



Australian Government

Department of Health

Application Form

Cardiac ablation devices for use in ventricular arrhythmia and supraventricular tachycardia

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

Please use this template, along with the associated Application Form Guidelines to prepare your application. Please complete all questions that are applicable to the proposed service, providing relevant information only. Applications not completed in full will not be accepted.

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

Email: hta@health.gov.au

Website: www.msac.gov.au

PART 1 – APPLICANT DETAILS

1. Applicant details (primary and alternative contacts)

Corporation name: Abbott Medical Australia Pty Ltd

ABN: 73 080 212 746

Business trading name: Abbott Medical

Corporation name: Boston Scientific Pty Ltd

ABN: 45 071 676 063

Business trading name: Boston Scientific

Corporation name: Johnson and Johnson Medical Pty Ltd

ABN: 85 000 160 403

Business trading name: Johnson and Johnson Medical

Corporation name: Medtronic Australasia Pty Ltd

ABN: 47 001 162 661

Business trading name: Medtronic Australasia

Primary contact name: REDACTED

Alternative contact name: REDACTED

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

Yes

No

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

N/A

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Cardiac ablation devices for use in ventricular arrhythmia (VA) and supraventricular tachycardia (SVT) regarding Part C of the Prostheses List (PL)

(This is not an application for a proposed new medical device/service, rather to amend reimbursement conditions on Part C of the PL).

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

The populations for whom expansion of the PL listing for cardiac ablation devices is sought, for ablation procedures, are patients with symptomatic VA or (non-atrial fibrillation [AF]) SVT.

A cardiac arrhythmia is a condition where a person's heart beats too fast (tachycardia), too slow (bradycardia), or with an irregular rhythm. This results from a disruption of the electrical conduction of the heart and may occur in brief episodes (paroxysmal), or it may be a longer-term or permanent condition. Arrhythmias are classified according to their origin in the heart - VAs originate from the ventricles of the heart and supraventricular arrhythmias arise from the atria and/or atrioventricular (AV) node (most commonly referred to as SVT). Cardiac arrhythmias including VA and SVT increase morbidity and are associated with increased mortality from sudden cardiac death (Brugada 2019, John 2012).

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

Cardiac ablation catheters are used in minimally invasive procedures in which a cardiac electrophysiologist advances a flexible thin wire (catheter) through the blood vessels to the heart to stop (ablate) electrical signals in the heart tissue (arrhythmias) using either radiofrequency catheter ablation (RFCA) or cryoablation.

RFCA systems deliver radiofrequency energy at the tip of the ablation catheter. Significant resistive heating occurs only at the catheter tip-tissue interface and in a small volume of surrounding tissue. The resultant scarring prevents arrhythmias by blocking conduction of electrical activity across it. Prior to the RFCA procedure, a mapping catheter is used to identify the sites to be ablated. RFCA procedures require mapping catheters, ablation catheters and patches.

Cryoablation involves the insertion of a probe into tissue and subsequently destroys the tissue by cooling the probe down to freezing temperatures. Cryoablation cardiac ablation procedures may require mapping catheters and patches when performing ablation in high-risk areas.

6. (a) Is this a request for MBS funding?

- Yes
 No

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

- Amendment to existing MBS item(s)
 New MBS item(s)

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

N/A.

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

- i. An amendment to the way the service is clinically delivered under the existing item(s)

- ii. An amendment to the patient population under the existing item(s)
- iii. An amendment to the schedule fee of the existing item(s)
- iv. An amendment to the time and complexity of an existing item(s)
- v. Access to an existing item(s) by a different health practitioner group
- vi. Minor amendments to the item descriptor that does not affect how the service is delivered
- vii. An amendment to an existing specific single consultation item
- viii. An amendment to an existing global consultation item(s)
- ix. Other (please describe below):

This is not an application for a proposed new medical device/service, rather to amend reimbursement conditions on Part C of the PL (expand the PL funding of cardiac ablation devices to patients with symptomatic VA or (non-AF) SVT with already existing MBS items).

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

N/A

(f) Are the proposed medical services/devices seeking public funding other than the MBS?

- Yes
- No

(g) If yes, please advise:

The current PL (Part C) covers private health insurance (PHI) funding for cardiac ablation of AF (MBS item 38290 services and MBS Item 38287 services related to ablation of AF). This ADAR seeks extension of the current PL listing of cardiac ablation catheters and related technologies ('cardiac ablation devices') to VA and (non-AF) SVT. These cardiac ablation procedures are described in MBS items 38287, 38293 and 38518.

