
1354

Final protocol to
guide the assessment
of intravascular
ultrasound guided
coronary stent
insertion

September 2014

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MSAC and PASC

The Medical Services Advisory Committee (MSAC) is an independent expert committee appointed by the Australian Government's Minister for Health to strengthen the role of evidence in health financing decisions in Australia. MSAC advises the Minister on the evidence relating to the safety, effectiveness, and cost-effectiveness of new and existing medical technologies and procedures and under what circumstances public funding should be supported.

The Protocol Advisory Sub-Committee (PASC) is a standing sub-committee of MSAC. Its primary objective is the determination of protocols to guide clinical and economic assessments of medical interventions proposed for public funding.

Purpose of this document

This document is intended to provide a draft protocol that will be used to guide the assessment of an intervention for a particular population of patients. The draft protocol will be finalised after inviting relevant stakeholders to provide input to the protocol. The final protocol will provide the basis for the assessment of the intervention.

The protocol guiding the assessment of the health intervention has been developed using the widely accepted "PICO" approach. The PICO approach involves a clear articulation of the following aspects of the research question that the assessment is intended to answer:

- P**atients – specification of the characteristics of the patients in whom the intervention is to be considered for use;
- I**ntervention – specification of the proposed intervention
- C**omparator – specification of the therapy most likely to be replaced by the proposed intervention
- O**utcomes – specification of the health outcomes and the healthcare resources likely to be affected by the introduction of the proposed intervention

Purpose of application

A proposal for an application requesting Medicare Benefits Schedule (MBS) listing for intravascular ultrasound (IVUS) guided coronary stent insertion for patients undergoing percutaneous coronary intervention (PCI) was received from Boston Scientific Pty Ltd by the Department of Health and Ageing in September 2013.

MSAC application 1032 (July 2001) assessed evidence for IVUS as a diagnostic tool, and a therapeutic tool adjunct for interventional coronary procedures.¹ MSAC did not recommend public funding for the service in that instance due to insufficient evidence of effectiveness and cost-effectiveness. The current application pertains to the assessment of evidence for IVUS as a therapeutic tool to assist coronary stent insertion. Use of IVUS as a diagnostic tool is not an intended purpose of the current application.

Intervention

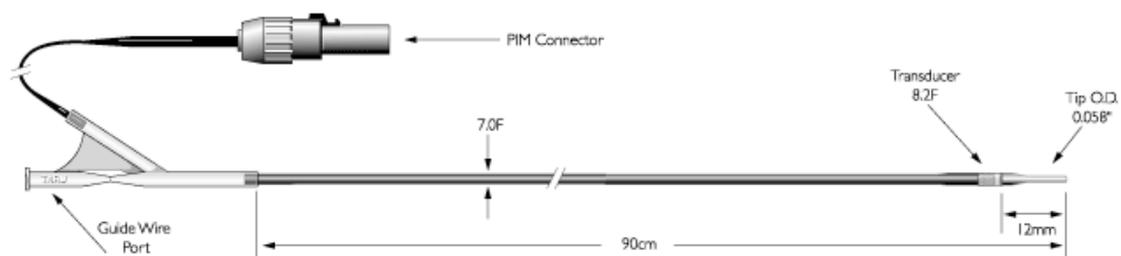
Description

Intravascular ultrasound (IVUS)

IVUS is the generic name for any ultrasound technology that provides tomographic, 3-dimensional, 360-degree images from inside the lumen of a blood vessel. During PCI, IVUS may be used to assess the degree of narrowing in the coronary vessels in ischaemic heart disease (IHD). The technology may also be used to guide coronary stent insertion, particularly in cases of left main coronary artery disease of indeterminate severity.² IVUS may be used as an adjunct to angiography in performing stent insertion.

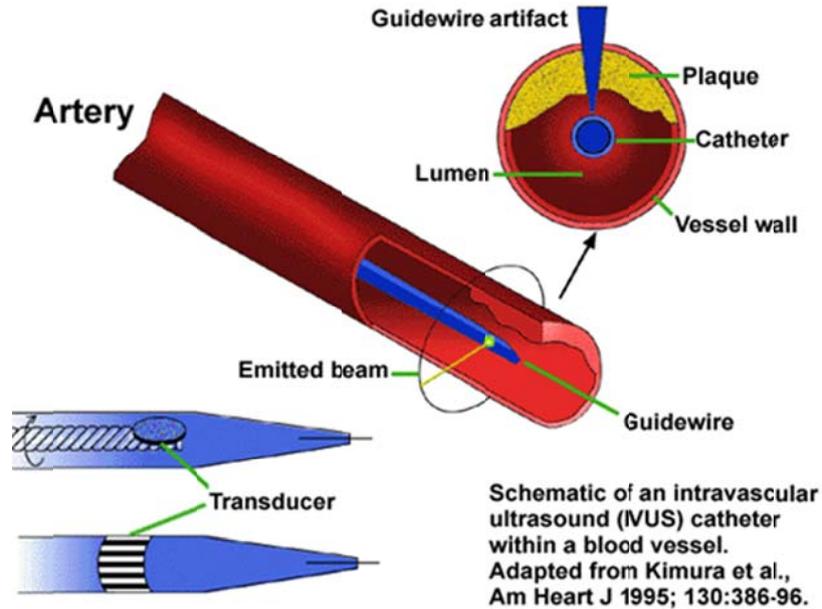
An IVUS system consists of an imaging catheter, a mini-transducer connected at the tip of the catheter (Figure 1), and a console.³ Ultrasound transducers generate, transmit and receive sound of an appropriate frequency and pulse rate. Sound is then processed by an ultrasound processor to generate on-screen. The catheter delivers the transducer at the narrowed coronary vessel (Figure 2). 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 (Figure 2).^{3, 4}

Figure 1: Intravascular ultrasound imaging catheter



Source: Medical Advisory Secretariat Ontario 2006⁵

Figure 2: Schematic of an intravascular ultrasound catheter within a blood vessel



Source: Medical Advisory Secretariat Ontario 2006⁵

The transducer produces high frequency sound waves. Structures such as blood, tissues, and plaques in the artery reflect sound waves differently because of differences in density. The reflected ultrasound waves are processed electronically to reconstruct black and white images that are displayed and recorded on the console. These images are interpreted to obtain information about lumen dimensions, plaque structure, extent and composition, presence of dissection, plaque rupture and thrombus, and to determine lumen area. This may provide physicians with a better understanding of atherosclerotic vessels to determine appropriate treatment strategy, stent selection and placement, and adequate deployment to restore blood flow.

For the purposes of this protocol, the intervention is the therapeutic use of IVUS when used for the placement of coronary stents. This excludes the use of IVUS for diagnostic purposes.

Angiography

Coronary angiography is an established procedure and is considered the gold standard for diagnosis of IHD.⁶ It provides key information about coronary lesions, allowing clinicians to decide on best management strategies from medical therapy, angioplasty, stenting or coronary artery bypass grafting (CABG). Angiography is also the most commonly used imaging modality to guide percutaneous coronary procedures such as stenting.

