MSAC Application 1743

Optical coherence tomography (OCT) guided coronary stent insertion for patients eligible for coronary revascularisation

PICO Confirmation

Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for optical coherence tomography (OCT) in guided coronary stent insertion: PICO Set 1

Component	Description
Population	Patients with myocardial ischaemia undergoing invasive coronary angiogram, percutaneous angioplasty and transluminal insertion of stents with at least one of the following lesion types or complexity: • Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel of ≥28 mm • Lesion located at a bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation • Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion) • Stent failure (including stent thrombosis or in-stent restenosis of diffuse or multi-focal pattern)
Intervention	Optical coherence tomography (OCT) guided coronary stent insertion as an adjunct to invasive coronary angiogram and percutaneous angioplasty for the transluminal insertion of stents (i.e. angiographic + OCT guided coronary stent insertion) performed by trained interventional cardiologists in the catheterisation laboratory.
Comparator/s	Invasive coronary angiogram and percutaneous angioplasty for the transluminal insertion of stents alone *(*i.e. coronary stent insertion guided by angiography alone). For the subpopulation of patients with long or multiple lesions (total stent length ≥28mm): Intravascular ultrasound (IVUS) as an adjunct to invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stents (i.e. angiographic + IVUS guided coronary stent insertion)
Outcomes	**Effectiveness** Target vessel failure [TVF], defined as the composite of: cardiac death, target vessel myocardial infarction, or ischemia-driven target vessel revascularisation. All cause / cardiac mortality Myocardial infarction Revascularisation Stent thrombosis In-stent restenosis Health-related quality of life e.g. SF-36 **Safety** Procedural complications / adverse events **Economic** Cost of treatment Cost of adverse events or complications
Assessment questions	What is the safety, effectiveness and cost-effectiveness of OCT adjunct to invasive coronary angiogram versus coronary angiogram alone for the purpose of guiding stent insertion in patients with myocardial ischaemia and prior stent failure or one of 3 documented lesion types (long/multiple, bifurcation, severe calcification)? What is the safety, effectiveness and cost-effectiveness of OCT adjunct to invasive coronary angiogram versus IVUS adjunct to invasive coronary angiogram for the purpose of guiding stent insertion in patients with myocardial ischaemia and long or multiple lesions?

Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of Optical Coherence Tomography (OCT) for coronary stent insertion was received from ABBOTT MEDICAL AUSTRALIA PTY LTD. by the Department of Health and Aged Care.

The clinical claim provided by the applicant is that the use of OCT adjunct to invasive coronary angiogram for the guidance of coronary stent insertion results in:

- Superior effectiveness and non-inferior safety in comparison to invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stents alone
- Non-inferior effectiveness and safety in comparison to IVUS as an adjunct to invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stents in patients with long lesions

The proposed listing is for OCT as an adjunct to coronary stent insertion guided by angiography alone, it is expected that any OCT item used for the guidance of coronary stent insertion will be claimed concurrently with one of the twelve percutaneous coronary interventions (PCI) items which are currently listed on the MBS.

PICO criteria

Population

The proposed population for OCT guided coronary stent insertion is patients with myocardial ischaemia undergoing invasive coronary angiogram, percutaneous angioplasty and transluminal insertion of stents with at least one of the following lesion types or complexity:

• Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm

• Lesion located at a bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation

• Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion)

• Stent failure (including stent thrombosis or in-stent restenosis of diffuse or multi-focal pattern)

The applicant confirmed that the initial patient population is limited only to patients who meet the eligibility criteria for the 12 MBS items used to claim stenting as part of primary PCIs. This population is then further restricted based on whether patients meet one of the four lesion-specific or complexity criteria listed above.

<u>Myocardial ischaemia</u>

Myocardial ischaemia is defined as occurring when the delivery of oxygen (via oxygenated blood) to the heart muscle (myocardium) is not sufficient to meet the myocardium's demand for oxygen (Lake &

Kingston, 2020). The condition can be caused by coronary heart disease (CHD), also known as ischaemic heart disease, however it can occur independently of CHD (Sedehi & Cigarroa, 2018). CHD is characterised by reduced blood flow to the myocardium resulting from blockages in the coronary arteries caused by atherosclerosis. The reduced blood flow can cause damage to the musculature of the heart and may also produce serious arrhythmia (Ahmed, 2019). Patients with myocardial ischaemia have an increased risk of experiencing acute coronary events including acute myocardial infarction, unstable angina, or death due to CHD (Australian Institute of Health and Welfare, 2023). Patients with myocardial ischaemia may present with symptoms of chest pain, shortness of breath, or fainting (Lake & Kingston, 2020).