7. What is the type of service:

- Therapeutic medical service
- Investigative medical service
- Single consultation medical service
- Global consultation medical service
- Allied health service
- Co-dependent technology
- Hybrid health technology

8. For investigative services, advise the specific purpose of performing the service (which could be one or more of the following):

N/A

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

- Pharmaceutical / Biological
- Prosthesis or device
- No

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

N/A

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

- Yes, most of the devices
- No, some are in the process of being considered by the PLAC

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

Billing code(s): Insert billing code(s) here

Trade name of prostheses: Insert trade name here

Clinical name of prostheses: Insert clinical name here

Other device components delivered as part of the service: Insert description of device components here

See Attachment A for details.

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

Yes, see Attachment A for details

No

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

Yes

No

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

Biotronik (see Attachment A for details)

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

Single use consumables: Insert description of single use consumables here

Multi-use consumables: Insert description of multi use consumables here

See Attachment A for details

PART 3 – INFORMATION ABOUT REGULATORY REQUIREMENTS

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

Type of therapeutic good: Insert description of single use consumables here

Manufacturer's name: Insert description of single use consumables here

Sponsor's name: Insert description of single use consumables here

See Attachment A for details

- (b) Is the medical device classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?

- Class III (catheters)
 AIMD
 N/A (patches are Class I)

14. (a) Is the therapeutic good to be used in the service exempt from the regulatory requirements of the *Therapeutic Goods Act 1989*?

- Yes (If yes, please provide supporting documentation as an attachment to this application form)
 No

- (b) If no, has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?

- Yes (if yes, please provide details below)
 No

See Attachment A for details

15. If the therapeutic good has not been listed, registered or included in the ARTG, is the therapeutic good in the process of being considered for inclusion by the TGA?

N/A

16. If the therapeutic good is not in the process of being considered for listing, registration or inclusion by the TGA, is an application to the TGA being prepared?

N/A

PART 4 – SUMMARY OF EVIDENCE

17. Provide an overview of all key journal articles or research published in the public domain related to the proposed service that is for your application (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

	Type of study design	Title of journal article or research project	Short description of research (max 50 words)	Website link to journal article	Date of publication
VENTRICULAR ARRHYTHMIA					
1	Systematic literature review with meta-analysis	Anderson, RD, Ariyaratna, N, Lee, G, et al. (2019). "Catheter ablation versus medical therapy for treatment of ventricular tachycardia associated with structural heart disease: Systematic review and meta-analysis of randomized controlled trials and comparison with observational studies." <i>Heart Rhythm</i> , 16(10): 1484-1491.	To assess the impact of cardiac ablation compared to medical therapy on outcomes in patients with monomorphic VT and structural heart disease. Primary outcome was arrhythmia recurrence. Secondary outcomes were mortality (all-cause and CV related), electrical storm and major procedural complications. 8 x RCTs N = 797	https://www.ncbi.nlm.nih.gov/pubmed/31150816	2019
2	Systematic literature review with meta-analysis	Atti, V, Vuddanda, V, Turagam, MK, et al. (2018). "Prophylactic catheter ablation of ventricular tachycardia in ischemic cardiomyopathy: a systematic review and meta-analysis of randomized controlled trials." <i>J Interv Card Electrophysiol</i> , 53(2): 207-215.	To perform a meta-analysis comparing cardiac ablation versus ICD alone in patients with VT and ischaemic cardiomyopathy. Primary outcome was appropriate ICD shocks. Secondary outcomes were mortality (all-cause and CV related), appropriate ICD therapies, electrical storm and major AEs. 3 x RCTs N = 346	https://www.ncbi.nlm.nih.gov/pubmed/29680972	2018

	Type of study design	Title of journal article or research project	Short description of research (max 50 words)	Website link to journal article	Date of publication
3	Systematic literature review with meta-analysis	Martinez, BK, Baker, WL, Konopka, A, et al. (2019). "Systematic review and meta-analysis of catheter ablation of ventricular tachycardia in ischemic heart disease." <i>Heart Rhythm</i> , 0: 1547-5271	To evaluate the use of cardiac ablation in preventing VT events in patients with IHD through a systematic review and meta-analysis. Outcomes were mortality, arrhythmia recurrence (VT/VF), cardiac hospitalisation, appropriate ICD shocks, appropriate ICD therapies, electrical storm and procedural-related AEs. 5 x RCTs N = 635	https://www.ncbi.nlm.nih.gov/pubmed/31082362	2019
4	Systematic literature review	Tilz, RR, Eitel, C, Lyan, E, et al. (2019). "Preventive Ventricular Tachycardia Ablation in Patients with Ischaemic Cardiomyopathy: Meta-analysis of Randomised Trials." <i>Arrhythm Electrophysiol Review</i> , 8(3): 173-179.	To assess the safety and efficacy of VT ablation prior to or at the time of secondary prevention ICD implantation in patients with coronary artery disease, as compared with deferred VT ablation. Outcomes were mortality, appropriate ICD shocks, appropriate ICD therapies, electrical storm and major complications. 3 x RCTs N = 346	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6702470/	2019
SUPRAVENTRICULAR TACHYCARDIA					
5	RCT, prospective study	Da Costa, A, Thevenin, J, Roche, F, et al. (2006). "Results from the Loire-Ardeche-Drome-Isere-Puy-de-Dome (LADIP) trial on atrial flutter, a multicentric prospective randomized study comparing amiodarone and radiofrequency ablation after the first episode of symptomatic atrial flutter." <i>Circulation</i> , 114(16): 1676-1681.	Multicentre RCT comparing RFCA vs no ablation for patients with symptomatic AFL over a mean follow-up period of 22 months. Outcomes were recurrence of AFL, development of AF, mortality, repeat ablation and complications. N = 104	https://www.ncbi.nlm.nih.gov/pubmed/17030680	2006