Angiography involves the insertion of a catheter to administer a contrast agent selectively into the coronary arteries to locate any lesions, assess left ventricular function, and to measure haemodynamic pressures. X-ray monitors the flow of the contrast agent through the arteries. It is a two-dimensional imaging technique, which depicts the cross-sectional coronary anatomy as a planar silhouette of the contrast-filled vessel lumen. Images may be interpreted using direct visual

assessment of lesions or by quantitative assessment using computer software. Images of the coronary vasculature depict any narrowing or lesions.⁷

MSAC Application 1032 identifies the following limitations of angiography:

- provides no information on the composition and structure of atherosclerotic lesions
- visual interpretation can result in clinically significant intra- and inter-observer variability
- in instances of diffuse vessel involvement, the measure of per cent diameter stenosis is likely to underestimate the true disease extent
- as a result of arterial remodelling, it may not detect plaque burden less than 40–50 per cent of the total vessel cross-sectional area.¹

The MSAC Application 1032 was based on the consideration of X-ray angiography. Other available angiographic techniques include computed tomography coronary angiography (CTCA) and magnetic resonance coronary angiography (MRCA). Hybrid imaging catheters are in development, which would allow the cardiologist to inject the contrast material for the angiographic images. The cardiologist would also be able to have the ultrasound transducers in the same catheter to get a cross-sectional view of a coronary vessel.⁸

Administration, dose, frequency of administration, duration of treatment

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 myocardial infarction. Coronary angiography is performed in these patients to locate and to define the extent and severity of atherosclerotic lesions. It also provides guidance during PCI procedures.

Following the finding of a lesion or narrowed coronary artery through diagnostic angiography, the cardiologist may elect to proceed immediately to insert a stent. In “high-risk” patients, IVUS may be a useful adjunct to coronary angiography. For further information on “high risk” patients, refer to the section on Patient Population (page 13).

Where further investigations and additional resources (e.g. a credentialed IVUS specialist) are not immediately available to perform IVUS-guided stent insertion, a follow-up procedure which includes IVUS may be necessary. Consecutive procedures are likely to be required in a substantial proportion of patients, as IVUS expertise is unlikely to be available consistently in all centres and at all times.

Surgical management 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.⁷

In Australia, angioplasty is performed in approximately 70 per cent, 35 per cent and 15 per cent of ST-segment elevation myocardial infarction (STEMI), non-STEMI (NSTEMI) and unstable angina patients, respectively. Of patients with a STEMI who undergo angioplasty, approximately 95 per cent will receive a stent.⁹ This is due to the high restenosis risk after angioplasty alone (30%) compared to restenosis risk after the addition of a stent (5%).⁹

Ultrasonography is a safe, non-invasive imaging procedure that does not produce ionizing radiation.¹⁰ 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 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.¹¹ 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.

Cardiologists perform the IVUS during a PCI. In Australia, this would typically be an interventional cardiologist. The Cardiac Society of Australia and New Zealand conduct proctoring programs and credentialling for these specialists.

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.

It is a common practice to perform follow-up angiography post-stenting. The timing and frequency of the follow-up angiography depend on clinical indications. If a patient presents with an unstable condition after stenting, immediate angiography is required to identify the root cause.

Co-administered interventions

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.

The PCI is generally performed under local anaesthesia. Oral or intravenous sedation is usually administered.¹¹ Fluoroscopy may be used to locate the femoral artery and to assist insertion of the guidewire.¹¹

Background

IHD, also known as coronary heart disease or atherosclerotic heart disease, is the most common form of cardiovascular disease.¹² High blood pressure and high cholesterol are the largest contributors to IHD in Australia, followed by physical inactivity, high body mass, tobacco use and low fruit and vegetable consumption.¹³

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. When the cerebral blood flow is compromised, IHD may result in stroke or cerebrovascular accident.

Prevalence

Based on self-reports from the 2007–08 National Health Survey, an estimated 3.4 million Australians (16% of the population) had at least one long-term cardiovascular disease.¹³ Similarly, estimates from the 2007 National Survey of Mental Health and Wellbeing (NSMHWB) show that 3.5 million Australians aged 16–85 years had a chronic cardiovascular condition. About 685,000 people (3% of the population) had IHD. Of those, 353,000 had experienced angina and 449,000 other conditions of IHD or myocardial infarction (note that a person may report more than one disease).¹⁴

The prevalence of IHD was higher among males than females in people aged over 35 years. More females than males were likely to have the disease in the age group 25–34. Men and women aged under 25 years had a similar but minimal prevalence of the disease. Overall, after adjusting for age, four per cent of males were estimated to have IHD, compared to two per cent of females. The prevalence of IHD increases markedly with age. In 2007–08, around seven per cent of Australians aged 55–64 years were estimated to have IHD, increasing to 24 per cent among those aged 85 years and over.¹⁵

In the 2004–05 National Aboriginal and Torres Strait Islander Health Survey, it was estimated that one per cent of Indigenous Australians (5,800 people) had IHD. Of these, 48 per cent (2,800) were males and 52 per cent (3,000) were females. When adjusted for age differences, the prevalence rate for Indigenous Australians was approximately twice as high as that for non-Indigenous Australians.¹⁵

In 2007–08, overall IHD prevalence was highest in the lowest socioeconomic group and lowest in the highest socioeconomic group.¹⁵

Incidence

There are no national data on the incidence of IHD in Australia.¹⁵ The Australian Institute of Health and Welfare (AIHW) estimates that in 2007 there were 49,391 major coronary events in Australia among 40–90 year olds (31,036 men and 18,355 women)—about 135 incidences per day. Nearly 40 per cent of these events were fatal (18,265 cases). The overall rate of major coronary events was twice as high among males as it was among females. After adjusting for age, there were 703 major coronary events per 100,000 males, compared with 331 per 100,000 females.¹⁵

The rate of major coronary events increased with age; rates among persons aged 75–90 years were over 16 times higher than amongst persons aged 40–54 years. The rate was higher among males for every age group. The rate for women aged 65–74 years was similar to that of men aged 55–64 years, indicating that men, on average, suffer from IHD at younger ages than women.¹⁵

Aboriginal and Torres Strait Islander people have considerably higher rates of major coronary events than other Australians; three times as high in 2002–03.¹⁶ Higher event rates among Indigenous Australians were also found in more recent studies in Western Australia and the Northern Territory where the incidence of acute myocardial infarction in the Indigenous population was found to have increased by 60 per cent between 1992 and 2004 but to have decreased by 20 per cent in the non-Indigenous population over the same period.^{17, 18}

Hospitalisations

Relevant AIHW hospital morbidity data are provided in Appendix A.

In 2009–10, there were 153,833 hospitalisations with a principal diagnosis of IHD, 32 per cent of hospitalisations for diseases of the circulatory system. Of hospitalisations for IHD, angina accounted for 65,158 (42%) and acute myocardial infarction for 55,033 (36%) (Table 11).¹⁹ During the same year, 14,499 PCI with acute myocardial infarction, and 19,037 PCI without acute myocardial infarction with stent implantation were performed (Table 12).²⁰ In total, 182,654 coronary artery procedures were conducted over this period, which included 37,038 transluminal coronary angioplasty procedures. The majority, 94 per cent of the transluminal coronary angioplasty procedures, involved stent insertion (Table 13).¹⁹ For stent insertion during transluminal coronary angioplasty procedures, 68 per cent involved a single stent inserted into a single coronary artery (

Table 14).¹⁹ In Australia, approximately 75–80 per cent of transluminal stent insertion procedures currently use a DES.