The prognosis for patients with myocardial ischaemia caused by CHD in Australia has improved over the last two decades, with rates of acute coronary events decreasing by 59% between 2001 and 2020. Similarly, the number of hospitalisations due to CHD have reduced by 39% between the years 2000 and 2021. The CHD-related mortality rates in Australia have been decreasing since the late 1960's. Between 1980 and 2021, mortality due to CHD has reduced by 44%, and the age-standardised mortality rate has declined by over 80%. These observed decreases in acute coronary events and the CHD-related mortality rate have been attributed to reductions across the population in levels of risk factors such as tobacco smoking, high blood pressure, and high cholesterol levels. In addition, decreased numbers of CHD-related events have also been attributed to improvements in treatment options, including novel medical and surgical therapies and increased uptake of antithrombotic drugs and medications that lower blood pressure and cholesterol. (Australian Institute of Health and Welfare, 2023)

Prevalence

It is estimated that 580,000 (3.1%) of the Australian adult population have been diagnosed with CHD (Australian Institute of Health and Welfare, 2023).

At-risk populations

In the Australian population, the prevalence of CHD amongst men (3.8%) was estimated to be twice that of Australian women (1.9%). However due to differences in pathophysiology, alongside unsubstantiated societal and clinical attitudes, CHD remains under-diagnosed and under treated in women (Keteepe-Arachi & Sharma, 2017). Age is a significant risk factor for CHD, occurring at a rate of 1.1% among those in the population aged 45-54 years and increasing to a rate of 14% in the 75 years and over age cohort. Indigenous Australians are at greater risk of CHD compared with the non-Indigenous population, recording a prevalence of 5.6%. Socio-economic status was also a factor influencing CHD risk, with adults who resided in areas categorised as being in the most socio-economically disadvantaged quintile having a 1.6-fold increase in CHD likelihood compared with those living in the least disadvantaged quintile. The risk of CHD was higher for men compared with women for those living in all but the least socio-economically disadvantaged quintile (Australian Institute of Health and Welfare, 2023).

Population size

The application reported that 21,401 procedures that included coronary stent(s) insertion were claimed under 12 individual MBS items in 2022, detail of these items are included in Table 4. Each item allows for the insertion of multiple stents into a specified coronary vascular territory. See Table 2 for details of the utilisation for each item. Only a subset of this overall patient population will meet the lesion-specific and complexity criteria outlined for OCT eligibility. The applicant provided modelling which estimated the

population meeting the proposed criteria to be 7,995 people. They have also estimated that the uptake rate of OCT if listed will increase by REDACTED in annual increments from REDACTED in Year 1 to REDACTED in Year 4, indicating that there would likely be REDACTED people who would receive OCT guided coronary stent insertion under the proposed listing in Year 1. It is uncertain how accurate these indicative estimates may be, and, in practice, may be dependent on the availability of OCT equipment as well as patients' accessibility to OCT-trained cardiologists.

Table 2 Utilisation of MBS Items for Percutaneous Coronary Intervention (PCI) (2022)

Item Number	Services Claimed
38307	6,626
38308	770
38310	46
38311	6,348
38313	705
38314	31
38316	1,958
38317	471
38319	50
38320	3,552
38322	769
38323	75
Total	21,401

Current practice

According to clinical expert advice, there are currently no Australian-specific guidelines for intracoronary imaging with regards to the guidance of stent placement. However, The Cardiac Society of Australia and New Zealand (CSANZ) have endorsed a consensus statement from the European Association of Percutaneous Cardiovascular Interventions (Räber et al., 2018) until they are able to produce their own guidelines. Presently, coronary angiography is the most commonly used technique to visually evaluate the coronary arteries and guide PCI for patients with CHD. Coronary angiography is an invasive diagnostic imaging technique which allows visualisation of the coronary circulation (Mendirichaga et al., 2018). Although it is considered the gold-standard of imaging the coronary arteries, the technique is limited to rendering only a two-dimensional image and may be subject to variability in interpretation between practitioners (Mariathas et al., 2022; Mendirichaga et al., 2018). Alternative options for imaging the coronary anatomy include the addition of OCT as an adjunct to coronary angiography (see *Intervention*) and intravascular ultrasound (IVUS), which the applicant has nominated as a comparator for the subpopulation of patients with long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel of ≥28mm.

