/Go/Show?GoUuid=5b899505-a6fe-4e38-b1ec-a607bf302229

knowledge and therefore a broad knowledge of these devices should also be valued in addition to the in-depth specialised knowledge of individual devices possessed by industry- employed cardiac technicians who only service their own devices.

- *Services are provided on-demand, and meet otherwise unmet need in regional and remote areas*

  ESC considered no data have been provided to support the statement that these services are provided on-demand and meet an otherwise unmet need in regional and remote areas.

- *Provide free training to cardiac technicians in the public sector*

  ESC questioned whether this claim was accurate given cardiac technicians are often trained in the public sector and are subsequently employed by industry. It was also noted that the training provided by industry is device-specific.

- *That existing MBS items for cardiac services go toward the clinician's time only with no reimbursement for industry-employed cardiac technicians*

  ESC noted that notwithstanding the input received that the fees for the remote monitoring MBS items may be too low for the service provided, there is nothing precluding a cardiologist using MBS revenue to pay technicians for their time.

- *Provide ongoing device education and support directly to patients*

  ESC agreed with the Commentary that direct contact between industry representatives and patients is ethically problematic and is not a practice that should be supported or encouraged.

- *That PL benefits for devices include costs for services delivered to public and private patients, and hence PL benefits for CIEDS subsidise the lower price of devices in the public sector*

  ESC noted that this is one of the key considerations of this application.

ESC noted that no evidence was presented in the ADAR to justify an incremental value of industry-employed cardiac technicians providing these services compared to non-industry employed cardiac technicians. ESC therefore considered there was no evidence to support that industry-employed cardiac technicians should be remunerated at a higher rate than non-industry employed cardiac technicians.

ESC noted the ADAR presented the results of a prospective data collection exercise conducted over a 4-week, or 28-day period (15 August 2022-11 September 2022). The aim was to collect information on all cardiac technical support services provided by industry-employed cardiac technicians from the five MTAA CF members during this time period.

ESC noted the ADAR estimated that the cost of cardiac technical services provided by industry-employed cardiac technicians was $73 million per year. ESC noted that approximately $20 million was for services provided in the public system. ESC noted that the data presented in the ADAR showed that 17.6% of all in-person support services and 16.4% of device implantations (not mutually exclusive) were provided by industry-employed cardiac technicians occurred in a public hospital (1,886 of 10,711 services) during the 4-week data collection period. ESC considered that given the purpose of the PL is to set out minimum benefits for privately insured patients, PL benefits should not be used to cross-subsidise public sector activity and that these costs should be removed from the calculation of the reasonable cost of follow-up services. ESC considered that sections of the public sector may not have sufficient capacity to take over

aspects of this work and therefore also rely on the use of industry-employed cardiac technicians, however this creates non-transparent funding arrangements for these services in the public sector.

ESC considered it was also reasonable to remove the costs included in the ADAR associated with peri-implantation services, including Day 1 checks (approx. $9 million for 2022). ESC acknowledged the applicant's pre-ESC response that these peri-implantation services are required, however considered them to be a component of the device price, consistent with how implantation support services have been managed for other devices on the PL requiring similar support. Therefore by removing the costs included in the ADAR associated with public sector activity and peri-implantation services, ESC considered the reasonable aggregate cost for cardiac technical support services provided to privately insured patients that could be quarantined from PL benefit reductions should be $44.4 million, instead of the $73 million proposed in the ADAR.

Table 39: ESC's revised calculation of cardiac technical support services for 2022

Component	Cost
Total cost of cardiac technical support services [a]	$73,275,912
Services for public hospitals	$19,797,096
Implantation and Day-1 services (private) [b]	$9,039,160
Revised cost (excluding public hospital and implantation associated services)	**$44,439,655**

Source: Table 4-17, p95 of the commentary and calculated for the ESC report.

[a] Revised from $73,275,613 in the ADAR.