Burden of disease

Cardiovascular disease was responsible for approximately 34 per cent of all deaths in 2008 and its health and economic burdens exceed that of any other disease.¹⁵ Approximately half of IHD deaths resulted from acute myocardial infarction. Between 1987 and 2007, the age-standardised IHD death rate more than halved in Australia, falling from 251 deaths per 100,000 population to 98 per 100,000.

The decline is attributed to a number of factors including the decline in levels of tobacco smoking, and the availability of better medical care.¹⁵

Major comorbidities associated with cardiovascular disease include diabetes and chronic kidney disease. They have common risk factors such as tobacco smoking, physical inactivity, high blood pressure, high blood cholesterol, and being overweight or obese. Each disease is itself a risk factor for the other disease. In 2007–08, nearly a third of hospitalisations with any diagnosis of IHD had a co-existing diagnosis of diabetes or chronic kidney disease, and six per cent had a diagnosis of all three.²⁰

IHD and stroke account for a considerable proportion of the public health expenditure. Thirty-one per cent (\$1,813 million) of CVD expenditure was spent on IHD, while a further nine per cent (\$546 million) was spent on stroke. In 2004–05, prescription pharmaceuticals represented 16 per cent of total IHD expenditure, with the comparable figure for stroke being 11 per cent. However, it is likely that the amount spent on prescription pharmaceuticals for CVD is greatly underestimated.¹⁵

Management

The current guidelines on management of IHD recommend the following strategies:²¹

- behavioural modification – weight control, pressure control and healthy lifestyle
- medical/pharmaceuticals (e.g. beta-blockers, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, aldosterone antagonists)
- surgical/revascularisation – CABG, PCI (e.g. stenting)²¹ (the decision regarding whether to perform CABG or PCI with stenting is at the discretion of the treating specialist and will be made considering the patient's comorbidities and circumstances;²² other surgical procedures include balloon angioplasty, rotational atherectomy and laser thrombectomy).²

PCI is the most commonly employed coronary revascularization procedure worldwide. It is a primary management strategy in patients with STEMI. It may be indicated in the treatment of NSTMI and angina. Patients with single- and multi-vessel coronary artery disease can receive PCI.²³

Current arrangements for public reimbursement

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, receive BMS or DES at the narrowed coronary artery segment to relieve the effects of myocardial ischemia and to improve symptoms and prognosis. Balloon dilatation may be used during the procedure.

Coronary angiography and stenting are well established in current Australian practice. Coronary angiography is claimed via MBS item 38246. Angiography involves the placement of a catheter and the injection of opaque materials (MBS items 38215 and 38243). MBS item 38306 covers PCI with stenting. MBS items 38312 and 38318 are used when rotational atherectomy is considered prior to

stenting. Their descriptors are provided in Appendix B: MBS items for percutaneous coronary stent insertion.

IVUS is not routinely used in Australia during percutaneous coronary stent insertion and is not listed on the MBS.

Regulatory status

A list of ARTG-listed IVUS transducers and delivery catheters intended to be used during a percutaneous coronary stent insertion is provided in Table 1. This submission does not pertain to a specific trademarked device. No new devices are proposed.

Table 1: TGA registered intravascular ultrasound devices

ARTG number	Approval date	Manufacturer	Product name	Intended purpose
126936 ^b	11/04/2006	Boston Scientific Pty Ltd	Atlantis SR Pro - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	Intended for ultrasound examination of coronary intravascular pathology 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.
153370 ^b	30/06/2008	Johnson & Johnson Medical Pty Ltd	SoundStar 3D Ultrasound Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	Indicated for intra-cardiac and intra-luminal visualisation of cardiac and great vessel anatomy and physiology as well as visualisation of other devices in the heart. Provides location information when used with a CARTO Navigation System.
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.
153485 ^b	7/07/2008	Medical Vision Aust Cardiology & Thoracic Pty Ltd	Visions PV 0.018 Intravascular Ultrasound Imaging 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. It is designed for use as an adjunct to conventional angiographic procedures to provide an image of the lumen and wall structures.
179135 ^b	13/01/2011	Medical Vision	Eagle Eye Platinum Digital	For use in the evaluation of vascular

		Aust Cardiology & Thoracic Pty Ltd		IVUS Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	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.
217814 ^a	28/11/2013	Boston Scientific Pty Ltd	Scientific	Eagle Eye Platinum Digital IVUS 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.
219096 ^b	10/01/2014	Boston Scientific Pty Ltd	Scientific	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.
219543 ^b	24/01/2014	Medical Vision Aust Cardiology & Thoracic Pty Ltd	Vision	Visions PV .035 - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use	Intended for use in the evaluation of vascular morphology in blood vessels of the peripheral vasculature by providing a cross-sectional image of such 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.
221253 ^b	13/03/2014	Johnson & Johnson Pty Ltd	Medical	SoundStar eco Diagnostic Ultrasound Catheter - Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular	Indicated for intra-cardiac and intraluminal visualization of cardiac and great vessel anatomy and physiology as well as visualization of other devices in the heart. When used with compatible CARTO® 3 EP Navigation Systems, the SOUNDSTAR® eco Catheter provides location information.

^a Medical device class I

^b Medical device class III

Note: MBS items 144151, 153370, 153484, 153485, 179135, 217814, 219096, 219543 and 221253 were added by the assessment group.

Source: <https://www.ebs.tga.gov.au/>, accessed March 2014

Catheters for IVUS systems were not identified on the prostheses list. Other technologies, stents and stent delivery systems used in association with the proposed service are listed in the prostheses list (Table 19). Various trade names fall under the general categories of BMS, DES and stent delivery systems.²⁴

Patient population

The intervention is proposed for patients eligible for coronary revascularisation undergoing PCI with coronary stent insertion. This includes patients undergoing initial stent insertion, or re-stenting or assessment for other interventions if there are complications or failure of the stent. Expert clinical advice from the HESP recommends that IVUS-guided percutaneous stent insertion is indicated for patients who are identified by their specialist as “high-risk” based on their coronary anatomy, lesion type and complexity. They may include patients with:

- 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.

These patients are diagnosed with acute coronary syndrome – STEMI, NSTEMI with higher risk of a cardiac event, unstable angina, stable angina with failed medical therapy or silent myocardial ischemia. However, the vast majority include those with STEMI.²⁵

Practice guidelines recommend DES over BMS, if the patient has no contraindications to prolonged dual antiplatelet therapy.²⁶ Higher risk patients, such as those with a difficult anatomical lesion or type 1 diabetes, commonly receive a DES while patients with heavily calcified plaques commonly receive BMS. Usually, the choice of stent is decided before insertion of an IVUS catheter.