	Type of study design	Title of journal article or research project	Short description of research (max 50 words)	Website link to journal article	Date of publication
6	RCT, prospective study	Natale, A, Newby, KH, Pisano, E, et al. (2000). "Prospective randomized comparison of antiarrhythmic therapy versus first-line radiofrequency ablation in patients with atrial flutter." <i>J Am Coll Cardiol</i> , 35(7): 1898-1904.	Multicentre RCT comparing RFCA vs no ablation for patients with symptomatic AFL over a mean follow-up period of 13 months. Outcomes were recurrence of AFL, development of AF, repeat ablation, cardiac hospitalisation and QoL. N = 61	https://www.ncbi.nlm.nih.gov/pubmed/10841241	2000
7	RCT, prospective study	Katritsis, DG, Zografos, T, Katritsis, GD, et al. (2017). "Catheter ablation vs. antiarrhythmic drug therapy in patients with symptomatic atrioventricular nodal re-entrant tachycardia: a randomized, controlled trial." <i>Europace</i> , 19(4): 602-606.	Compared cardiac ablation vs AAD therapy (low dose oral bisoprolol and slow release diltiazem) for patients with symptomatic AVNRT for a follow-up period of five years. Outcomes were cardiac hospitalisation and recurrence of arrhythmia (any type). N = 61	https://www.ncbi.nlm.nih.gov/pubmed/28431060	2017

AAD, anti-arrhythmia drug; AVNRT, atrioventricular nodal re-entrant tachycardia; AE, adverse event; AF, atrial fibrillation; AFL, atrial flutter; CA, cardiac ablation; CV, cardiovascular; CI, confidence interval; I2, indicator of heterogeneity; ICD, implantable cardioverter defibrillator; IHD, ischaemic heart disease; N = total number of patients in study/review; QoL, quality of life; RCT, randomised controlled trial; vs, versus; VA, ventricular arrhythmia; VT, ventricular tachycardia

18. Identify yet to be published research that may have results available in the near future that could be relevant in the consideration of your application by MSAC (limiting these to the English language only). *Please do not attach full text articles, this is just intended to be a summary.*

N/A

PART 5 – CLINICAL ENDORSEMENT AND CONSUMER INFORMATION

- 19. List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the service (please attach a statement of clinical relevance from each group nominated):**

The Cardiac Society of Australia and New Zealand - REDACTED

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

As above.

- 21. List the consumer organisations relevant to the proposed medical service (please attach a letter of support for each consumer organisation nominated):**

'hearts4heart' – REDACTED

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

Biotronik Australia

- 23. Nominate two experts who could be approached about the proposed medical device and the current clinical management of the service(s):**

Name of expert 1: A/Professor Saurabh Kumar

REDACTED

Name of expert 2: A/Professor Haris Haqqani (MBBS(Hons) PhD FRACP FCSANZ FHRS FACC)

REDACTED

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

PART 6 – POPULATION (AND PRIOR TESTS), INTERVENTION, COMPARATOR, OUTCOME (PICO)

PART 6a – INFORMATION ABOUT THE PROPOSED POPULATION

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

The populations for whom expansion of the PL listing for cardiac ablation devices is sought, for ablation procedures, are patients with symptomatic VA or (non-AF) SVT.

A cardiac arrhythmia is a condition where a person's heart beats too fast (tachycardia), too slow (bradycardia), or with an irregular rhythm. This results from a disruption of the electrical conduction of the heart and may occur in brief episodes (paroxysmal), or it may be a longer-term or permanent condition. Arrhythmias are classified according to their origin in the heart.

Ventricular arrhythmia

Ventricular arrhythmias originate from the ventricles of the heart and include premature ventricular contractions, ventricular tachycardia (VT) and ventricular fibrillation (VF). Patients may present with symptoms ranging from a total lack of symptoms to symptoms relating to implantable cardioverter defibrillator (ICD) therapy to cardiac arrest (Al-Khatib 2017).