The population proposed for OCT use

The application cited a combination of expert advice and the eligibility criteria of the ILUMIEN IV trial (Ali et al. 2021) as providing the underlying rationale for this proposed population. There are some differences in the wording of the bifurcation lesion, with the trial stating that it must be intended to be treated with 2 planned stents (see Table 3 below).

The proposed population includes the criteria "stent failure…" that is broader than the criteria used in the ILUMIEN trial. The clinical roundtable convened by the applicant with 5 interventional cardiologists argued that "There is an unequivocally high clinical need for OCT in patients with stent failure. The roundtable advised that stent failure be used, rather than the ILUMIEN IV criterion 'in-stent restenosis of diffuse or multifocal pattern', to allow use of OCT in stent thrombosis (consistent with European Association of Percutaneous Cardiovascular Interventions (EAPCI) guidelines 'Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions' European Hearth Journal. 2018. 39:3281–3300)". The ILUMIEN trial will inform the effectiveness of OCT in a narrower population than the more broadly defined stent failure population.

PASC queried the inclusion of stent thrombosis in the eligible population for OCT use under the proposed indication of stent failure. The applicant's clinical expert indicated that the prevalence of stent thrombosis is likely reduced for patients using OCT versus coronary angiography alone for stent insertion. The applicant's clinical expert also acknowledged the difficulty of conducting a randomised trial in this patient population due to stent thrombosis being a rare event and typically occurring in an emergency setting. PASC considered that the inclusion of this patient subgroup may be supported by observational evidence.

Table 3. Comparison of OCT criteria for use in the application and the ILUMIEN trial

Proposed indications for OCT use	ILUMIEN trial protocol inclusion criteria
Long or multiple lesions defined as intended total stent length (continuous or separated) in any single target vessel ≥28mm	Long or multiple lesions defined as intended total stent length (continuous or separated) in any single target vessel ≥28mm
Lesion located at a bifurcation and where the planned side branch is ≥2.5mm in diameter by angiographic visual estimation	Bifurcation intended to be treated with 2 planned stents, where the planned side branch is ≥2.5mm in diameter by angiographic visual estimation
Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion)	Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion)
Stent failure including stent thrombosis or in-stent restenosis of diffuse or multi-focal pattern	Diffuse or multi-focal pattern in-stent restenosis at or within the existing stent margin(s).

- Target lesion(s) must be located in a native coronary artery with a visually estimated or quantitatively assessed %Diameter Stenosis (DS) of ≥70% or ≥50% respectively, plus one or more of the following:
    - An abnormal functional test (e.g., invasive physiological lesion assessment, stress test) signifying ischemia in the distribution of the target lesion(s) or
    - Biomarker positive acute coronary syndromes suggestive of plaque disruption or thrombus
- Target lesion(s) must be located in a native coronary artery with reference vessel diameter by visual estimation of ≥2.50 and ≤3.5 mm.
- Maximum 2 target lesions in any single vessel and in maximum 2 separate target vessels (including branches) can be included.
- Target lesions are amenable to OCT-guided PCI (i.e., no lesion-specific angiographic exclusion criteria are present

PASC confirmed that OCT is suitable to be used in patients with stable angina with documented ischaemia (along with patients with acute coronary syndrome or high risk CT findings) based on the 24% of patients in the ILUMIEN IV trial who had non-ST-elevation myocardial infarctions (NSTEMIs).

PASC advised that the assessment of vessel lesion type, and therefore eligibility for the service, should be based on angiogram findings rather than OCT findings. The applicant confirmed that even though OCT is now used routinely prior to PCI, the proposed MBS item for OCT would only be billed if the patient had at least one of the four eligible lesion types.

Unsuitable patients

The application has not indicated any patient/demographic group for whom this intervention is not appropriate for. The ILUMIEN IV trial excluded patients with chronic kidney disease (defined as creatinine clearance ≤30 ml/min/1.73 m^2) and who were not on dialysis, patients who experienced ST-segment myocardial infarction within 24 hours of symptom onset were also excluded.