PCI with coronary stenting is not recommended if the patient is not likely to be able to tolerate and comply with dual antiplatelet therapy for an appropriate duration.²¹ If dual antiplatelet therapy is discontinued prematurely, the risk of stent thrombosis is increased dramatically. Stent thrombosis is associated with a mortality rate of 20–45 per cent.²⁷

Patients with diabetes, impaired renal function, and acute coronary syndrome are known to be at higher risk of cardiac events post-PCI; therefore, these patients may constitute a subpopulation.

Proposed MBS listing

The proposed MBS item descriptor is provided in Table 2. The proposed schedule fee is based on MBS item 38241 (use of a coronary pressure wire during selective coronary angiography to measure fractional flow reserve (FFR) and coronary flow reserve in one or more intermediate coronary artery or graft lesions...) which most closely resembles IVUS in terms of complexity and time. The fee for item 38241 is \$469.70 as of March 2014.

Table 2: Proposed MBS item descriptor for Intravascular Ultrasound-guided PCI with stent insertion

Category 3 – Therapeutic Procedures
<p>MBS xxxxx</p> <p>Selective Coronary Intravascular Ultrasound (IVUS), placement of IVUS catheter into the native coronary arteries, associated with the service to which item 38306 applies</p> <p>Multiple Services Rule (Anaes.)</p> <p>Fee: \$469.70 Benefit: 75% = \$352.30 85% = \$399.25</p> <p>[Relevant explanatory notes]</p> <p>Fee only payable when the service is provided in association with insertion of coronary stent/s (item 38306)</p>

The number of coronary stent insertions performed using MBS item 38306 in the period 2008—2012 is provided in Appendix B: MBS items for percutaneous coronary stent insertion. The proposed service is not expected to impact the natural growth in utilisation for coronary stent insertion.

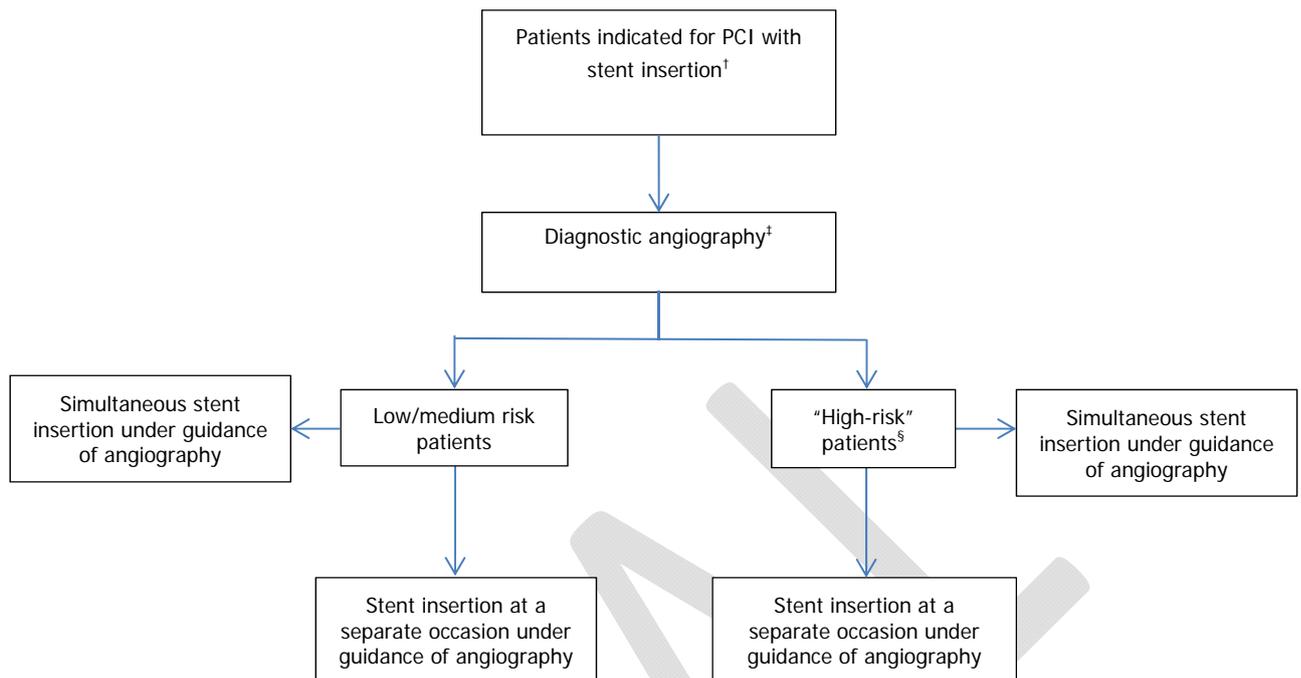
PASC agreed that the creation of two MBS items may be warranted: one item for the initial insertion of a stent under guidance of IVUS; and a second item a subgroup of patients who will require stent insertion at a subsequent occasion under guidance of IVUS. This should be resolved at the assessment stage.

Clinical place for proposed intervention

The current clinical pathway up to the point at which the intervention is provided is generally accepted in Australian clinical practice and is not expected to change with the introduction of IVUS. The rationale for the use of IVUS at the time of stenting arises from limitations of coronary angiography in terms of assessing the severity of coronary stenosis.²⁸

The current and proposed decision-making algorithms are shown in Figures 3 and 4.

Figure 3: The current clinical decision algorithm for patients indicated for coronary stent insertion

