Australian Government

Department of Health

MSAC Application 1354.1

Intravascular Ultrasound (IVUS) Guided Coronary Stent Insertion

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 / partnership details (where relevant):
Corporation name: BOSTON SCIENTIFIC PTY LTD
ABN: 45 071 676 063
Business trading name: Boston Scientific

Primary contact name: REDACTED

Primary contact numbers
Business: REDACTED
Mobile: REDACTED
Email: REDACTED

Alternative contact name: REDACTED

Alternative contact numbers
Business: REDACTED
Mobile: REDACTED
Email: REDACTED

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

☐ Yes
☒ No

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

☐ Yes
☐ No

PART 2 – INFORMATION ABOUT THE PROPOSED MEDICAL SERVICE

3. Application title

Intravascular Ultrasound (IVUS) Guided Coronary Stent Insertion

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)

Ischaemic heart disease (IHD), also known as coronary heart disease is the most common form of cardiovascular disease. The main underlying pathology in IHD is atherosclerosis, which can lead to occlusion of the coronary arteries and oxygen starvation of the heart, which presents as acute coronary syndrome (ACS). ACS is the result of atheromatous plaques or endothelial disruption with associated transient or permanent thrombotic occlusion of the coronary vascular tree leading to unstable angina or myocardial ischaemia. When one or more of the coronary arteries are completely blocked, a myocardial infarction may occur. When the cerebral blood flow is compromised, IHD may result in stroke or cerebrovascular accident.

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

Interventional cardiologists who perform coronary stent insertion in Australia are currently guided by the use of angiography to provide a two-dimensional image of the coronary artery. IVUS is the generic name provided to any ultrasound technology that provides tomographic, three-dimensional, 360-degree images from inside the lumen of a blood vessel. During percutaneous coronary intervention (PCI), IVUS may be used to guide coronary stent insertion as an adjunct to angiography.

IVUS, compared with angiography alone, provides physicians with a better understanding of the atherosclerotic vessels, thus supporting appropriate treatment strategy, stent selection, stent placement, visualisation of stent apposition to the vessel, and adequate stent deployment to restore blood flow at the target site. The service therefore involves a therapeutic aspect and an investigative aspect. The proposed service in this Application is for the therapeutic use of IVUS during PCI for stent optimization, which has clinically shown to significantly improve patient outcomes in terms of reduced mortality, and adverse events in the short- and long-term.

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):

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

i. ☐ A new item which also seeks to allow access to the MBS for a specific health practitioner group
ii. ☒ A new item that is proposing a way of clinically delivering a service that is new to the MBS (in terms of new technology and / or population)
iii. ☐ A new item for a specific single consultation item
iv. ☐ A new item for a global consultation item(s)

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

☐ Yes
☒ No

(g) If yes, please advise:

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)*:

i. ☐ To be used as a screening tool in asymptomatic populations
ii. ☐ Assists in establishing a diagnosis in symptomatic patients
iii. ☐ Provides information about prognosis
iv. ☐ Identifies a patient as suitable for therapy by predicting a variation in the effect of the therapy
v. ☐ Monitors a patient over time to assess treatment response and guide subsequent treatment decisions

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?

☐ Yes
☐ No

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

Not applicable

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

Not applicable

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

Not applicable

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

☒ Yes
☐ No

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

Billing code(s): Numerous (see Appendix II)
Trade name of prostheses: Numerous (see Appendix II)
Clinical name of prostheses: coronary drug eluting stent
Other device components delivered as part of the service: Not applicable

(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
☐ 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):

Per the published protocol for application 1354. There are several TGA registered intravascular ultrasound devises, as specified in Appendix I.

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

Single use consumables: Single use consumables used to deliver IVUS include guide wire, guide catheter, introducer sheath, sterile pullback sled and a sterile bag.
Multi-use consumables: Not applicable

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: IVUS transducers and delivery catheters (see Appendix I)
Manufacturer's name: Multiple (see Appendix I)
Sponsor's name: Multiple (see Appendix I)

(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
☐ AIMD
☐ N/A

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

ARTG listing, registration or inclusion number: Multiple (see Appendix I)
TGA approved indication(s), if applicable: Multiple (see Appendix I)
TGA approved purpose(s), if applicable: Multiple (see Appendix I)

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?

☐ Yes (please provide details below)
☐ No

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?

☐ Yes (please provide details below)
☐ No

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 (including any trial identifier or study lead if relevant)**	**Short description of research (max 50 words)****	**Website link to journal article or research (if available)**	**Date of publication*****
1.	Meta-analysis of 10 RCTs	Intravascular Ultrasound-Guidance Is Associated with Lower Cardiovascular Mortality and Myocardial Infarction for Drug-Eluting Stent Implantation — Insights from an Updated Meta-Analysis of Randomized Trials	Meta-analysis of RCTs (listed #2-#11) representing PCI population eligible for DES	https://www.jstage.jst.go.jp/article/circj/83/6/83_CJ-19-0209/_html/-char/en	2019
2.	RCT	ULTIMATE. Intravascular ultrasound-guided versus angiography-guided implantation of drug-eluting stent in all-comers: The ULTIMATE trial.	Trial in low/medium and high-risk population	https://www.onlinejacc.org/content/72/24/3126	2018
3.	RCT	Lu et al. Intravascular ultrasound-guided drug-eluting stent implantation for patients with unprotected left main coronary artery lesions: A single-center randomized trial.	Trial in unprotected left main lesions.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6457420/pdf/AJC-21-83.pdf	2019
4.	RCT	Zhang et al. Application of intravascular ultrasound in stent implantation for small coronary arteries	Trial in small vessels (2.25-2.75mm).	https://pdfs.semanticscholar.org/722e/39de44a446e008bc6e5d1dcda9272db4096b.pdf	2016
5.	RCT	IVUS-XPL. Effect of intravascular ultrasound-guided vs. angiography-guided everolimus-eluting stent implantation: The IVUS-XPL Randomized Clinical Trial.	Trial in long lesions (≥28mm).	https://jamanetwork.com/journals/jama/fullarticle/2469205	2015
6.	RCT	CTO-IVUS. Clinical impact of intravascular ultrasound-guided chronic total occlusion intervention with zotarolimus-eluting versus biolimus-eluting stent implantation: Randomized study.	Trial in chronic total occlusions.	https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.115.002592?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed	2015