PASC queried whether patients with significant kidney disease or who were at risk of dialysis should be specifically excluded from OCT eligibility due to the use of contrast dye during the procedure, which can be harmful to the kidneys. The applicant's clinical expert clarified that the same amount of contrast would be used for OCT as is currently used for coronary angiography. The applicant's clinical expert also noted that IVUS allows for the use of a 50/50 solution of saline and contrast, allowing reduced exposure to the contrast, and so would be the preferred option for patients with chronic kidney disease. PASC resolved that there was no need to exclude patients with chronic kidney disease from the population as IVUS would be preferred for such patients.

Intervention

OCT is an imaging technique which allows for three-dimensional cross-sectional images of body tissue to be developed (Warger et al., 2014). The mechanism used to obtain images with OCT is similar to that used in ultrasound, however light is used instead of sound, allowing for improved spatial resolution and increased imaging speed in comparison (Lamirel, 2014). Initially, OCT had been developed to image the eye and continues to be utilised for the diagnosis of ocular diseases such as age-related macular degeneration. More recently, the technology has been adapted for use in other parts of the anatomy including for intracoronary imaging (Warger et al., 2014).

The use of OCT for intracoronary imaging is considered to have multiple therapeutic applications including evaluating plaque morphology, identifying thrombus, and optimising stent size and placement (Kayani & Levine, 2018). The application has indicated that OCT is to be used in tandem with an invasive coronary angiogram.

A coronary angiogram consists of an x-ray which is able to visualise the coronary arteries following the injection of radioactive dye (Healthdirect Australia, 2022). Angiography can be used to diagnose coronary artery disease by the visual estimation of the stenosis (narrowing) of the artery (Fearon, 2018). As noted previously, compared with OCT, coronary angiography is limited to two-dimensional imagery (Mariathas et al., 2022; Mendirichaga et al., 2018). The specific technology that is the subject of this application enables both intracoronary OCT and coronary angiography to occur simultaneously.

The device consists of the computerised OPTIS system and a specialised imaging catheter with an insertable length of 135cm and a diameter of 2.7 Fr (see figure 1 & 2 of the application for images). The device uses near infra-red light to produce three-dimensional cross-sectional scans of the interior of the

artery. There have been no limitations stipulated regarding the frequency of use for this technology by the applicant.

PASC noted that there does not appear to be any data which suggests the repeat use of OCT has negative implications for patient safety and considered no need for separate items for repeat procedures.

The applicant indicated that the use of the proposed technology for the guidance of stent insertion during PCI should occur as an inpatient procedure at a public or private hospital. The application has also stated that coronary imaging with OCT and angiography would occur in the catheterisation laboratory, which would also be the setting for PCI procedures.

In the application it is also mentioned that the procedure could also be used in an emergency setting or as an elective procedure. However, as a 75% rebate is supported for this service, it is implied that this should be an in-hospital service only.

The application indicated that specific training and accreditation will be required for practitioners who wish to administer this therapeutic technology. However, the application suggests that the intended criteria for such practitioners (referred to as trained OCT cardiologists) is yet to be determined. It is unclear how many trained OCT cardiologists are in Australia, the application indicated that a shortage of such cardiologists may limit the accessibility of the therapy to some patients.

PASC considered it appropriate the existing CSANZ committee be responsible for outlining and clarifying the necessary accreditation and training. PASC noted that due to capacity issues CSANZ may not be able to provide guidance documents prior to implementation.

The required OCT infrastructure includes a catheterisation laboratory, and the OCT system itself including software. The application indicated that there are REDACTED OCT systems used across private hospitals in Australia, serving REDACTED% of the nation's total private hospitals. This suggests that the majority of hospitals in Australia (both public and private) are presently ill-equipped to carry out OCT guided coronary stent insertion procedures and further proliferation of OCT systems would be required to support the adoption of this technique. Presently, there are no government subsidies provided for the use of this technology within Australia's public healthcare system.

Comparator(s)

Coronary angiography

The comparator nominated by the applicant is the use of a coronary angiogram alone to guide the insertion of intracoronary stents. As described above, this entails the use of an x-ray which is able to visualise the coronary arteries following the injection of an iodinated contrast medium. This procedure represents current clinical practice for the insertion of coronary stents and the applicant has indicated that it will continue to be used as an adjunct to OCT should the application be successful. PCI for the purposes of guiding the transluminal insertion of stents is currently listed on the MBS under 12 individual items. These items were tabulated by the applicant and organised by patient clinical indication, time since previous coronary angiography, and number of coronary vascular territories involved.