[b] Calculated from Attachment 5 of the ADAR. Included Labour and Travel costs for private sector. Training costs were calculated as the proportion of training costs for scheduled services x proportion of scheduled services that were implantation support or Day 1 post implantation services

ESC considered the estimates presented in the ADAR, and its revised cost for private patients to be overestimated as they are based on the costs of an inefficient system and appeared to include inflated costs (such as $212,000 - $250,000 onboarding costs).

ESC considered there are currently no incentives for cardiologists to move away from expecting on-demand service provision even for scheduled services (e.g. by scheduling patients for review on the same day) and in future there will likely be a reduction in the need for cardiac technicians to be present for unscheduled services, noting the increasing availability of remote monitoring and the already diminishing need for cardiac technicians to be present in radiation oncology and emergency department settings. ESC noted that the applicant provided revised costs of cardiac technical support services based on a further 4-week data collection. ESC noted the estimated cost of cardiac technical support services provided by industry-employed cardiac technicians rose from $73 million to $91.3 million as a result of this additional data collection. ESC considered the revised figures could not be adequately evaluated.

ESC noted the PL benefits paid for remote monitoring systems associated with CIEDs listed in Part C of the PL, were not accounted for in the ADAR as an additional source of funding cardiac services provided. ESC noted the PL benefit amount for the remote monitoring systems is $1,450, paid at the time of implantation in addition to the PL benefit associated with the device. The benefit includes both the price of the transmitter and lifetime access to remote monitoring services. Given this benefit is provided in addition to the benefit paid for the device at the time of implantation and it is associated with the provision of remote monitoring services provided by industry, ESC queried whether it should be removed from the cost of cardiac services presented in the ADAR. ESC requested the applicant addresses this issue in its pre-MSAC response.

ESC noted that in 2020-21 (the most recent financial year with mostly complete Casemix data) total CIED PL benefits were $199 million. Quarantining $44.4 million for the provision of cardiac

technical support services would result in a 'gap' of $74.3 million to which the reductions would be applied (Table 40).

Table 40: Calculations of the gap for CIEDs in 2020-21

CIED	Total items	PL Benefits (private sector)	Public weighted average price [a]	Gap (PL benefits – public)
ICDs	1,436			
PPMs	12,058			
CRTDs	2,201			
ILRs	4,092			
Total	**19,787**	**$100 million to < $200 million**	**$80 million to < $90 million**	**$100 million to < $200 million**
Public sector costs (ADAR)	-	$19,797,096	-	-
Implementation and Day 1 services [b]	-	$9,039,160	-	-
Total excluding peri-implantation and public sector costs	-	-	-	$70 million to < $80 million [c]

Source: Table 4-17, p95 of the commentary and calculated for the ESC report.

[a] The public weighted average price has been calculated by applying the Independent Health and Aged Care Pricing Authority Weighted Average Price to CIED items recorded in the 2020-21 Hospital Casemix Protocol data collection. The data presented was considered by ESC and MSAC and correct at the time of provision.

[b] Calculated from Attachment 5 of the ADAR. Included Labour and Travel costs for private sector. Training costs were calculated as the proportion of training costs for scheduled services x proportion of scheduled services that were implantation support or Day 1 post implantation services

[c] Calculated as the 'gap' ($100 million to < $200 million) minus the reasonable cost of technical support services ($44,439,655).

13. Applicant comments on MSAC's Public Summary Document

The MTAA Cardiac Forum (CF) welcomes that MSAC has recognised cardiac support services provided by IECTs to be clinically necessary and important for people with CIEDs. We support MSAC's advice to conduct further work on determining the most effective service models, the most appropriate funding models, and where required the best way to transition to any new arrangements. Our goal is to ensure patients with CIEDs maintain the highest possible quality of life through access to high-quality, universal and on-demand services with no out-of-pocket costs. We will continue to engage with all relevant stakeholders in ongoing work to achieve this goal with the most efficient service delivery model.