The main risk factor for developing VT/VF is ischaemic heart disease (IHD); however, a prior history of hypertension, prior myocardial infarction (MI), ST-segment changes of the heart beat at presentation, chronic obstructive pulmonary disease, family history and specific genetic variants also increases risk (Al-Khatib 2017). It is estimated that up to 86% of patients with VT/VF have IHD and only 10% of patients with VT/VF have non-IHD (Goyal and Rottman 2018). Ventricular arrhythmias increase morbidity and are attributable to approximately half of all sudden cardiac deaths (John 2012, Goyal and Rottman 2018).

Patients with VA and an ICD may suffer from appropriate ICD shocks or electrical storms (defined as three or more sustained VT/VF or appropriate ICD shocks within 24 hours). Treatment of electrical storm may require a multi-modal approach including device reprogramming, pharmacotherapy, sedation, neuraxial modulation and RFCA (Geraghty 2019). Electrical storms cause significant morbidity and increase hospitalisation rates and mortality. Cardiac ablation for these patients eliminates recurrent VA in most cases (Al-Khatib 2018, Cronin 2019, Geraghty 2019, Nayyar 2013, Sesselberg 2007). Patients with VA and an ICD therefore have a high clinical need for cardiac ablation, which reduces their morbidity and improves their life expectancy.

Prevalence of VA is uncertain due to its spontaneous and variable occurrence (Lip 2015) although it is known that VA is present in most patients with heart failure, and its severity increases with the severity of heart failure (Priori 2015). The incidence of electrical storm is approximately 10 – 30% in patients with VT and an ICD (Geraghty 2019).

The MBS data show that 644 private sector ablations were performed in 2017/18 for MBS items 38293 and 38518, which corresponds to the number of patients undergoing cardiac ablation for VA (a proportion will be re-ablations on the same patient).

Supraventricular tachycardia

Supraventricular tachycardia usually manifests as recurrent sudden episodes of tachycardia which are experienced by patients as palpitations, dyspnoea, dizziness and pounding in the neck or head and occasionally chest pain and presyncope (Brugada 2019, Medi 2009). More than a year of symptoms may pass before an SVT diagnosis is made.

Supraventricular tachycardia can be categorised by the origin of the tachyarrhythmia (WSHCA 2013):

- Atrial tachyarrhythmias initiate within the atrium and include: sinus tachycardia; atrial tachycardia (AT, including focal and multifocal); macro-reentrant atrial tachycardia (MART), commonly referred to as atrial flutter (AFL); and AF.

- Atrioventricular tachyarrhythmias originate within the AV node or the surrounding area and include: Atrioventricular nodal re-entrant tachycardia (AVNRT); symptomatic atrioventricular reciprocating tachycardia (AVRT), which includes Wolf-Parkinson-White Syndrome; focal junctional ectopic tachycardia; and non-paroxysmal junctional tachycardia.

People with excessive alcohol and caffeine use, history of smoking tobacco or illicit drug use, extreme psychological stress and anxiety, hyperthyroidism, low potassium and magnesium levels, family history of tachycardia, structural abnormalities of the heart or with certain medical conditions (e.g., cardiovascular disease, long-term respiratory disease, diabetes, anaemia, cancer) have an increased risk of developing SVT (Terrie 2011).

Although SVT is not usually life-threatening, many patients suffer recurrent symptoms that have a major impact on their quality of life (QoL). The uncertain and sporadic nature of episodes of tachycardia can cause considerable anxiety — many patients curtail their lifestyle as a result (Medi 2009). In extreme circumstances, SVT may lead to sudden cardiac death (Brugada 2019).

The prevalence of SVT in the general population is 2.25/1000 persons and the incidence is 35/100,000 person-years (Medi 2009). Women are two times more likely to develop SVT than men and people aged ≥65 years are five times more likely to develop SVT than younger individuals (Brugada 2019). For patients referred for cardiac ablation, the most common types of SVT are AVNRT, followed by AFL and AVRT. The incidence of AFL is estimated as 88/100,000 person-years and can co-exist with AF. Peak incidence of presentation for ablation occurs at 48 years for AVNRT, 36 years for AVRT, and 50 years for AT (Medi 2009).

The MBS data show that 4,360 private sector ablations were performed in 2017/18 for MBS item 38287 (of which MSAC estimated 75% of services to be for less complex SVT in the AF review). This represents approximately 3,270 patients undergoing cardiac ablation for SVT annually.

25. Specify any characteristics of patients with the medical condition, or suspected of, who are proposed to be eligible for the proposed medical service, including any details of how a patient would be investigated, managed and referred within the Australian health care system in the lead up to being considered eligible for the service:

Cardiac ablation is current clinical practice in Australia for patient with cardiac arrhythmia.