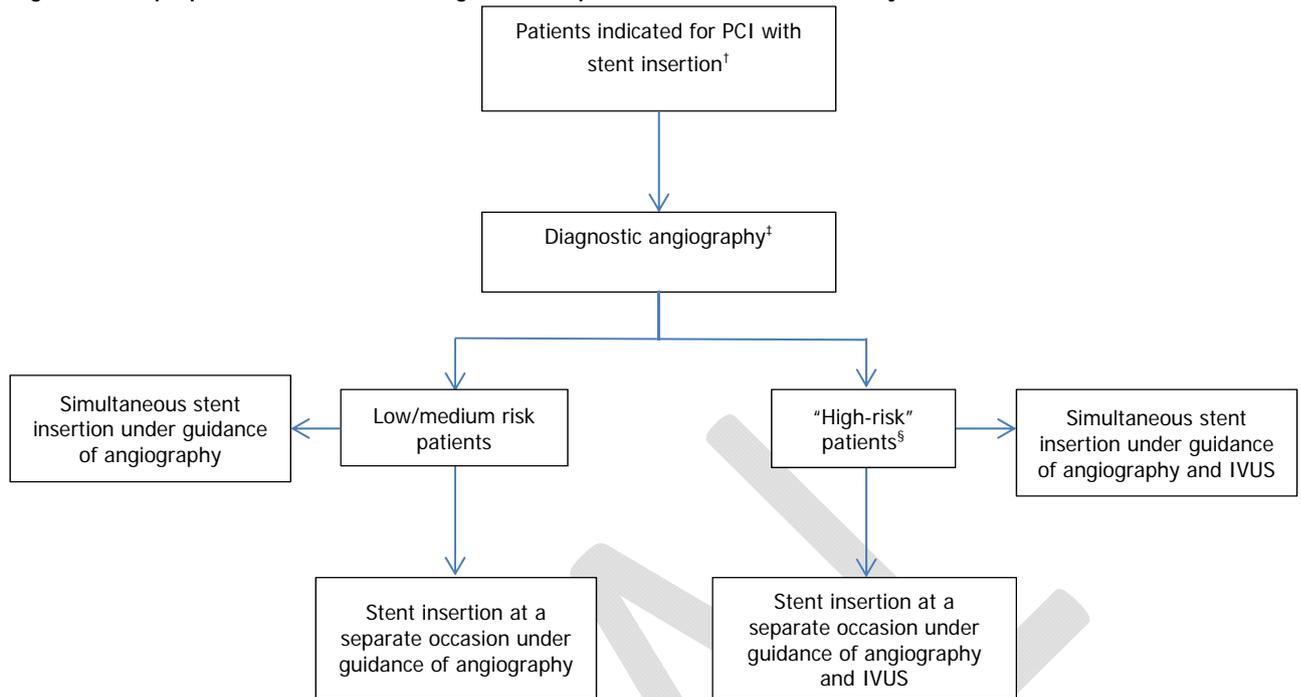


† Patients with acute coronary syndrome – STEMI, NSTEMI with higher risk of a cardiac event, unstable angina, stable angina who fail medical therapy or who have silent myocardial ischemia may be indicated for PCI/stenting as an elective, ad hoc or emergency procedure. Patients may undergo initial stent 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. They may include patients with coronary lesions that are intermediate in severity, especially when located in the left main coronary stem, patients undergoing complex coronary interventional procedures of ostial, coronary bifurcation, chronic total occlusions and lesions that are moderate to severely calcified, patients with challenging coronary anatomy, and patients who previously received a stent/s to identify underlying pathology for complications.

Figure 4: 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. They may include patients with coronary lesions that are intermediate in severity, especially when located in the left main coronary stem, patients undergoing complex coronary interventional procedures of ostial, coronary bifurcation, chronic total occlusions and lesions that are moderate to severely calcified, patients with challenging coronary anatomy, and patients who previously received a stent/s to identify underlying pathology for complications.

Comparator

Invasive coronary angiography without IVUS is the comparator for the proposed intervention, because angiography is predominantly used in Australian clinical practice to guide PCI with stenting.

PASC acknowledged that whilst CTCA and MRCA may be used to diagnose coronary stenosis, coronary interventions are guided only by invasive coronary X-ray angiography which should be used as the comparator. The types of angiography reported in the evidence and the types of angiography in use in Australia should be provided in the assessment.

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.²⁹ 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 evidence²⁸, and not routinely used in Australian clinical practice. For the purposes of this protocol, OCT and FFR are not comparators.

Clinical claim

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 (Table 3).

In an unknown proportion of (elective) stent insertions an IVUS assisted intervention may be considered to be necessary following angiography by a non-IVUS cardiologist. This will involve additional consultation and procedure costs to the MBS for an IVUS cardiologist at a later time to perform IVUS guided stent insertion. PASC agreed that the economic evaluation should consider stenting during a single procedure and during a second procedure, for example when the initial stent insertion is attempted by a non-IVUS credentialed cardiologist.

Table 3: Classification of an intervention for determination of economic evaluation to be presented

		Comparative effectiveness versus comparator				
		Superior		Non-inferior	Inferior	
Comparative safety versus comparator	Superior	CEA/CUA		CEA/CUA	Net clinical benefit	CEA/CUA
					Neutral benefit	CEA/CUA*
					Net harms	None^
	Non-inferior	CEA/CUA		CEA/CUA*	None^	
	Inferior	Net clinical benefit	CEA/CUA	None^	None^	
		Neutral benefit	CEA/CUA*			
Net harms		None^				

Abbreviations: CEA = cost-effectiveness analysis; CUA = cost-utility analysis

* May be reduced to cost-minimisation analysis. Cost-minimisation analysis should only be presented when the proposed service has been indisputably demonstrated to be no worse than its main comparator(s) in terms of both effectiveness and safety, so the difference between the service and the appropriate comparator can be reduced to a comparison of costs. In most cases, there will be some uncertainty around such a conclusion (i.e. the conclusion is often not

indisputable). Therefore, when an assessment concludes that an intervention was no worse than a comparator, an assessment of the uncertainty around this conclusion should be provided by presentation of cost-effectiveness and/or cost-utility analyses.

- ^ No economic evaluation needs to be presented; MSAC is unlikely to recommend government subsidy of this intervention.

FINAL

Outcomes and health care resources affected by introduction of proposed intervention

Outcomes

Effectiveness

Primary effectiveness outcome

- late stent thrombosis/restenosis

Secondary effectiveness outcomes

- health-related quality of life
- survival
- major adverse cardiac events (MACE (e.g. revascularisation, myocardial infarction, sudden cardiac death)
- target lesion/vessel revascularisation (TLR/TVR)
- angina

Where data permits, the clinical outcomes should be assessed separately for left main coronary artery (LMCA) disease and non-LMCA disease.

PASC acknowledged that there is no standard definition for MACE, which may compromise comparison and interpretation of MACE endpoints across trials. The assessment should assess and report the relevance of MACE endpoints.

Safety

Any adverse events or complications that occur as a result of the use of the intervention should be considered a safety concern. They include any untoward medical condition that results in mortality, was life threatening, required hospitalisation, or prolongation of existing hospitalisation, or resulted in persistent or significant disability.

Health care resources

A patient is likely to require IVUS only once during their lifetime. Approximately 4,500 patients would utilise the proposed service during the first fully funded provisional year. Currently, 3,000 patients are being treated using IVUS. With physician reimbursement to provide the service, an increase of approximately 50 per cent is expected in the number of patients who are treated using IVUS. This population is not expected to grow, as the PCI rate in Australia is currently steady.

Various capital and incremental cost components are involved. Capital costs associated with IVUS include purchase price of IVUS Generator and its maintenance. Currently, a portable IVUS machine costs approximately \$150,000. Associated incremental costs are associated with the cost of consumables, staff, hospitalisation and medication (Table 4).

Consumables and prostheses

The cost of consumables associated with an IVUS procedure is between \$1,000 and \$1,500, which includes the IVUS catheter. Use of IVUS is not expected to change the other consumables and prostheses (e.g. stents, catheters, wires) used in the stent placement procedure. Details of these costs are available at the Department of Health's National Hospital Cost Data Collection. A more detailed breakdown of capital costs associated with the proposed medical service will be required at the assessment phase.

Table 4: Calculation of average capital costs per procedure

Item	Cost \$AUS	Life	Annual cost \$AUS/machine (range)
Generator	150,000	8	18,750
Forgone capital return	4% of \$150,000	Annual	\$6,000
Maintenance	\$1,940	Annual	\$1,940
Total opportunity cost of capital	-	-	\$26,690
Average cost based on current procedures/machines/year	-	3,000	\$9
Average cost based on expected procedures/machines/year	-	4,500	\$6

Staff

The same health professionals who insert coronary stents would perform the IVUS service. This would typically be an interventional cardiologist who is also credentialed to perform IVUS. Where the need for IVUS guidance is identified after a stent insertion attempted by a non-IVUS credentialed cardiologist, additional consultation and procedure costs to the MBS would be incurred by an additional procedure undertaken by an IVUS accredited cardiologist. The typical time taken to perform the service by an experienced cardiologist is 10–15 minutes (intra-operative component). No pre-service or post-service components are involved. The proposed service does not change the current standard of care.