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
7.	RCT	AIR-CTO. Angiographic and clinical comparisons of intravascular ultrasound versus angiography-guided drug-eluting stent implantation for patients with chronic total occlusion lesions: Two-year results from a randomised AIR-CTO study.	Trial in chronic total occlusions.	http://www.pcronline.com/eurointervention/83th_issue/245	2015
8.	RCT	Tan et al. Intravascular ultrasound-guided unprotected left main coronary artery stent in the elderly	Trial in unprotected left main lesions.	https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4436750/pdf/SaudiMedJ-36-549.pdf	2015
9.	RCT	Kim et al. Randomized comparison of clinical outcomes between intravascular ultrasound and angiography-guided drug-eluting stent implantation for long coronary artery stenoses.	Trial in long lesions (≥28mm).	https://linkinghub.elsevier.com/retrieve/pii/S1936-8798(13)00432-9	2013
10.	RCT	AVIO. A prospective, randomized trial of intravascular-ultrasound guided compared to angiography guided stent implantation in complex coronary lesions: the AVIO trial.	Trial in complex lesions.	https://linkinghub.elsevier.com/retrieve/pii/S0002-8703(12)00661-8	2013
11.	RCT	HOME DES IVUS. Long-term health outcome and mortality evaluation after invasive coronary treatment using drug eluting stents with or without the IVUS guidance: Randomized control trial.	Trial in complex lesions.	https://onlinelibrary.wiley.com/doi/abs/10.1002/ccd.22244	2013
12.	RCT	IVUS-XPL 5-year follow up. Effect of Intravascular Ultrasound–Guided Drug-Eluting Stent Implantation: 5-Year Follow-Up of the IVUS-XPL Randomized Trial	Trial in long lesions (≥28mm).	https://pubmed.ncbi.nlm.nih.gov/31918944/	2020 (follow-up to publication # 5)
13.	Retrospective observational study	Long-Term outcomes of coronary stenting with and without use of intravascular ultrasound	Real-world propensity matched analysis of 1,877,177 US patients who underwent PCI with or without IVUS	https://interventions.onlinejacc.org/content/13/16/1880	2020

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
14	Large prospective, multicentre, observational study	Relationship Between Intravascular Ultrasound Guidance and Clinical Outcomes After Drug-Eluting Stents Two-Year Follow-Up of the ADAPT-DES Study	Nonrandomized all-comers study of 8,582 consecutive patients at 11 US and German sites designed to determine the frequency, timing, and correlates of adverse events after drug-eluting stents, and with and without IVUS.	https://www.ahajournals.org/doi/10.1161/CIRCINTERVENTIONS.117.006243	2018
15.	Meta-analysis of RCT and observational studies	Meta-analysis and systematic review of intravascular ultrasound versus angiography-guided drug eluting stent implantation in left main coronary disease in 4,592 patients	Meta-analysis of patients who underwent PCI with DES for treatment of left main lesions	https://bmccardiovascdisord.biomedcentral.com/articles/10.1186/s12872-018-0843-z	2018
16.	Economic evaluation (Cost-utility Analysis)	Understanding the economic impact of intravascular ultrasound (IVUS)	A CUA using Markov model comparing costs and health outcomes between IVUS-guided PCI and PCI guided solely by angiography, from an Italian healthcare payer perspective. The population examined included CAD patients undergoing PCI with DES.	https://pubmed.ncbi.nlm.nih.gov/25669755/	2016
17.	Economic evaluation (Cost-utility Analysis)	Cost-Effectiveness of Intravascular Ultrasound (IVUS) during Drug-Eluting Stent Implantation in Korea	A CUA comparing costs and health outcomes associated with PCI using IVUS versus angiography alone, from the Korean healthcare payer perspective. The population examined included eligible patients for PCI with DES.	https://www.ispor.org/heor-resources/presentations-database/presentation/asia2020-3264/103581	2020

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.*

**** If the publication is a follow-up to an initial publication, please advise*

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.*

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	RCT	ULTIMATE: Three-Year Outcomes After IVUS-Guided vs Angiography Guided DES Implantation Lecturer: Junjie Zhang Clinical Trial: NCT02215915	ULTIMATE 3-year follow-up data will be presented at the TCT conference (October 15, 2020 1:15pm) Late-Breaking Clinical Science Session II 12:30 AM – 1:30 PM Moderator: Ziad A. Ali, George D. Dangas Discussants: Anthony H. Gershlick, Gary S. Mintz	https://www.tctconnect.com/tct-program-late-breaking-trials-and-clinical-trials/	October 15, 2020 (follow-up to publication #2 in above table)

** Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.*

***Provide high level information including population numbers and whether patients are being recruited or in post-recruitment.*

****Date of when results will be made available (to the best of your knowledge).*

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):**

    Cardiac Society of Australia and New Zealand (CSANZ)

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

    Cardiac Society of Australia and New Zealand (CSANZ)

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

    None

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

    Philips Electronics Australia Ltd

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

    Name of expert 1: REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

    Name of expert 1: REDACTED

    Email address: REDACTED

    Justification of expertise: REDACTED

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

PART 6 – 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:

Ischemic heart disease (IHD) or coronary artery disease (CAD) is a medical condition that induces narrowing of the coronary arteries. The main underlying pathology in IHD is atherosclerosis, which can lead to occlusion of the coronary arteries and oxygen starvation of the heart, which presents as angina pectoris. Angina is a chronic condition in which short episodes of chest pain occur periodically. When one or more of the coronary arteries are completely blocked, a myocardial infarction may occur. IHD may also compromise blood flow to the brain, resulting in a stroke or cerebrovascular accident.

IHD/CHD is the leading cause of death in Australia for both males and females. It is also the leading cause of death on a global scale. In 2017, heart disease caused 11.6% (18,590) of the 160,909 deaths in Australia, and 8.76 million deaths (15.5%) worldwide.(1) In 2017-18, the prevalence of heart disease amongst Australians was approximately one in twenty, or 1.2 million people. Regarding acute coronary syndrome (ACS), there were around 227,300 people experiencing angina while 430,000 had a heart attack or another form of CHD during this period.(2)

Current guidelines on management of ACS recommend PCI (via stenting) for coronary revascularisation (3). Coronary angiography is performed prior to stent insertion to acquire diagnostic information to decide on the strategy for management. Patients, who are indicated for and consent to PCI with stenting, commonly receive a drug eluting stent (DES) at the narrowed coronary artery segment to relieve the effects of myocardial ischemia and to improve symptoms and prognosis. Balloon dilatation may also be used during the procedure.