There are no Australian guidelines for the management of patients with symptomatic VA. However, the European Society of Cardiology (ESC) 2019 guidelines on catheter ablation of VA (Cronin 2019), which supplement the 2017 AHA/ACC/HRS guidelines and the 2015 ESC guidelines for the management of patients with VA (Al-Khatib 2018, Priori 2015), strongly recommend cardiac ablation for treatment of symptomatic VA over anti-arrhythmic drug (AAD) therapy. Prof Kumar has advised that these guidelines are followed in Australia.

Prior to or following ablation, patients with VA and the following conditions may undergo ICD implantation:

- documented VF or haemodynamically not tolerated VT in the absence of reversible causes or within 48 h after MI who are receiving chronic optimal medical therapy;
- recurrent sustained VT (not within 48 hours after MI) who are receiving chronic optimal medical therapy, have a normal left ventricular ejection fraction (LVEF).

There are no Australian guidelines for the management of patients with symptomatic SVT. However, the 2019 ESC guidelines for the management of SVT recommend cardiac ablation as first-line treatment for symptomatic and recurrent SVT (particularly AVNRT) because it substantially improves QoL and reduces costs (Brugada 2019). If cardiac ablation is not desirable or feasible, AADs should be considered.

26. Define and summarise the current clinical management pathway *before* patients would be eligible for the proposed medical service (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway up to this point):

As per the ESC clinical algorithms, patients with VA (including patients with IHD and an ICD who have recurrent ICD therapies (shocks, i.e. recurrent VT)) and patients with SVT (including symptomatic and recurrent AFL or AVNRT) are indicated for cardiac ablation.

PART 6b – INFORMATION ABOUT THE INTERVENTION

27. Describe the key components and clinical steps involved in delivering the proposed medical service:

Cardiac ablation procedures occur in a hospital room and patients usually remain conscious though sedated. The groin area (top of the leg) is shaved before a local anaesthetic is administered and catheters (narrow plastic tubes usually 2-3 mm in diameter) are gently inserted into the groin (via a sheath) through veins until they reach the heart (an x-ray machine may be used to guide the catheter). The cardiologist will determine the exact location of the arrhythmia using a 'mapping' technique before placing the catheter tip at this location to scar the areas of heart tissue responsible (via RFCA or cryoablation). The ablation procedure can take up to four hours or more. Afterwards, a dressing is applied and the patient is monitored. Most patients return to their usual activities after a few days. Patients may feel tired or experience a sore chest or leg (at the catheter entry point) or experience arrhythmias for up to three days (St Vincent's Hospital Heart Health 2019).

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

N/A

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

No, cardiac ablation is current practice in Australia.

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

N/A

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

Healthcare resources delivered at the same time as cardiac ablation include a pre-anaesthesia consultation, anaesthesia initiation and attendance, trans-oesophageal echocardiogram, electrophysiology study (mapping) service, physician assistance and hospitalisation.

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

Cardiologists and electrophysiologists

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

N/A

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

N/A

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

N/A, these devices are already being used for cardiac ablation procedures performed in Australia.

36. (a) Indicate the proposed setting(s) in which the proposed medical service will be delivered (select ALL relevant settings):

- Inpatient private hospital (admitted patient)
- Inpatient public hospital (admitted patient)
- Private outpatient clinic
- Public outpatient clinic
- Emergency Department
- Private consulting rooms - GP
- Private consulting rooms – specialist

- Private consulting rooms – other health practitioner (nurse or allied health)
- Private day surgery clinic (admitted patient)
- Private day surgery clinic (non-admitted patient)
- Public day surgery clinic (admitted patient)
- Public day surgery clinic (non-admitted patient)
- Residential aged care facility
- Patient's home
- Laboratory
- Other – please specify below

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

N/A

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

- Yes
- No – please specify below

PART 6c – INFORMATION ABOUT THE COMPARATOR(S)

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

The comparator for cardiac ablation for the treatment of VA and SVT has been broadly defined for this submission as ‘no cardiac ablation’. This includes medical treatment with AADs such as amiodarone. Current clinical guidelines for VA and SVT used in Australia recommend cardiac ablation for first-line treatment over AAD therapy (Brugada 2019, Cronin 2019). Therefore, the comparator is essentially hypothetical since patients should typically undergo cardiac ablation in current practice either in public hospitals or privately.