Other personnel involved include a circulating nurse, scrub nurse, technician (registrar), radiographer and radiologist. The attendance of an anaesthetist is required for the duration of the procedure (Table 5).

Table 5: Staff costs

Item	Description	Fee
Circulating nurse	Nurse assistant – experienced – \$724.50 per week	\$19.07 per hour
Theatre/scrub nurse	Registered theatre nurse (RN) – Level 4 Grade 3 – \$1366.70 per week	\$35.97 per hour
Technician (registrar)	Queensland Health registrar – Level 4 – \$105,148 per annum	\$53.21 per hour
Radiographer	NSW Health Employees' Medical Radiation Scientists (State) Award – Level 4 – \$1,964.90 per week	\$51.69 per hour

Hospitalisation related costs

Hospital admission and medication related costs can be calculated based on TGA, PBS and MBS data (Table 6 and Table 7).

Table 6: Hospital admissions

Resource	References
Initial PCI with Angiography	AR-DRG
Revascularisation with PCI (no MI)	AR-DRG
Revascularisation with CABG (no MI)	AR-DRG
Myocardial infarction (no revascularisation)	AR-DRG
Myocardial infarction with PCI	AR-DRG
Myocardial infarction with CABG	AR-DRG

Table 7: Medical management

Resource	References
Medical treatment post-MI	Pharmaceutical Benefits Schedule and Medicare Benefits Schedule

Other direct costs include:

- ward medical - \$30 (estimated from DRG F15Z)
- ward nursing - \$214 (estimated from DRG F15Z)
- non clinical salaries - \$81 (estimated from DRG F15Z)
- pathology - \$5 (estimated from DRG F15Z)
- imaging (X-ray) - \$6 (estimated from DRG F15Z)
- allied health - \$12 (estimated from DRG F15Z)
- pharmacy - \$71 (estimated from DRG F15Z)
- critical care unit - \$1,008 (estimated from DRG F15Z)
- operating room - \$564 (estimated from DRG F15Z)
- emergency department - \$36 (estimated from DRG F15Z)
- supplies - \$51 (estimated from DRG F15Z)
- specialist procedure suites - \$1,190 (estimated from DRG F15Z)
- prostheses - \$5,291 (estimated from DRG F15Z) BMS and DES will be modelled separately
- on-costs - \$282 (estimated from DRG F15Z)
- hotel - \$352 (estimated from DRG F15Z)
- depreciation - \$406 (estimated from DRG F15Z)
- payroll tax - \$23 (estimated from DRG F15Z)
- no of hospitals - \$41 (estimated from DRG F15Z).

The following MBS items are appropriate for use during the procedure and will be considered in the cost-effectiveness analysis for IVUS in addition to angiography:

- MBS Item 22025: intra-arterial cannulation when performed in association with the administration of anaesthesia.
- MBS Item 11600: blood pressure monitoring.
- MBS Item 38246: coronary angiography.

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Table 8: Healthcare resources to be considered in the decision analysis

	Provider	Setting	Resource	Details / Cost†	Units
Pre-procedure resources used to for the current and proposed intervention					
Initial consultation	Cardiologist	Surgery or hospital	MBS item 110	Fee: \$150.90 Benefits: 75%=\$113.20 85%=\$128.30	1
12 lead ECG	Cardiologist	Surgery or hospital	MBS item 11700	Fee: \$31.25 Benefits: 75%=\$23.45 85%=\$26.60	1
Chest X-ray	Cardiologist	Surgery or hospital	MBS Item 58503	Fee: \$47.15 Benefit: 75%=\$35.40 85%=\$40.10	1
Pathology	Pathologist	Surgery or hospital	MBS item 65070	Fee: \$16.95 Benefit: 75%=12.75 85%=\$14.45	1
Pathology – quantitation	Pathologist	Surgery or hospital	MBS item 66512	Fee: \$17.70 Benefit: 75%=13.30 85%=\$15.05	1
Resources used to deliver the current and proposed intervention					
Subsequent consultation	Cardiologist	Hospital	MBS item 116	Fee: \$75.50 Benefit: 75%=\$56.65	1
Initial consultation	Anaesthetist	Hospital	MBS item 110	Fee: \$150.90 Benefit: 75%=\$113.20	1
12 lead ECG	Cardiologist	Hospital	MBS item 11700	Fee: \$31.25 Benefit: 75%=\$23.45	1
Blood pressure monitoring	Anaesthetist	Hospital	MBS Item 11600	Fee: \$69.30 Benefit: 75%=\$52.00	1
Intraarterial cannulation	Anaesthetist	Hospital	MBS Item 22025	Fee: \$79.20 Benefit: 75%=\$59.40	1
Initiation of anaesthesia	Anaesthetist	Hospital	MBS item 21941	Fee: \$138.60 Benefit: 75%=\$103.95	1
Anaesthesia (1 hour)	Anaesthetist	Hospital	MBS item 23043	Fee: \$79.20 Benefit: 75%=\$59.40	1
Angiography	Cardiologist	Hospital	MBS item 38246	Fee: \$887.20 Benefit: 75%=\$665.40	1
Fluoroscopy	Cardiologist	Hospital	MBS item 59925	Fee: \$362.45 Benefit: 75%=\$271.85	1
Stent insertion	Cardiologist	Hospital	MBS item 38306	Fee: \$762.35 Benefit: 75%=\$571.80	1
Hospital costs	Hospital	Hospital Episode	AR-DRG Weighted Ave	Accommodation, nursing, allied health	1
Additional resources used to deliver the proposed intervention					
Proposed item fee for IVUS	Cardiologist	Hospital	Based on item 38241 coronary pressure wire	Fee: \$460.95 Benefit: 75%=352.30	1
Equipment	Capital cost	Hospital	Life: 8 years	\$150,000	1
IVUS Catheter	Consumable	Hospital	List Price	\$1,000 - \$1,500	1
Follow-up resources used to for the current and proposed intervention					
Subsequent consultation	Cardiologist	Pre-discharge	MBS item 116	Fee: \$75.50 Benefit: 75%=\$56.65	1
Chest X-ray	Cardiologist	Pre-discharge	MBS Item 58503	Fee: \$47.15 Benefit: 75%=\$35.40 85%=\$40.10	1
Incident cost of MI without revascularisation	Hospital	Adverse Event	AR-DRG Weighted Ave	TBD	
Incident cost of MI with PCI	Hospital	Adverse Event	AR-DRG Weighted Ave	TBD	
Incident cost of MI with CABG	Hospital	Adverse Event	AR-DRG Weighted Ave	TBD	
Incident cost of revascularisation with PCI	Hospital	Adverse Event	AR-DRG Weighted Ave	TBD	
Incident cost of revascularisation with CABG	Hospital	Adverse Event	AR-DRG Weighted Ave	TBD	
Post-MI medical costs	Pharmacy	Adverse Event	PBS and MBS	TBD	

AR-DRG: Australian refined diagnosis-related groups; MBS: Medicare Benefits Schedule; TBD: to be determined; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft; MI: myocardial infarction; IVUS: intravascular ultrasound.