Coronary angiography and stenting are well established in current Australian practice (coronary angiography is claimed via MBS item 38246). The rationale for use of IVUS at the time of stenting arises from limitations of coronary angiography in terms of assessing the severity of coronary stenosis.(4) Specifically, IVUS provides tomographic, 3-dimensional, 360-degree images from inside the lumen of a blood vessel. Compared to angiography, IVUS provides physicians with a better understanding of atherosclerotic vessels to determine appropriate treatment strategy, stent selection and implantation, and adequate deployment to restore blood flow.

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:

This application has previously been submitted to MSAC on two occasions. The first application was submitted in 2001 (application 1032). In this application, IVUS was assessed as both a diagnostic and a therapeutic tool for cardiac stent optimisation, however MSAC deemed the clinical evidence and cost-effectiveness data insufficient to support IVUS use.

In 2015 Boston Scientific submitted an MSAC application for IVUS as a therapeutic tool for optimisation of DES or bare metal stent (BMS) placement (application 1354). The application was rejected due to uncertain clinical effectiveness and cost-effectiveness estimates. In application 1354, the proposed patient population in the published protocol was defined as 'high-risk' based on coronary anatomy, lesion type and complexity:

- intermediate left main coronary stenosis;
- complex coronary lesions (e.g. ostial or bifurcation lesions, calcified lesions, chronic total occlusions);

- challenging coronary anatomy (e.g. coronary artery ectasia, giant coronary arteries, hazy coronary lesions); and
- previous stents

The 2015 MSAC submission for application 1354 included clinical evidence from meta-analyses which included a broader patient population than the published protocol (termed 'all comers'). The economic analyses presented in the submission provided a high-risk subgroup analysis, although due to a lack of evidence, the patient criteria did not align specifically with the high-risk definition in the published protocol.

The application was rejected by MSAC and key concerns were as follows:

- There were differences between the clinical algorithm in the final submission and the clinical algorithm in the protocol which increased the level of clinical uncertainty. It was noted that the algorithm in the submission allows 'low/medium risk' patients to receive IVUS guidance. However, in the protocol, IVUS guidance was restricted to only 'high-risk' patients.
- There was a limited number of primary studies included in the analysis and the reliance on systematic reviews and meta-analyses, which do not allow assessment of the safety and efficacy of IVUS guidance for stent insertion of either bare metal stents (BMS) or drug-eluting stents (DES) for the types of 'high-risk' patients nominated in the protocol.
- The data were heterogeneous and therefore the 95% confidence intervals (CIs) approached 1. MSAC was concerned that there were no significant differences in important clinical outcomes such as myocardial infarctions (MIs) and mortality and that pooling of major adverse cardiac events (MACE) may be inappropriate. In addition, due to the short follow-up (2-3 years) in the clinical evidence base, it is not possible to assess whether the short-term benefits of IVUS are maintained over a longer period of time.

Based on the Health Expert Standing Panel (HESP) advice, the MSAC further expanded the definition of high-risk patients to include one or more of the following characteristics:

- intermediate left main coronary stenosis
- complex coronary lesions (e.g. ostial or bifurcation lesions, calcified lesions, chronic total occlusions)
- challenging coronary anatomy (e.g. coronary artery ectasia, giant coronary arteries, hazy coronary lesions)
- previous stents
- previous myocardial infarction (MI)
- acute coronary syndrome
- diabetes
- renal insufficiency.

Given the uncertainty with the correct patient population and the addition of several new published randomised trials (5), Boston Scientific convened an expert KOL panel in August 2020 to provide guidance on a MSAC resubmission. KOL feedback indicated that the MSAC proposed criteria would capture the vast majority of their current patient cohort with some notable exceptions. KOLs advised the high-risk definition previously proposed by MSAC would be more suitable for a diagnostic rather than therapeutic use of IVUS. The KOL preferred indication for therapeutic use would include characteristics with an objective and measurable definition (e.g., lesion length ≥28mm and lesions associated with the left main coronary artery).

KOLs also noted that there is now published randomised evidence covering a broader population (through the ULTIMATE trial (6)) and a narrower population (through IVUS-XPL (7)) – relative to the MSAC definition included in the Public Summary Document (noted above). Based on this, the KOL panel recommended two patient criteria *options* for IVUS use in combination with DES only (noting BMS is no longer used in practice):

1. Patients undergoing PCI who have had a coronary lesion eligible for DES implantation.
2. Patients undergoing PCI who have had a coronary lesion eligible for DES implantation with either:
    a. Lesions associated with the left main coronary artery; and/or where suitability of percutaneous coronary intervention has appropriately been determined by a Heart Team

approach for significant stenoses (≥50% as defined on IVUS) of the left main coronary artery, including in cases of unprotected left-main disease; or

b. Lesion length ≥ 28mm.

Compared to the published protocol for application 1354, the three notable differences are as follows:

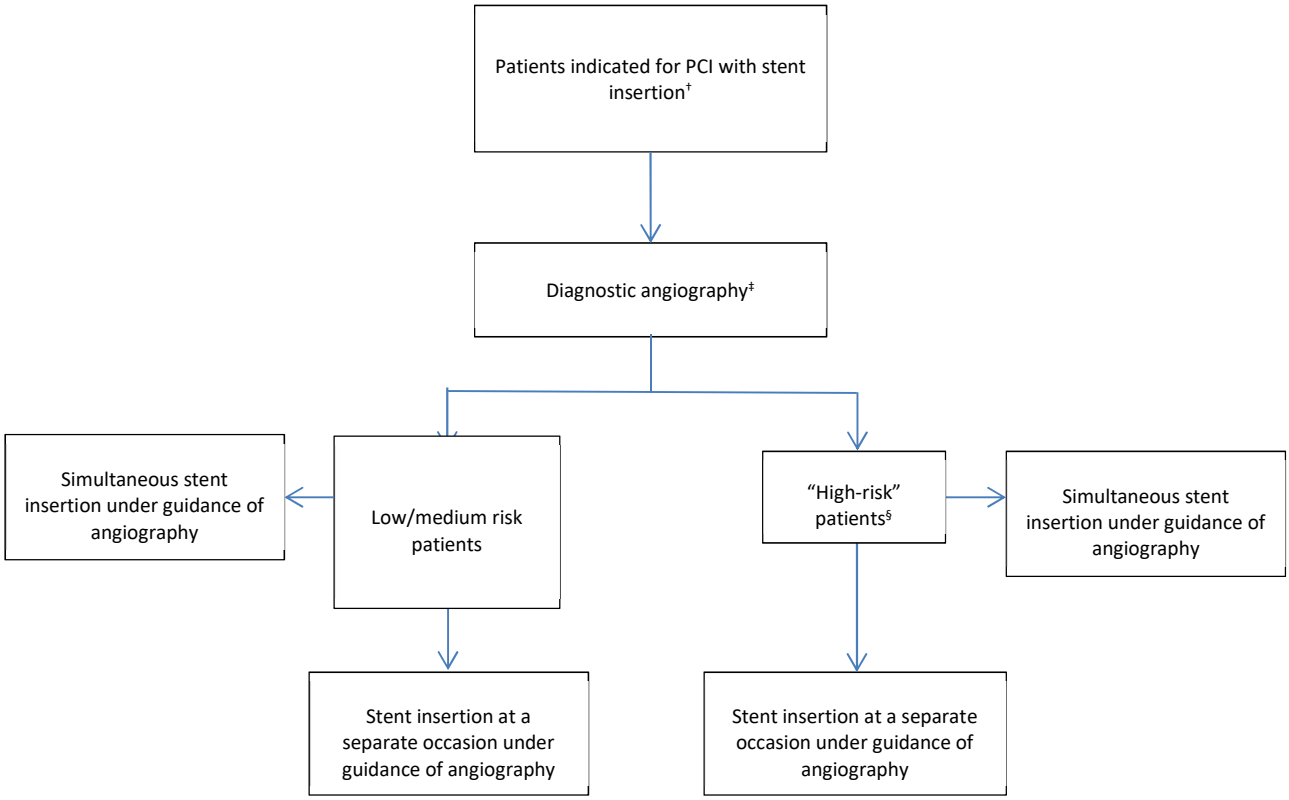
1. It is proposed that IVUS can be used in low/medium risk patients based on the results of ULTIMATE trial (6).
2. A new definition of high risk is proposed which aligns with contemporary clinical practice and new evidence from IVUS-XPL (7) and other trials (8-10)
3. The inclusion of lesion length in the criteria will cover a proportion of re-stenting procedures (due to stent thrombosis or in-stent restenosis). Therefore, there is no requirement to create a separate MBS item code for this group.

Boston Scientific intends to provide evidence and cost-effectiveness assessments for both populations as options for reimbursement of IVUS by MSAC.

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):

The current clinical management pathway remains unchanged from the published protocol for application 1354. Specifically, patients indicated for a PCI with stent insertion undergo angiography for diagnostic purposes, to understand the extent and severity of the atherosclerotic lesion. Following this, patients will receive a DES guided by angiography. Importantly application 1354 stratified the population as low/medium-risk and high-risk. Noting the change in the definition of high risk (see Question 25), the algorithm has been updated with the new definition of high-risk as recommended by the Boston Scientific KOL panel.

Figure 1: The current clinical decision algorithm for patients indicated for coronary stent insertion



† Patients with acute coronary syndrome – STEMI, NSTEMI with higher risk of a cardiac event, unstable angina, stable angina who fail medical therapy or who have silent myocardial ischemia may be indicated for PCI/stenting as an elective, ad hoc or emergency procedure. Patients may undergo initial stent insertion, or re-stenting or assessment for other interventions if there are complications or failure of the stent.

‡ Diagnostic angiography may be performed in addition to the functional assessments (e.g. fractional flow reserve) of coronary arteries.

§ "High-risk" patients are identified based on their coronary anatomy, and the type and complexity of coronary lesions.

PART 6b – INFORMATION ABOUT THE INTERVENTION

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

The eligible population is identified by preliminary screening tests such as exercise stress tests and stress imaging studies. The majority of patients are diagnosed following an episode of angina or a myocardial infarction. Coronary angiography is performed in these patients to locate and to define the extent and severity of atherosclerotic lesions. This procedure also provides guidance during PCI procedures.

Following the identification of a lesion or narrowed coronary artery through diagnostic angiography, the cardiologist may elect to proceed immediately to insert a stent. Relative to angiography, IVUS may provide physicians with a better understanding of atherosclerotic vessels to determine appropriate treatment strategy, stent selection and implantation, and adequate deployment to restore blood flow. In a majority of cases, IVUS will be used as an adjunct to angiography. However, in some cases, such as patients with renal impairment, IVUS may be used as a replacement for angiography, in order to avoid the use of contrast dyes.

Surgical management atherosclerosis also involves balloon angioplasty, plaque modification procedures such as cutting balloon, or rotational atherectomy. Angioplasty is performed by inserting a catheter with a small balloon at the tip, which is directed to the site of the lesion. The cardiologist inflates the balloon several times to restore blood flow to the heart. The cardiologist will commonly choose to place a stent during the procedure to keep the blood vessel open.

In patients presenting with acute chest pain to the emergency department in Australia, the prevalence of different diagnostic groups are: 2–5% ST-segment elevation myocardial infarction (STEMI), 5–10% non-STEMI (NSTEMI), 5–10% unstable angina, 15–20% other cardiac conditions and 50–70% non-cardiac diseases.(11) In Australia, angioplasty is performed in approximately 70%, 35% and 15% of STEMI , NSTEMI and unstable angina patients, respectively. Of patients with a STEMI who undergo angioplasty, approximately 95% will receive a stent.(12) This is due to the high restenosis risk after angioplasty alone (30%) compared to restenosis risk after the addition of a stent (5%).(12)

Ultrasonography via IVUS is a safe, non-invasive imaging procedure that does not produce ionizing radiation.(13) IVUS system consists of an imaging catheter, a mini-transducer connected at the tip of the catheter, and a console. Ultrasound transducers generate, transmit and receive sound of an appropriate frequency and pulse rate. Sound is then processed by an ultrasound processor to generate an image. The catheter delivers the transducer at the narrowed coronary vessel. The transducer may be mechanical, consisting of a single rotating transducer driven by a flexible drive cable, or it may be electronic, where the scanning is performed using an array of multiple transducing crystals.

Sound frequencies used in medical sonography range from 1MHz to 40MHz and are poorly transmitted by air and calcified tissue, but effectively transmitted by fluid and soft tissues. Higher frequencies provide a more detailed image, but are less able to penetrate into deep tissues. As such, IVUS is generally capable of providing precise images of the coronary wall structure.