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

- Yes (please list all relevant MBS item numbers below)
 No

- 40. Define and summarise the current clinical management pathway/s that patients may follow *after* they receive the medical service that has been nominated as the comparator (supplement this summary with an easy to follow flowchart [as an attachment to the Application Form] depicting the current clinical management pathway that patients may follow from the point of receiving the comparator onwards, including health care resources):**

As advised by A/Prof Kumar, and consistent with MSAC’s review of cardiac ablation devices for AF, patients receiving AAD therapy would be followed up on an ongoing basis. Follow-up consists of two specialist (cardiology) visits (MBS item 105), one chest x-ray (MBS item 58500), one ophthalmology test (MBS item 10911), four electrocardiograms (ECGs; MBS item 11700), four hepatic liver function tests (MBS item 66509), four thyroid function tests (MBS item 66509) and four GP visits (MBS item 23) annually.

A/Prof Kumar also advised that cardiac ablation would not affect the long-term use of warfarin therapy for patients in any of the patient groups. Therefore, the costs of warfarin and associated monitoring are expected to be identical between the proposed intervention and comparator (i.e. costs of warfarin, International Normalised Ratio (INR) blood tests, and GP visits specific to warfarin monitoring).

- 41. (a) Will the proposed medical service be used in addition to, or instead of, the nominated comparator(s)?**

- In addition to (i.e. it is an add-on service)
 Instead of (i.e. it is a replacement or alternative)

- (b) If instead of (i.e. alternative service), please outline the extent to which the current service/comparator is expected to be substituted:**

Current clinical guidelines for VA and SVT used in Australia recommend cardiac ablation for first-line treatment over AAD therapy.

- 42. Define and summarise how current clinical management pathways (from the point of service delivery onwards) are expected to change as a consequence of introducing the proposed medical service, including variation in health care resources (Refer to Question 39 as baseline):**

There is anticipated to be a 10% increase in the number of patients undergoing cardiac ablation under an extension to the PL Rules. This is consistent with the assumptions made in MSAC’s review of cardiac ablation devices for AF.

PART 6d – INFORMATION ABOUT THE CLINICAL OUTCOME

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

The clinical claim is that cardiac ablation for the treatment of VA or SVT is superior in terms of effectiveness and safety compared to no cardiac ablation (i.e., medical treatment with AADs).

44. Please advise if the overall clinical claim is for:

- Superiority
- Non-inferiority

45. Below, list the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be specifically measured in assessing the clinical claim of the proposed medical service versus the comparator:

Safety Outcomes:

Cardiac hospitalisation/re-admission

Repeat ablation

Peri-procedural complications and other safety outcomes

Clinical Effectiveness Outcomes:

All-cause mortality

Recurrence of arrhythmia

Appropriate ICD shocks (electric shock sent by the ICD to the heart in an attempt to restore rhythm)

Appropriate ICD therapies (appropriate ICD shock or anti-tachycardia pacing)

Electrical storm (or VT storm) (≥ 3 ICD shocks within 24 hours)

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

46. Estimate the prevalence and/or incidence of the proposed population:

MBS data show that, in 2017/18, a total of 644 private sector ablations were performed for MBS items 38293 and 38518 (VA) and 4,360 private sector ablations were performed for MBS item 38287 (SVT). Since MSAC estimate 25% of these MBS item 38287 services to be for AF, this represents approximately 3,270 procedures for (less complex) SVT. Patient numbers will be slightly lower than procedure numbers since some services will be re-ablations on the same patient.

47. Estimate the number of times the proposed medical service(s) would be delivered to a patient per year:

Patients typically undergo cardiac ablation once and up to once repeat ablation.

48. How many years would the proposed medical service(s) be required for the patient?

N/A

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

Under a linear projection of the historical data, and an anticipated 10% increase in service volumes if the PL listing is extended, the expected numbers of MBS services for the year 2020 are 4,159 (consisting of 3,408, 730 and 21 services for MBS items 38287, 38293 and 38518 respectively).

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

See above

PART 8 – COST INFORMATION

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

The cost of cardiac catheters per procedure under the proposed scenario is the current PL bundled price of \$6,399.

- 52. Specify how long the proposed medical service typically takes to perform:**

The cardiac ablation procedure takes up to 4 hours.

- 53. If public funding is sought through the MBS, please draft a proposed MBS item descriptor to define the population and medical service usage characteristics that would define eligibility for MBS funding.**

N/A

ATTACHMENT A cardiac ablation devices on the Prostheses List (Part C)

Details of the cardiac ablation devices currently on the Prostheses List (PL) Part C (dated November 2019) for treatment of AF