† MBS fees and benefits as at 1 March 2014

Proposed structure of economic evaluation (decision-analytic)

Given the chronic nature of the condition under study and the impact of patient attributes on the model output, an individual-based model is recommended. Two extended PICOs are proposed: the first for patients undergoing initial stent placement (Table 9); the second for patients requiring re-stenting or other interventions following a complication or failure of the initial stent (Table 10).

Table 9: Summary of extended PICO to define research questions that assessment will investigate – PCI with stent placement

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
<p>Patients eligible for coronary revascularisation and undergoing PCI with coronary stent insertion at the time of initial stent placement.</p> <p>Sub-population: Patients deemed "high-risk" based on their coronary anatomy, lesion type and complexity.^a They may include patients with:</p> <ul style="list-style-type: none"> • intermediate left main coronary stenoses; • 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). 	Coronary stent insertion guided by IVUS and invasive coronary angiography ^b	Coronary stent insertion guided by invasive coronary angiography ^b without IVUS	<p>Effectiveness</p> <p><u>Primary effectiveness</u></p> <ul style="list-style-type: none"> • Late stent thrombosis/restenosis <p><u>Secondary effectiveness</u></p> <ul style="list-style-type: none"> • Health-related quality of life • Survival • MACE^c (e.g. revascularisation, myocardial infarction, sudden cardiac death) • Target lesion/vessel revascularisation (TLR/TVR) • Angina <p>Safety</p> <p>Any adverse events or complications that occur as a result of the use of the intervention should be considered as a safety concern.</p> <p>Where data permits, the clinical outcomes should be assessed separately:</p> <ul style="list-style-type: none"> - for left main coronary artery (LMCA) disease and non-LMCA disease, - for types of stents (e.g. BMS, DES)^d 	See Table 8

BMS: bare metal stent; DES: drug-eluting stent; MACE: major adverse cardiac events; PCI: percutaneous coronary intervention; IVUS: intravascular ultrasound

^a Patients with diabetes, impaired renal function, and acute coronary syndrome may also be at higher risk of cardiac events post-PCI.

- b The assessment should report the type of angiography used (e.g. X-ray, CT, MRI, hybrid) and explain its relevance to Australian clinical practice.
- c There is no standard definition for MACE, which may compromise comparison and interpretation of MACE endpoints across trials. The assessment should assess the relevance of MACE endpoints.
- d Typically BMS and DES are used in specific patient populations with different risks and clinical indications.

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Table 10: Summary of extended PICO to define research questions that assessment will investigate – following a complication or failure of the stent requiring re-stenting or other interventions

Patients	Intervention	Comparator	Outcomes to be assessed	Healthcare resources to be considered
<p>Patients eligible for coronary revascularisation and undergoing PCI with coronary stent insertion following a complication or failure of the stent requiring re-stenting or other interventions.</p> <p>Sub-population: Patients deemed “high-risk” based on their coronary anatomy, lesion type and complexity.^a They may include patients with:</p> <ul style="list-style-type: none"> • intermediate left main coronary stenoses; • 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. 	<p>Coronary stent insertion guided by IVUS and invasive coronary angiography^b</p>	<p>Coronary stent insertion guided by invasive coronary angiography^b without IVUS</p>	<p>Effectiveness</p> <p><u>Primary effectiveness</u></p> <ul style="list-style-type: none"> • Late stent thrombosis/ restenosis <p><u>Secondary effectiveness</u></p> <ul style="list-style-type: none"> • Health-related quality of life • Survival • MACE^c (e.g. revascularisation, myocardial infarction, sudden cardiac death) • Target lesion/vessel revascularisation (TLR/TVR) • Angina <p>Safety</p> <p>Any adverse events or complications that occur as a result of the use of the intervention should be considered as a safety concern.</p> <p>Where data permits, the clinical outcomes should be assessed separately:</p> <ul style="list-style-type: none"> - for left main coronary artery (LMCA) disease and non-LMCA disease, - for types of stents (e.g. BMS, DES).^d 	<p>See Table 8</p>

BMS: bare metal stent; DES: drug-eluting stent; MACE: major adverse cardiac events; PCI: percutaneous coronary intervention; IVUS: intravascular ultrasound

^a Patients with diabetes, impaired renal function, and acute coronary syndrome may also be at higher risk of cardiac events post-PCI.

^b The assessment should report the type of angiography used (e.g. X-ray, CT, MRI, hybrid) and explain its relevance to Australian clinical practice.

^c There is no standard definition for MACE, which may compromise comparison and interpretation of MACE endpoints across trials. The assessment should assess the relevance of MACE endpoints.

^d Typically BMS and DES are used in specific patient populations with different risks and clinical indications.

Research questions

Primary research questions

1. For patients undergoing PCI with stent insertion, what is the safety of IVUS in addition to angiography compared with angiography without IVUS?
2. For patients undergoing PCI with stent insertion, what is the effectiveness of IVUS in addition to angiography compared with angiography without IVUS?
3. For patients undergoing PCI with stent insertion, what is the cost-effectiveness of IVUS in addition to angiography compared with angiography without IVUS?

The assessment should address these questions in line with the two populations defined in Table 9 and Table 10.

Fee, cost and financial impact modelling: In an unknown proportion of (elective) stent insertions an IVUS assisted intervention may be considered to be necessary following angiography by a non-IVUS cardiologist. This will involve additional consultation and procedure costs to the MBS for an IVUS cardiologist at a later time to perform IVUS guided stent insertion. The assessment should test the impact of this in the economic modelling.

Appendix A: AIHW Hospital morbidity data

Table 11: Annual growth rate in hospital separations for ischemic heart diseases²⁰

ICD-10-AM	Number of separations					
	2004—05	2005—06	2006—07	2007—08	2008—09	2009—10
I20 Angina pectoris	80,229	77,242	75,109	71,801	66,312	65,158
I21 Acute myocardial infarction	47,633	49,534	51,667	55,676	55,233	55,003
I22 Subsequent myocardial infarction	290	294	310	321	197	216
I23 Certain current complications following acute myocardial infarction	22	23	28	45	173	112
I24 Other acute ischemic heart disease	376	391	363	307	340	351
I 25 Chronic ischemic heart disease	33,733	33,883	34,851	33,267	32,553	32,993
Total	1,62,283	1,61,367	1,62,328	1,61,417	1,54,808	1,53,833
Change from previous year	-	-0.56%	0.60%	-0.56%	-4.09%	-0.63%

ICD-10-AM: Australian modification of the WHO International classification of diseases – version 2010

Source: AIHW²⁰

Table 12: Hospital separations for surgical procedures of the cardiovascular system, classified using the Australian refined diagnosis-related groups