IVUS-guided coronary stent insertion is performed in a catheterisation laboratory. The imaging catheter is inserted into the femoral artery, and navigated to the narrowed coronary artery. The Judkins technique is commonly used.(14) The catheter is usually positioned distally to the lesion (or stent), and withdrawn through the lesion (or stent) at a constant speed, manually or with an automatic mechanical pullback device.

The service may be useful in both elective and emergency PCI procedures. It is provided at a public or private hospital as an inpatient procedure. IVUS imaging takes 10–15 minutes; this is in addition to the stent insertion procedure, which usually takes 10–20 minutes.

Bare metal stents (BMS) and drug-eluting stents (DES) are deployed at the narrowed part of a coronary vessel. BMS are mesh-like tubes of thin wire. DES are covered with a drug, which is slowly released to reduce cell proliferation. This prevents fibrosis, which together with thrombosis could narrow the stented

artery, a process called restenosis. Feedback from the KOL panel indicated the vast majority of patients receive DES in current clinical practice.

The PCI is generally performed under local anaesthesia. Oral or intravenous sedation is usually administered.(14) Fluoroscopy may be used to locate the femoral artery and to assist insertion of the guidewire.(14)

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

This submission does not pertain to a specific trademarked device.

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?

Coronary angiography and stenting are well established in current Australian practice. The rationale for use of IVUS at the time of stenting arises from limitations of coronary angiography in terms of assessing the severity of coronary stenosis.(4) MBS item 38306 covers PCI with stenting.

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):

The proposed medical service will be provided by a trained IVUS accredited cardiologist, and these individuals may not be present in all hospitals where PCI procedures take place.

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

The proposed service would take place in combination with insertion of a DES through item 38306. In a majority of cases, IVUS will be used as an adjunct to angiography, delivered through item 38246.

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

The same health professionals who insert coronary stents would perform the IVUS service. This would typically be an interventional cardiologist who is also credentialled to perform IVUS.

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:

The Cardiac Society of Australia and New Zealand conduct proctoring programs and credentialing.

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

The service may be useful in both elective and emergency PCI procedures. It is provided at a public or private hospital as an inpatient procedure. IVUS imaging takes 10–15 minutes; this is in addition to the stent insertion procedure, which usually takes 10–20 minutes.

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):

Coronary angiography is used in Australia for diagnostic purposes (to define the extent and severity of atherosclerotic lesions) and therapeutic purposes to guide PCI with DES insertion. Other imaging modalities, for example FFR and optical coherence tomography (OCT), are sometimes used when conducting PCI. FFR provides a functional assessment of stenosis significance.(15) It is useful as a diagnostic modality to identify whether a lesion should be treated with stent placement due to restricted blood flow. It does not assist with stent selection or placement and is not useful following stent placement to confirm stent position or apposition. OCT provides high resolution images but has limited depth penetration through the vessel wall, and is an emerging imaging modality with limited clinical evidence (4), and not routinely used in Australian clinical practice.

In a majority of cases, IVUS will be used as an adjunct to angiography. However, in some cases, such as patients with renal impairment, IVUS may be used as a replacement for angiography in order to avoid the use of contrast dyes.

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

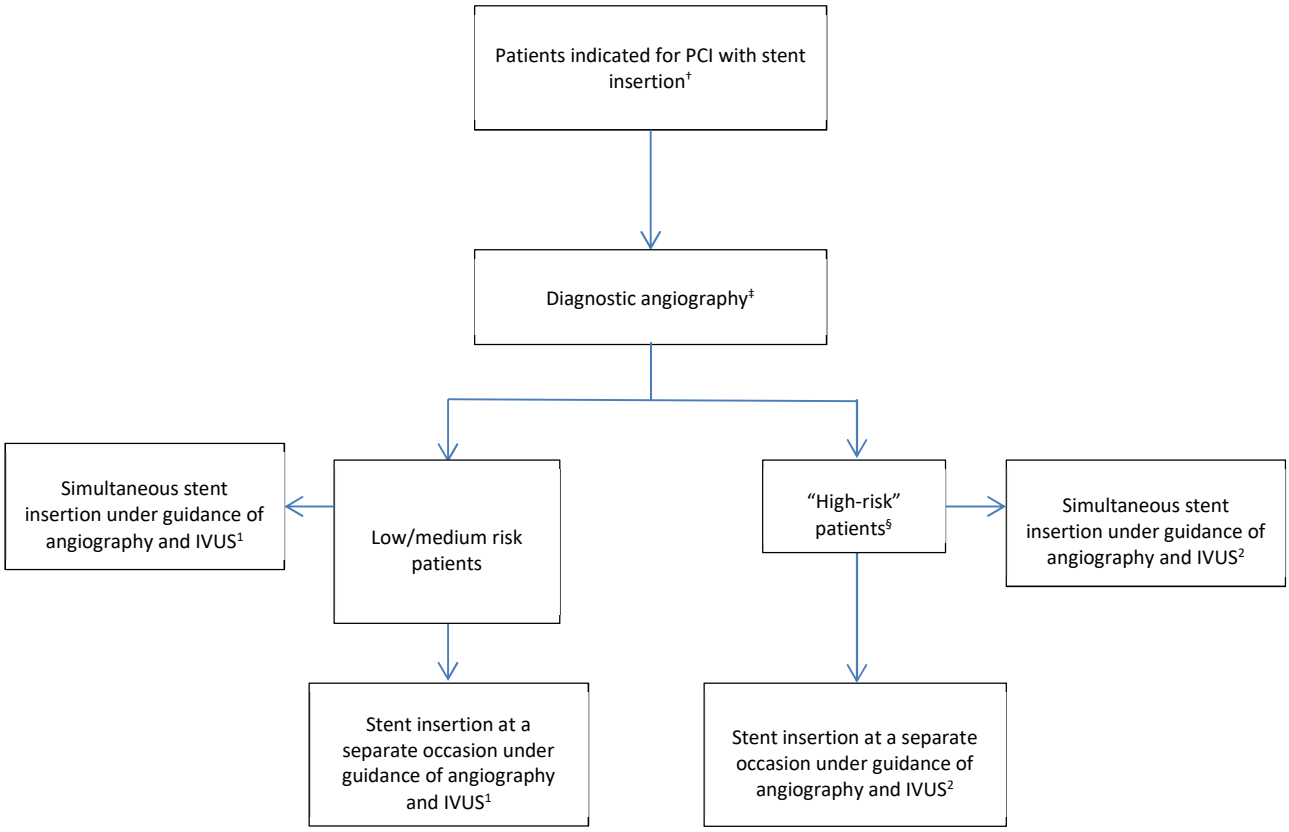
Coronary angiography is claimed via MBS item 38246.