Product Sub Group	Billing Code	Benefit	Sponsor	Product Name	Description	Size	ARTG	TGA Registered Intended Purpose of the Device(s)
08.18.01.01 - Ablation Catheter	SJ409	\$3,500	Abbott Medical Australia	FlexAbility Ablation Catheter	Sensor Enabled and Non-Sensor Enabled	D, F, J, D-F, F-J, D-D, F-F, J-J	279829 231489 231490 279828 327822** 327823** 327824** 327825**	Creating focal lesions during cardiac ablation procedures (mapping, stimulation, and ablation) for the treatment of arrhythmias. Epicardial ablation should be limited to appropriately selected patients with VT.
08.18.01.01 - Ablation Catheter	SJ410	\$3,500	Abbott Medical Australia	TactiCath™ Contact Force Ablation Catheter	Sensor Enabled and Non-Sensor Enabled catheter	DD, DF, FF, FJ, JJ, D, F.	295544 229891 295543 327316** 327321**	For use in cardiac EP mapping (stimulation and recording), and, when used in conjunction with a RF generator, for cardiac ablation of SVT in right and left atrium, including AF.
08.18.01.01 - Ablation Catheter	BT221	\$3,280	Biotronik Australia*	AlCath Force	Mapping and Ablation Cardiac Catheter, Advanced 3D irrigation (eXtra), Gold Tip(G) High Thermal Conduction Ablation, FullCircle Deflection with Optical Contact Force Sensor	7F, 110cm , 3.5mm tip	279638	Mapping and irrigated radiofrequency ablation of cardiac arrhythmias.
08.18.01.01 - Ablation Catheter	BT222	\$3,280	Biotronik Australia*	AlCath G FullCircle	Mapping and Ablation Cardiac Catheter, Gold Tip(G) High Thermal Conduction Ablation, FullCircle Deflection, Standard or Long Tip	7F, 110cm , 4 mm Tip Gold (G) and 8mm (LT) Long Tip Gold(G)	281003	A temporary, unidirectional steerable quadripolar catheter for intracardiac RF ablation as well as for sensing of intracardiac signals and diagnostic pacing. Intended for treatment of supraventricular, ventricular and atrioventricular cardiac tachyarrhythmia and AVNRT.
08.18.01.01 - Ablation Catheter	BT223	\$3,280	Biotronik Australia*	AlCath Flux G eXtra	Mapping and Ablation Cardiac Catheter, Advanced 3D irrigation (eXtra), Gold Tip(G) High Thermal Conduction Ablation, FullCircle Deflection	7F, 110cm , 3.5mm irrigated gold tip	193331	

Product Sub Group	Billing Code	Benefit	Sponsor	Product Name	Description	Size	ARTG	TGA Registered Intended Purpose of the Device(s)
08.18.01.01 - Ablation Catheter	BT224	\$3,280	Biotronik Australia*	AIcath Flutter Flux G eXtra	Mapping and Ablation Cardiac Catheter, Gold Tip(G) High Thermal Conduction Ablation, Advanced 3D irrigation (eXtra), FullCircle Deflection, Optimised stability,control & length for flutter	7F ,95cm , 3.5mm Gold tip	221411	
08.18.01.01 - Ablation Catheter	BT225	\$3,280	Biotronik Australia*	AIcath Flutter LT G	Mapping and Ablation Cardiac Catheter, Gold Tip(G) High Thermal Conduction Ablation, FullCircle Deflection, Long 8mm Tip (LT), Optimised stability,control & length for flutter	7F , 95cm , 8mm(LT) gold tip	221412	
08.18.01.01 - Ablation Catheter	BS361	\$2,700	Boston Scientific Australia	IntellaNav™ MiFi™ Open-Irrigated Ablation Catheter	IntellaNav™ Open-Irrigated, MiFi™ Mini-electrode Technology, Nav-abled	110cm, shaft size 7.5F	300198	For use in patients who require catheter-based cardiac EP mapping (stimulating and recording) and, when used in conjunction with a RF generator, for cardiac ablation.
08.18.01.01 - Ablation Catheter	MN238	\$3,700	Johnson & Johnson Medical	CARTO: SMARTTOUCH/SMARTTOUCH SF	Contact Force Sensing Catheter: with/without Porous Tip	One size only	184035 198574 233354 233355	Catheter-based cardiac EP mapping (stimulating and recording) and, when used in conjunction with a RF generator, for cardiac ablation. Provides a real-time measurement of contact force between the catheter tip and heart wall, as well as location information when used with CARTO 3 Navigation System.
08.18.01.01 - Ablation Catheter	MI300	\$6,399	Medtronic Australasia	PVAC Gold Phased RF catheter	The Pulmonary Vein Ablation Catheter (PVAC) Gold is a three-dimensional, anatomically designed, multielectrode phased RF catheter used to map, pace, and ablate the pulmonary veins	9Fr	235158	Creation of endocardial lesions (focal and linear) during cardiac ablation procedures for the treatment of symptomatic AF. Intended for cardiac EP mapping of pulmonary vein potentials, delivery of diagnostic pacing stimuli and verifying electrical isolation of the pulmonary veins post-treatment.
08.18.01.02 - Patch	SJ408	\$350	Abbott Medical Australia	EnSite Patch	Surface Electrodes	Patch/Kit	195707 274633	For use with a cardiac mapping system in order to provide a fixed reference point (for the tip of an electrophysiology catheter).