While the MTAA CF supports further work among stakeholders and the Department to reconcile cost estimates in the evaluation with the real-world costs of delivering IECT services in the public and private settings, they contest several key assumptions in the MSAC evaluation. MTAA CF conducted two rounds of robust data collection to gather actual utilisation data for total services and used real-world, plausible assumptions to estimate the total cost to the CF member companies of delivering IECT services in the public and private settings in Australia. In contrast, the MSAC have advised that flawed inputs be used that are not evidence-based to assess what they consider to be the "reasonable" cost or "value" of cardiac technical services provided by IECTs. Details of the contested assumptions are given below. The MTAA CF considers that this evaluation has not followed MSAC's usual rigorous standards.

Excluding peri-implantation support from the cardiac services under evaluation does not reflect the reality of providing services for CIEDs in Australia.

MSAC has advised that peri-implantation services should be included in the device benefit, as opposed to grouping it together with the post-implantation follow-up services. The MTAA CF has significant concerns over this recommendation due to the following reasons:

1. Implications for PL device benefit adjustment

Under the current MoU, the private PL benefit for a device will be compared to the Weighted Average Public Price (WAPP) for this device type with the PL benefit reduced based on this gap between the public sector weighted average price and the PL benefit. This methodology was conceived on the assumption that the product (and any embedded services) was similar across both the public and private sectors.

If peri-implantation services were to be included in the public sector average price, this would create a substantial distortion because these services are provided and paid for in completely different ways across the two sectors for CIEDs. In the public sector, the peri-implantation support is provided by cardiac physiologists employed by the public hospital system. The price paid, usually tender based, is therefore for the device only and excludes routine implantation support. In the private sector, however, the peri-implantation services are routinely provided by the device manufacturers funded through the current PL benefit.

If as per MSACs advice the private peri-implantation service costs were to be included in the PL device benefit, the reference pricing and PL benefit adjustment methodology would now compare "device+ peri-implantation service" in the private sector with "device only" in the public sector. This should therefore be accounted for through either the inclusion of peri-implantation costs in the total costs of cardiac technical services or an adjustment in the PL benefit reduction methodology.

2. Future CPI considerations for high-cost peri-implantation service component

Private peri-implantation services are one of the higher cost components of the entire cardiac services offering. Highest accreditation level requirements on IECT staff, broad inventory requirements to cater for every patient and clinical scenario, short-notice availability, out of hours and weekend service provision all mean that this service component has a higher-than-average service unit cost. Like so many other service costs, these are generally locally funded and subject to annual CPI increases.

Reducing the wage rate of cardiac technician to $50 per hour is implausible, undervalues the experience of highly skilled workforce and does not consider the reality of private healthcare sector salary.

IECTs work in a highly demanding role providing universal, on-demand services that have been recognised by the MSAC to be 'necessary and clinically important'. The Australian IECT workforce is a highly trained, highly experienced group of workers paid a fair wage to perform this demanding role. They are often required to work non-office hours including weekends and public holidays. Accordingly, the base case costing model included an assumption of $85 per hour, which was verified through published sources. The majority of IECTs employed by the MTAA CF member companies currently have more than 10 years of experience in this field, further validating the $85 assumption. In contrast, MSAC has used an unsubstantiated estimate of $50 per hour as an appropriate average hourly rate, which would mean these skilled technicians are taking an effective 40% salary cut.

Reducing onboarding costs to $30,000 per cardiac technician is inconsistent with real-world training required for IECTs to be able to work independently.

The MSAC proposes the onboarding and training costs for new IECTS should be $30,000 per employee based on the unjustified salary rate of $50 per hour. The industry bears a significant cost burden to employ and train this workforce to a point where they no longer require any supervision when conducting technical services. This measure includes the cost of time to provide on-the-job training for a new IECT as well as time towards supervision until the IECT can conduct services independently.

To become proficient across a range of device types to treat simple and complex cardiac arrythmias typically takes up to two years. Companies only sign off for an IECT to support implantation and follow-up services once the employee has demonstrated mastery of training modules related to the type of device and the various conditions the devices are designed to treat.

To send an IECT into the field with only 6 months of training, as considered sufficient by MSAC, is potentially dangerous and could harm patient safety. MTAA CF, as employers of the IECTs, would not be comfortable eroding or reducing internal safety and training protocols about the proficiency of their patient-facing employees.

14. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: visit the MSAC website