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):

The proposed clinical management pathway is largely consistent with the published protocol for application 1354 and the previous MSAC submission. There are two notable differences:

1. The published protocol for application 1354 does not specify IVUS use in low/medium risk patients however the proposed MSAC resubmission will include these patients based on the new evidence from the ULTIMATE trial (6).
2. The definition of high risk has changed to align with evidence and recommendations from the recent KOL panel convened by Boston Scientific.

Figure 2: The proposed clinical decision algorithm for patients indicated for coronary stent insertion



† Patients with acute coronary syndrome – STEMI, NSTEMI with higher risk of a cardiac event, unstable angina, stable angina who fail medical therapy or who have silent myocardial ischemia may be indicated for PCI/stenting as an elective, ad hoc or emergency procedure. Patients may undergo initial stent insertion, or re-stenting or assessment for other interventions if there are complications or failure of the stent.

‡ Diagnostic angiography may be performed in addition to the functional assessments (e.g. fractional flow reserve) of coronary arteries.

§ "High-risk" patients are identified based on their coronary anatomy, and the type and complexity of coronary lesions.

[1] Population option 1: patients undergoing PCI who have had a coronary lesion eligible for DES implantation

[2] Population option 2: patients undergoing PCI who have had a coronary lesion eligible for DES implantation with either:

- Lesions associated with the left main coronary artery ; and/or where suitability of percutaneous coronary intervention has appropriately been determined by a Heart Team approach for significant stenoses (≥50% as defined on IVUS) of the left main coronary artery, including in cases of unprotected left-main disease; or
- Lesion length ≥ 28mm

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:

In a majority of cases, IVUS will be used as an adjunct to angiography. However, in some cases, such as patients with renal impairment, IVUS may be used as a replacement for angiography, in order to avoid the use of contrast dyes.

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):

The use of IVUS enhances DES placement during PCI. A recent pooled analysis of 10 RCTs shows that IVUS guided PCI compared with angiography alone leads to significant reduction of cardiac mortality (Odds ratio[OR]=0.44; p=0.003; 95% CI 0.26–0.75), target lesion revascularisation (TLR; OR=0.57; p<0.001) , myocardial infarction (MI; OR=0.55; p<0.03) and stent thrombosis (OR=0.44; p=0.006) at 12-24 months.(5)

Additionally, a recently published real-world analysis of 1,877,177 US Medicare patients found IVUS to be associated with significant long term (median follow-up of 3.7 years) risk reduction in mortality (adjusted hazard ratio[aHR]=0.903; 95% CI 0.885–0.922; p<0.001), MI (aHR=0.899; 95% CI 0.893–0.904; p<0.001) and repeat revascularisation (aHR=0.893; 95% CI 0.887–0.898; p<0.001).(16)

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 remains unchanged from the published protocol. Specifically, use of IVUS to guide PCI with coronary stents insertion is expected to enhance post-procedure clinical outcomes. The intervention is expected to be superior in terms of effectiveness, and non-inferior in terms of safety compared to guidance with angiography without IVUS.

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:

Key outcomes will be updated from the published protocol to align with the new published evidence.

Safety Outcomes: Per application 1354, any adverse events or complications that occur as a result of the use of the intervention will be considered a safety concern. These include untoward medical condition that results in mortality; is considered life-threatening; requires hospitalisation; prolongs existing hospitalisation; or results in persistent or significant disability.

Clinical Effectiveness Outcomes: Cardiac mortality, myocardial infarction, target lesion revascularisation and definitive/probable stent thrombosis.

PART 7 – INFORMATION ABOUT ESTIMATED UTILISATION

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

As stated in Question 24, the prevalence of heart disease amongst Australians in 2017-18 was approximately one in twenty, or 1.2 million people. Regarding ACS, there were around 227,300 people experiencing angina while 430,000 had a heart attack or another form of CHD during this period.

The previous submission assumed IVUS would be limited to a proportion of all stent insertions (between 5% and 25%). This resulted in an estimated range of 760-1,280 procedures in year 1 and 4,210-7,010 procedures in year 5. The proposed resubmission will include updated estimates to address MSACs concerns and to align with the new patient definitions and Australian epidemiology estimates.

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

N/A

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:

The proposed resubmission will include updated estimates to address MSACs concerns and to align with the new patient definitions.

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:

The estimates from the previous submission will be updated in the resubmission.

PART 8 – COST INFORMATION

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

REDACTED

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

IVUS imaging takes 10–15 minutes; this is in addition to the stent insertion procedure, which usually takes 10–20 minutes.

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.

REDACTED

Option 1: Patients undergoing PCI who have had a coronary lesion eligible for DES implantation.

Category 3 – Therapeutic Procedures
MBS XXXXX Therapeutic use of Intravascular Ultrasound (IVUS) associated with the service to which item 38306 applies, for optimisation of stent placement in coronary vessels with significant stenoses (≥50% as defined on IVUS). Multiple Services Rule (Anaes.) Fee: **REDACTED** [Relevant explanatory notes] Fee only payable when the service is provided in association with insertion of coronary stent/s (item 38306)

Option 2: High-risk population

Category 3 – Therapeutic Procedures
MBS XXXXX Therapeutic use of Intravascular Ultrasound (IVUS) associated with the service to which item 38306 applies, for optimisation of stent placement in either: (a) lesions with significant stenosis (≥50% as defined on IVUS) associated with the left main coronary artery; and/or where suitability of percutaneous coronary intervention has appropriately been determined by a Heart Team approach for significant stenoses (≥50% as defined on IVUS) of the left main coronary artery, including in cases of unprotected left-main disease; or (b) coronary lesion length ≥28mm, as defined on IVUS. Multiple Services Rule (Anaes.) Fee: **REDACTED** [Relevant explanatory notes] Fee only payable when the service is provided in association with insertion of coronary stent/s (item 38306)