Table 4 MBS item pertaining to PCI with coronary stent insertion

Timing of coronary angiography	Acute coronary syndrome (ACS) or high-risk CT findings ('selective coronary angiography')			Stable angina with documented ischemia		
Invasive coronary angiography has not been completed in the previous 3 months	1 coronary vascular territory	2 coronary vascular territories	3 coronary vascular territories	1 coronary vascular territory	2 coronary vascular territories	3 coronary vascular territories
MBS item	38307	38308	38310	38311	38313	38314
Invasive coronary angiography has been completed in the previous 3 months	1 coronary vascular territory	2 coronary vascular territories	3 coronary vascular territories	1 coronary vascular territory	2 coronary vascular territories	3 coronary vascular territories
MBS item	38316	38317	38319	38320	38322	38323

CT = computed tomography, MBS = Medicare Benefits Schedule, PCI = percutaneous coronary intervention.
Source: Table 2 of the application

Intravascular Ultrasound

Intravascular Ultrasound (IVUS) has also been nominated as a near-market comparator. IVUS has been supported by MSAC for MBS listing but the relevant item has not yet been published. IVUS utilises ultrasound signals to produce two-dimensional images of the arterial lumen and outer wall (Athanasiou et al., 2017). The technology makes use of a catheter with an ultrasound transducer located in the tip to emit ultrasound waves (Athanasiou et al., 2017). IVUS enables the visualisation of atherosclerotic plaque, allowing for the characterisation of different plaque types (Athanasiou et al., 2017). During the PICO process, the applicant clarified that IVUS as an adjunct to invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stents was the intended comparator for OCT as an adjunct to invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stents rather than IVUS alone.

The proposed MBS restriction for IVUS is included below. It is noted that IVUS only represents a comparator to OCT in 1 of the 4 proposed OCT patient populations – the subgroup who have lesions with intended stent length of ≥28mm. The proposed listing for IVUS indicates that it is also an eligible treatment option for guiding insertion of stents targeting lesions in the left main coronary artery, a patient group for whom OCT has not been requested for MBS listing. This is consistent with the RENOVATE trial where the majority of left main lesions were supported by IVUS. The PICO for OCT additionally includes stent failure, bifurcation and severe calcification which are not included for IVUS. The proposed MBS listing for IVUS is described below.

MBS XXXXX Use of Intravascular Ultrasound (IVUS) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients documented with: a) Left main coronary artery lesions; or b) Other lesion locations with lesion length ≥28mm. Being a service associated with items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323. Service is claimable once in a single episode of care (for one or more lesions). Multiple Operation Rule (Anaes.) Fee: $488.70 Benefit: 75% = $366.550 85% = $415.40 [Relevant explanatory notes] Fee only payable when the service is provided in association with insertion of coronary stent/s (items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323).
TN.8.XX
Acute Coronary Syndromes (ACS – items 38307, 38308, 38310, 38316, 38317, 38319) Item XXXXX (IVUS) can only be claimed in association with items 38307, 38308, 38310, 38316, 38317 or 38319 if; The patient meets one or more of the indications in subclause 2 of explanatory note TR.8.2; and The patient meets one of the indications listed in item XXXXX for the lesion being treated. **Stable Coronary Syndromes (items 38311, 38313, 38314, 38320, 38322, 38323)** Item XXXXX (IVUS) can only be claimed in association with items 38311, 38313, 38314, 38320, 38322, 38323 if; The patient meets the requirements of Clause 5.10.17C referenced in explanatory note TR.8.4; and The patient meets one of the indications listed in item XXXXX for the lesion being treated

Source: Public Summary Document Application 1354.1

PASC noted clinical expert advice that it would be very unlikely for a patient with lesions length ≥28mm to receive both OCT and IVUS within the one procedure. The choice between IVUS and OCT for patients who have lesions with length ≥28mm would likely be influenced by clinician discretion, access to resources, clinician expertise, or whether patients have advanced chronic kidney disease (and therefore they would be more suitable for IVUS).

PASC considered the comparator was appropriate as described in the PICO summary.