Product Sub Group	Billing Code	Benefit	Sponsor	Product Name	Description	Size	ARTG	TGA Registered Intended Purpose of the Device(s)
08.18.01.02 - Patch	BS360	\$299	Boston Scientific Australia	Rhythmia™ Location Reference Patch Kit	Rhythmia™ Location Reference Patch Kit (Box of 1)	50mm diameter	282996	A component of a cardiac mapping system that is an adhesive device placed on the surface of a patient's body to provide a fixed reference point for the tip of a catheter during an EP and electromechanical real-time mapping of the heart. It is typically used with a cardiac mapping system computer to assist in the location and navigation of the catheter tip. This is a single-use device.
08.18.01.02 - Patch	MN239	\$499	Johnson & Johnson Medical	CARTO Reference	External Reference	One size only	157549	Used with a cardiac mapping system to provide a reference point for the tip of an electrophysiology catheter.
08.18.01.03 - Mapping Catheter	SJ404	\$2,549	Abbott Medical Australia	Inquiry Optima Diagnostic Catheter	mapping catheter	5F-8F	136233	Steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic EP studies. As well as, mapping atrial regions of the heart.
08.18.01.03 - Mapping Catheter	SJ405	\$2,549	Abbott Medical Australia	Reflexion Spiral Variable Radius Catheter	mapping catheter	5F-8F	145053	Recording intracardiac signals and for cardiac stimulation during electrophysiology studies. It can also be used to map the atrial regions of the heart.
08.18.01.03 - Mapping Catheter	SJ406	\$2,549	Abbott Medical Australia	Advisor mapping catheter	mapping catheter	5F-8F	282187 282186** 308920** 327686** 327732** 327761**	Sensor enabled steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. Used to map the atrial regions of the heart and compatible with St. Jude Medical visualisation and navigation systems to enable real-time positioning and navigation.
08.18.01.03 - Mapping Catheter	SJ407	\$2,549	Abbott Medical Australia	Afocus II EB Inquiry Steerable Catheter	mapping catheter	5F-8F	136211	Recording intracardiac signals and cardiac stimulations during diagnostic EP studies as well as, mapping atrial regions of the heart.
08.18.01.03 - Mapping Catheter	BS359	\$3,400	Boston Scientific Australia	IntellaMap Orion High Resolution Mapping Catheter	High resolution 64-electrode steerable mapping catheter	8.5F, 115cm	271032	EP mapping (recording or stimulating only) of the cardiac structures of the heart.

Product Sub Group	Billing Code	Benefit	Sponsor	Product Name	Description	Size	ARTG	TGA Registered Intended Purpose of the Device(s)
08.18.01.03 - Mapping Catheter	MN240	\$2,200	Johnson & Johnson Medical	LASSO/ PENTARAY	Circular/High Density	Various	121901 122187 145997 203362 231772 278955 278956	For multiple electrode EP mapping of the cardiac structures of the heart using recording or stimulation only to obtain electrograms in the atrial region of the heart.
08.18.02.01 - Ablation Catheter	MI301	\$5,100	Medtronic Australasia	Arctic Front Advance Cardiac CryoAblation Catheter / Pro	A flexible, over-the-wire balloon catheter used to ablate cardiac tissue	23mm, 28mm	302439 201541	Treatment of patients with atrial fibrillation.
08.18.02.02 - Mapping Catheter	MI302	\$1,299	Medtronic Australasia	Achieve / Achieve Advance Mapping Catheter	Intracardiac electrophysiology circular mapping catheter	15mm, 20mm, 25mm	188676 231648 286735	Multiple electrode EP mapping of the cardiac structure of the heart, i.e. recording or stimulation only (designed to obtain electrograms in the atrial regions of the heart).

3D, three-dimensional; AF, atrial fibrillation; AVNRT, atrioventricular nodal re-entrant tachycardia; EP, electrophysiological; mm, millimetres; PL, Prostheses List; RF, radiofrequency; SVT, supraventricular tachycardia; TM, trademark; VT, ventricular tachycardia

Notes: *Biotronik devices are not the subject of this submission, they are only listed here for completeness. ** The addition of ARTG 327822, 327823, 327824 and 327825 are subject to PLMS application A024120. The addition of ARTG 327316 and 327321 are subject to PLMS A024118. The addition of ARTG 282186, 308920, 327686, 327732 and 327761 are subject to PLMS application A024128 for July 2020 PL listing.

Source: ARTG details from TGA eBS website <https://www.ebs.tga.gov.au/> (accessed 25 November 2019). Prostheses List information from Department of Health <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm> (accessed 25 November 2019).