Appendix I

Table 1: TGA registered intravascular ultrasound devices

ARTG number	Approval date	Manufacturer	Product name	Intended purpose
315943[b]	29/03/2019	Boston Scientific Pty Ltd	Opticross HD 60 MHz Coronary Imaging Catheter - Ultrasound system, imaging, cardiovascular	This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.
315942[b]	29/03/2019	Boston Scientific Pty Ltd	Opticross 6 HD 60 MHz Coronary Imaging Catheter - Ultrasound system, imaging, cardiovascular	This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.
219096[b]	10/01/2014	Boston Scientific Pty Ltd	OptiCross Coronary Imaging Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	This catheter is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures. The Catheter is packaged with a Sterile Bag, extension tube, 3 cm3 (cc) and 10 cm3 (cc) syringes and a 4-way stopcock.
289984[b]	9/06/2017	Bracco Pty Ltd	ACIST Kodama Coronary Imaging Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use	The Kodama intravascular ultrasound catheter is a medical device for use by or on the order of a physician and is intended for ultrasound examination of coronary intravascular pathology only. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal coronary interventional procedures.
144141[b]	3/09/2007	Johnson & Johnson Medical Pty Ltd	ACUNAV Ultrasound Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular???	For intracardiac and intra-luminal visualisation of cardiac and great vessel anatomy and physiology as well as visualisation of other devices in the heart.
153484[b]	7/07/2008	Medical Vision Aust Cardiology & Thoracic Pty Ltd	Revolution 45 MHz Rotational Intravascular Ultrasound Imaging Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	To enable intravascular ultrasound images of coronary arteries by insertion into the vascular system when attached to an ultrasound system operator console. Indicated for patients who are candidates for transluminal interventional procedures.
179135[b]	13/01/2011	Medical Vision Aust Cardiology & Thoracic Pty Ltd	Eagle Eye Platinum Digital IVUS Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	For use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. It is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.
321187[b]	1/08/2019	Philips Electronics Australia Ltd	REFINITY ST Rotational IVUS Catheter Model 89900 - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use	Intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. Designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.
321186[b]	1/08/2019	Philips Electronics Australia Ltd	REFINITY Rotational IVUS Catheter Model 89800 - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use	Intended for the intravascular ultrasound examination of coronary arteries. Intravascular ultrasound imaging is indicated in patients who are candidates for transluminal interventional procedures. Designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.
300898[b]	16/03/2018	Philips Electronics Australia Ltd	Visions PV .035 Digital IVUS Catheter - Transducer assembly,	Intended for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such

			ultrasound, diagnostic, intracorporeal, intravascular, single-use	vessels. It is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures and dimensional measurements from the image.
299651[b]	14/02/2018	Philips Electronics Australia Ltd	Eagle Eye Platinum ST RX Digital IVUS Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use	For use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. It is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.
299650[b]	14/02/2018	Philips Electronics Australia Ltd	Eagle Eye Platinum RX Digital IVUS Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use	For use in the evaluation of vascular morphology in blood vessels of the coronary and peripheral vasculature by providing a cross-sectional image of such vessels. This device is not currently indicated for use in cerebral vessels. It is designed for use as an adjunct to conventional angiographic procedures to provide an image of the vessel lumen and wall structures.

a Medical device class I
b Medical device class III
Source: https://www.ebs.tga.gov.au/, accessed September 2020

Appendix II

Table 2: Coronary stents currently listed on the Protheses List.

Product Category	Sub Category	Product Group	Product Sub Group	Billing Code	Benefit	Sponsor	Product Name	Description	Size	ARTG
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	AY023	$2,298	Abbott Australasia Pty Ltd	Xience Everolimus Eluting Stent System	Everolimus Eluting Stent System	2.25mm to 4.0mm widths, 8mm to 28mm lengths	135963
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	AY037	$2,298	Abbott Australasia Pty Ltd	Xience PRIME LL Everolimus Eluting Coronary Stent; Xience PRIME Everolimus Eluting Coronary Stent; Xience PRIME SV Everolimus Eluting Coronary Stent	Coronary Artery Stent, Drug Eluting	XIENCE PRIME LL 2.50; 2.75; 3.00; 3.50; 4.0 x 33MM; XIENCE PRIME LL 2.50; 2.75; 3.00; 3.50; 4.0 x 38MM; XIENCE PRIME SV 2.25 x 08; 12; 15; 18; 23; 28MM; XIENCE PRIME 2.50 x 08; 12; 15; 18; 23; 28MM; XIENCE PRIME 2.75 x 08; 12; 15; 18; 23; 28MM; XIENCE PRIME 3.00 x 08; 12; 15; 18; 23; 28MM; XIENCE PRIME 3.50 x 08; 12; 15; 18; 23; 28MM; XIENCE PRIME 4.00 x 08; 12; 15; 18; 23; 28MM	167859 167878 167879
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	AY040	$2,298	Abbott Australasia Pty Ltd	XIENCE Xpedition Everolimus Eluting Coronary Stent System	Coronary Artery Stent, Drug Eluting	Xience Xpedition DES - 2.25 x (8,12,15,18,23,28) RX CE, 2.50 x (8,12,15,18,23,28,33,38,48) RX CE; 2.75 x (8,12,15,18,23,28,33,38,48) RX CE; 3.00 x (8,12,15,18,23,28,33,38,48) RX CE; 3.25 x (8,12,15,18,23,28,33,38) RX CE; 3.50 x (8,12,15,18,23,28,33,38,48) RX CE; 4.00 x (8,12,15,18,23,28,33,38) RX CE;	215602 215603 215604 264373
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	AY044	$2,298	Abbott Australasia Pty Ltd	XIENCE Alpine Everolimus Eluting Coronary Stent System	Drug eluting coronary artery stent	2.00 mm x (08, 12, 15, 18, 23, 28) mm 2.25 mm x (08, 12, 15, 18, 23, 28) mm 2.50 mm x (08, 12, 15, 18, 23, 28, 33, 38) mm 2.75 mm x (08, 12, 15, 18, 23, 28, 33, 38) mm 3.00 mm x (08, 12, 15, 18, 23, 28, 33, 38) mm 3.25 mm x (08, 12, 15, 18, 23, 28, 33, 38) mm 3.50 mm x (08, 12, 15, 18, 23, 28, 33, 38) mm 4.00 mm x (08, 12, 15, 18, 23, 28, 33, 38) mm	266175
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	AY047	$2,298	Abbott Australasia Pty Ltd	XIENCE Sierra Everolimus Eluting Coronary Stent System	Drug eluting coronary artery stent	Diameter: 2.00mm to 4.0mm. Length: 8mm to 38mm	313811
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	BE002	$2,298	Bio Excel Australia Pty Ltd	CRE8 Coronary Stent	Coronary Artery Drug Eluting Stent	The stent is available in 7 diameters: 2.25mm; 2.5mm; 2.75mm; 3.0mm; 3.5mm; 4.0mm; 4.5mm and 8 lengths: 8mm; 12mm; 16mm; 20mm; 25mm; 31mm; 38 mm and 46 mm.	230863 230864 230865
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	BS272	$2,298	Boston Scientific Australia Pty Ltd	SYNERGY	Everolimus-Eluting Platinum Chromium Coronary Stent System with Bioabsorbable Polymer	8mm to 48mm in length, diameter of 2.25 mm - 4.0 mm	220361
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	BS273	$2,298	Boston Scientific Australia Pty Ltd	PROMUS PREMIER	Platinum chromium alloy stent coated with a blended polymer mixed with everolimus.	8mm to 38mm in length, diameter of 2.25 mm - 4.0 mm	220360
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	BS366	$2,298	Boston Scientific Australia Pty Ltd	Promus ELITE	Everolimus-Eluting Platinum Chromium Coronary Stent System	8mm - 38mm in length, diameter of 2.25mm - 4.0mm	327735
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	BT178	$2,298	Biotronik Australia Pty Ltd	Orsiro	Sirolimus Coronary Artery Stent, Drug Eluting Co/Cr Alloy coated in PLLA	Stent diameters ø 2.25 - 4.0mm Lengths: 9-40mm	220414
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	DO001	$2,298	CARDINAL HEALTH AUSTRALIA	BioFreedom Drug Coated	Coronary Artery Stent, Drug Coated	Diameter: 2.25mm to 4.0mm Length: 8mm to 36mm	280282