Outcomes

Safety

- Procedural complications
- Adverse events
- Serious adverse events

Effectiveness

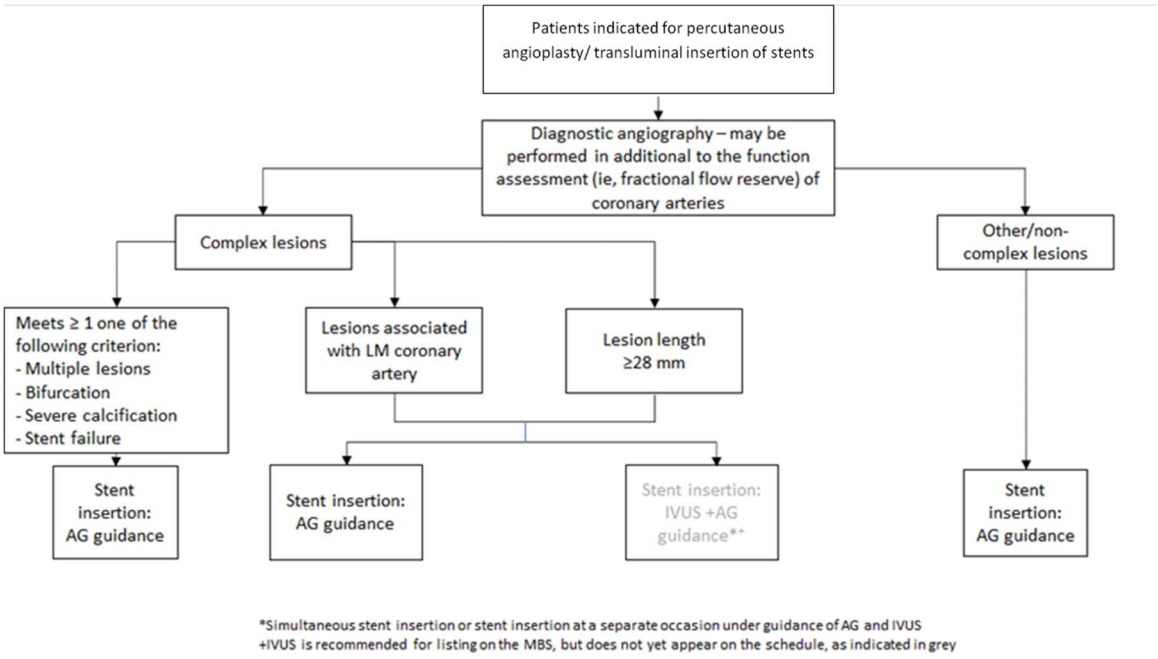
- Target vessel failure – composite of cardiac death, target vessel myocardial ischaemia, or ischaemia-driven target vessel revascularisation
- Mortality- all cause and cardiac specific
- Myocardial infarction
- Revascularisation
- Stent thrombosis
- In-stent restenosis
- Health-Related Quality of Life (HRQoL) *(e.g. Short Form (SF)-36, EuroQoL (EQ)-5D)*

PASC considered that the outcomes defined in the PICO document were appropriate but noted a lack of data within the clinical evidence pertaining to quality of life.

Clinical management algorithms

The management algorithm provided by the applicant to reflect current clinical guidelines is presented in Figure 1. The applicant noted that this algorithm was based on the algorithm presented in Application 1354.1 for the use of IVUS to guide PCI. Both the current clinical management algorithm (Figure 1) and the proposed clinical management algorithm (Figure 2) have included IVUS as a comparator in subpopulation with lesion length ≥ 28mm in anticipation of its listing on the MBS.