AR-DRG	Number of separations					
	2004—05	2005—06	2006—07	2007—08	2008—09	2009—10
F10Z Percutaneous coronary intervention with acute myocardial infarction	10,721	11,849	12,863	13,553	13,765	14,499
F15Z Percutaneous coronary intervention (without acute myocardial infarction), with stent implantation	20,417	20,682	20,136	18,842	18,928	19,037

Source: AIHW^{19, 20}

Table 13: Hospital separations for coronary artery procedures, classified using the Australian Classification of Health Interventions

ACHI	Number of separations					
	2004—05	2005—06	2006—07	2007—08	2008—09	2009—10
667 cardiac catheterisation	1,100	1,078	1,057	1,105	1,128	1,262
670 Transluminal coronary angioplasty	2,162	2,216	2,174	2,275	2,418	2,333
671 Transluminal coronary angioplasty with stenting	32,529	33,849	34,047	33,325	33,884	34,705

Source: AIHW¹⁹

Table 14: Hospital separations for transluminal coronary angioplasty with stenting, classified using the Australian Classification of Health Interventions

ACHI	Number of separations					
	2004—05	2005—06	2006—07	2007—08	2008—09	2009—10
Percutaneous insertion of 1 transluminal stent into single coronary artery	21,227	21,695	22,273	22,400	22,754	23,618
Percutaneous insertion of ≥ 2 transluminal stents into single coronary artery	6,269	6,812	6,767	6,712	6,680	6,717
Percutaneous insertion of ≥ 2 transluminal stents into multiple coronary arteries	5,019	5,327	4,995	4,207	4,433	4,347
Open insertion of 1 transluminal stent into single coronary artery	NR	NR	NR	NR	10	12

NR: not reported.

Source: AIHW¹⁹

Appendix B: MBS items for percutaneous coronary stent insertion

Table 15: MBS item descriptors for percutaneous stent insertion, MBS item 38306

Category 3 – Therapeutic Procedures
<p>MBS 38306</p> <p>TRANSLUMINAL INSERTION OF STENT OR STENTS into 1 occlusional site, including associated balloon dilatation for coronary artery, percutaneous or by open exposure, excluding associated radiological services and preparation, and excluding aftercare</p> <p>Multiple Services Rule (Anaes.) (Assist.)</p> <p>Fee: \$762.35</p> <p><u>Explanatory notes</u></p> <p>Refer to T8.63 (see below)</p>

T8.63 Transluminal insertion of stent or stents

Item 38306 should only be billed once per occlusional site. It is not appropriate to bill item 38306 multiple times for the insertion of more than one stent at the same occlusional site in the same artery. However, it would be appropriate to claim this item multiple times for insertion of stents into the same artery at different occlusional sites or into another artery or occlusional site. It is expected that the practitioner will note the details of the artery or site into which the stents were placed, in order for the Department of Human Services to process the claims.

Table 16: MBS item descriptors for percutaneous stent insertion, MBS item 38312

Category 3 – Therapeutic Procedures
<p>MBS 38312</p> <p>PERCUTANEOUS TRANSLUMINAL ROTATIONAL ATHERECTOMY of 1 coronary artery, including balloon angioplasty with insertion of 1 or more stents, where:</p> <ul style="list-style-type: none"> - no lesion of the coronary artery has been stented; and - each lesion of the coronary artery is complex and heavily calcified; and - balloon angioplasty with or without stenting is not suitable; <p>excluding associated radiological services or preparation, and excluding aftercare.</p> <p>Multiple Services Rule (Anaes.) (Assist.)</p> <p>Fee: \$1,132.35</p> <p><u>Explanatory notes</u></p> <p>Refer to T8.42 (see below)</p>

Table 17: MBS item descriptors for percutaneous stent insertion, MBS item 38318

Category 3 – Therapeutic Procedures
<p>MBS 38318</p> <p>PERCUTANEOUS TRANSLUMINAL ROTATIONAL ATHERECTOMY of more than 1 coronary artery, including balloon angioplasty, with insertion of 1 or more stents, where:</p> <ul style="list-style-type: none"> - no lesion of the coronary arteries has been stented; and - each lesion of the coronary arteries is complex and heavily calcified; and - balloon angioplasty with or without stenting is not suitable, <p>excluding associated radiological services or preparation, and excluding aftercare</p> <p>Multiple Services Rule (Anaes.) (Assist.)</p> <p>Fee: \$1,586.35</p> <p><u>Explanatory notes</u></p> <p>Refer to T8.42 (see below)</p>

T8.42 Percutaneous Transluminal Coronary Angioplasty

A coronary artery lesion is considered to be complex when the lesion is a chronic total occlusion, located at an ostial site, angulated, tortuous or greater than 1cm in length. Percutaneous transluminal coronary rotational atherectomy is suitable for revascularisation of complex and heavily calcified coronary artery stenoses in patients for whom coronary artery bypass graft surgery is contraindicated.

Each of the items 38309, 38312, 38315 and 38318 describes an episode of service. As such, only one item in this range can be claimed in a single episode.

Table 18: Use of coronary stent insertion services, MBS item 38306, during 2008—2012

Year	Total Service	Total Growth
2008	20,780	
2009	22,383	8%
2010	22,193	-1%
2011	23,159	4%
2012	23,514	2%
2013	24,197	3%

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Appendix C Stents and stent delivery systems listed in the prostheses list

Table 19: Stents and stent delivery systems listed in the prostheses list

Billing code	Product name
AC030	Cinatra Cobalt Chromium Coronary Stent System
AY012	JoStent Coronary Stent Graft
AY023	Xience Everolimus Eluting Stent System
AY028	Multilink Coronary Stent System - Vision
AY037	Xience PRIME LL Everolimus Eluting Coronary Stent; Xience PRIME Everolimus Eluting Coronary Stent; Xience PRIME SV Everolimus Eluting Coronary Stent
AY039	MULTI-LINK 8 Coronary Stent System, MULTI-LINK 8 SV Coronary Stent System and MULTI-LINK 8 LL Coronary Stent System
BE001	Gazelle Coronary Stent
BS069	Liberte Coronary Stent System
BS175	PROMUS Element
BS176	Taxus Element
BS211	OMEGA Bare Metal Stent
BS224	PROMUS Element Plus
BT082	PRO-Kinetic
BT107	PRO-Kinetic Energy
DY534	Presillion Plus CoCr Coronary Stent on RX System
IX001	Amazonia CroCo
IX002	Nile CroCo
IX003	Minvasys Nile Delta Coronary Stent System
MC329	Medtronic Driver, Micro Driver Coronary Stent System
MC732	Endeavour Drug Eluting Coronary Stent System
MC769	Endeavor Sprint Drug Eluting Stent System
MC816	Endeavor Resolute Drug Eluting Coronary Stent System
MC932	Driver Sprint Coronary Stent System
MC956	Integrity Coronary Stent System
MI037	Resolute Integrity Zotarolimus-Eluting Coronary Stent System
NM004	Azule Coronary Stent Delivery System
TU001	Tsunami Gold
TU044	Kaname Coronary Stent System

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F E M N A L