						503 PTY LTD.	Coronary Stent System			
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	MI037	$2,298	Medtronic Australasia Pty Ltd	Resolute Integrity Zotarolimus-Eluting Coronary Stent System	Cobalt-alloy, ABT-578, BioLinx Polymer	Small Vessel - Diameter: 2.25mm-2.75mm; Length: 8.0mm-30.0mm Medium Vessel - Diameter: 3.0mm-4.0mm; Length: 9.0mm-38.0mm	188598
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	MI189	$2,298	Medtronic Australasia Pty Ltd	Resolute Onyx Zotarolimus-Eluting Coronary Stent System	coronary stent system; drug eluting	diameter: 2mm to 5mm	263413
08 - Cardiac	08.12 - Coronary Stents	08.12.01 - Drug Eluting	08.12.01.01 - General Purpose	TU064	$2,298	Terumo Australia	Ultimaster Sirolimus Eluting Coronary Stent System	The Ultimaster Sirolimus Eluting Coronary Stent System is a device/drug combination comprised of a Co-Cr stent coated with sirolimus in a matrix of poly(D,L-Lactide-co-Caprolactone), mounted on a balloon delivery catheter	length 9-38mm; diameter 2.25-4.0mm	288132

Source: https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm

References

1. Australian Bureau of Statistics. Causes of Death, Australia 2015 [Available from: https://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/3303.0Main+Features100012015?OpenDocument#:~:text=Ischemic%20heart%20disease%20is%20the,%25)%20worldwide%20(Endnote%208).

2. AIHW. Cardiovascular disease. Canberra: Australian Institute of Health and Welfare; 2020.

3. Qaseem A, Fihn SD, Dallas P, Williams S, Owens DK, Shekelle P, et al. Management of stable ischemic heart disease: summary of a clinical practice guideline from the American College of Physicians/American College of Cardiology Foundation/American Heart Association/American Association for Thoracic Surgery/Preventive Cardiovascular Nurses Association/Society of Thoracic Surgeons. Ann Intern Med. 2012;157(10):735-43.

4. Lotfi A, Jeremias A, Fearon WF, Feldman MD, Mehran R, Messenger JC, et al. Expert consensus statement on the use of fractional flow reserve, intravascular ultrasound, and optical coherence tomography: a consensus statement of the Society of Cardiovascular Angiography and Interventions. Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions. 2014;83(4):509-18.

5. Elgendy IY, Mahmoud AN, Elgendy AY, Bavry AA. Outcomes With Intravascular Ultrasound-Guided Stent Implantation: A Meta-Analysis of Randomized Trials in the Era of Drug-Eluting Stents. Circ Cardiovasc Interv. 2016;9(4):e003700.

6. Zhang J, Gao X, Kan J, Ge Z, Han L, Lu S, et al. Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation: The ULTIMATE Trial. Journal of the American College of Cardiology. 2018;72(24):3126-37.

7. Hong SJ, Kim BK, Shin DH, Nam CM, Kim JS, Ko YG, et al. Effect of Intravascular Ultrasound-Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation: The IVUS-XPL Randomized Clinical Trial. Jama. 2015;314(20):2155-63.

8. Chew DP, Scott IA, Cullen L, French JK, Briffa TG, Tideman PA, et al. National Heart Foundation of Australia & Cardiac Society of Australia and New Zealand: Australian Clinical Guidelines for the Management of Acute Coronary Syndromes 2016. Heart, Lung and Circulation. 2016;25(9):895-951.

9. Chew DP, Amerena JV, Coverdale SG, Rankin JM, Astley CM, Soman A, et al. Invasive management and late clinical outcomes in contemporary Australian management of acute coronary syndromes: observations from the ACACIA registry. Med J Aust. 2008;188(12):691-7.

10. Marhofer P, Greher M, Kapral S. Ultrasound guidance in regional anaesthesia. Br J Anaesth. 2005;94(1):7-17.

11. Davidson C, Bonow R. Cardiac catheterization. In: Bonow R, Mann DZ, DP; et al., editors. Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine. 9 ed: Elsevier; 2012.

12. Christou MA, Siontis GC, Katritsis DG, Ioannidis JP. Meta-analysis of fractional flow reserve versus quantitative coronary angiography and noninvasive imaging for evaluation of myocardial ischemia. Am J Cardiol. 2007;99(4):450-6.

13. Mentias A, Sarrazin MV, Saad M, Panaich S, Kapadia S, Horwitz PA, et al. Long-Term Outcomes of Coronary Stenting With and Without Use of Intravascular Ultrasound. JACC: Cardiovascular Interventions. 2020;13(16):1880-90.