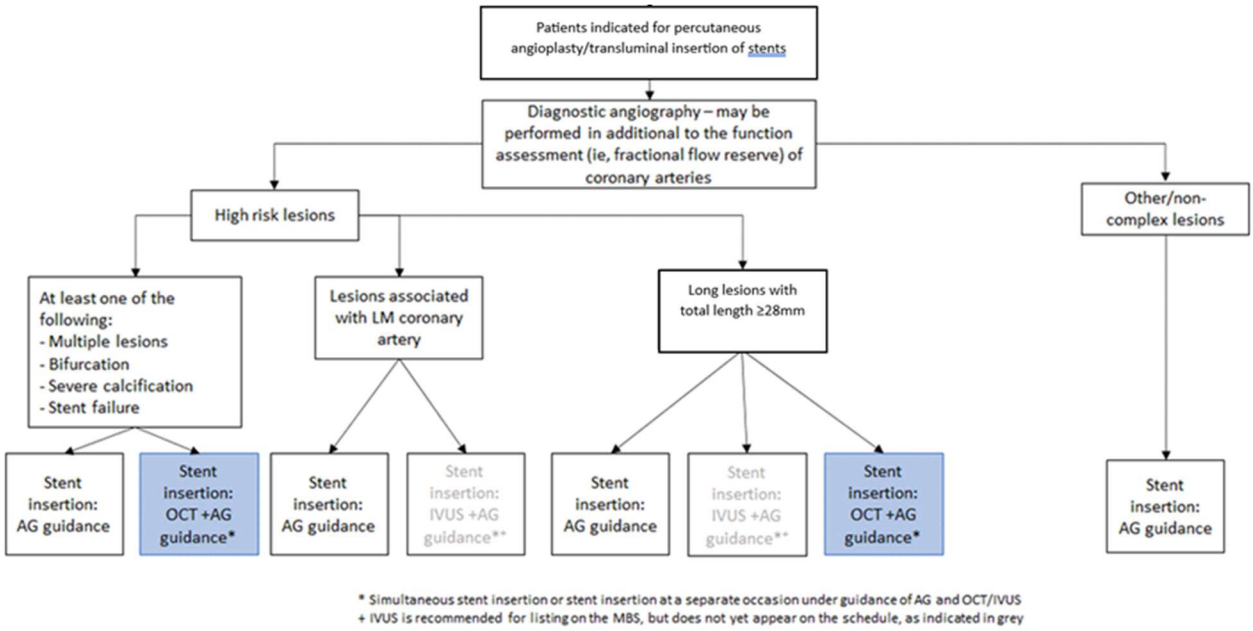
Figure 1 Current clinical management algorithm



AG = Coronary angiogram, IVUS = Intravenous ultrasound, LM = Left main, PCI = Percutaneous coronary intervention

As outlined above, IVUS only represents a viable comparator to OCT for patients with intended stent length of ≥28mm. Patients with lesions associated with the left main coronary artery may also be eligible for IVUS, however, in this application, OCT has not been nominated for this patient subgroup. The current clinical management algorithm also reflects that coronary angiography remains the currently used guidance technology for all other patients requiring coronary stent insertion.

Figure 2 Proposed clinical management algorithm with OCT included



AG = Coronary angiogram, IVUS = Intravenous ultrasound, LM = Left main, OCT = Optical coherence tomography, PCI = Percutaneous coronary intervention

The proposed clinical management algorithm included in the application presents OCT as an adjunct to coronary angiography as a treatment option for patients requiring coronary stent insertion. For patients who have intended stent length of ≥28mm in length, both coronary stent insertion guided by angiography alone and IVUS plus coronary angiography represent comparators to OCT with coronary angiography as an adjunct. However, patients who have any or a combination of multiple lesions, bifurcation, severe calcification, or stent failure are proposed to have OCT and adjunct coronary angiography or coronary stent insertion guided by angiography alone as their treatment options. The use of OCT occurs in the final line of intervention and as such is not expected to displace the use of other therapies/technologies in other lines of treatment. In the proposed clinical management algorithm OCT will compete with the use of IVUS for patients with intended stent length of ≥28mm.

The clinical algorithm does not specifically mention patients with other clinical presentations included in the ILUMIEN trial such as patients at high clinical risk due to medicated diabetes mellitus, and other complex lesions such as NSTEMI (non-ST elevation myocardial infarction), and chronic total occlusion. It is assumed that these patients will be treated with stent insertion with angiographic guidance under current and proposed algorithms.

Proposed economic evaluation

The clinical claims are summarised by comparator in Table 5 along with recommended economic evaluation method.

Table 5 Summary of clinical claims for OCT by comparator and recommended economic evaluation method.

Comparator	Clinical effectiveness claim	Safety claim	Recommended economic evaluation
Coronary angiogram alone	OCT superior	OCT non-inferior	CUA
IVUS + coronary angiogram	OCT non-inferior	OCT non-inferior	CMA

CUA= cost utility analysis; IVUS= intravenous ultrasound; OCT= optical coherence tomography

For the comparison with coronary stent insertion guided by angiography alone there is a potential impact on health-related quality of life, therefore the MSAC guidelines suggest a cost utility (CUA) analysis rather than a cost-effectiveness analysis (CEA) as the preferred method for the economic evaluation.

Table 6 provides a guide for determining which type of economic evaluation is appropriate.

Table 6 Classification of comparative effectiveness and safety of the proposed intervention, compared with likely comparators, and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	**Uncertain[a]**	**Noninferior[b]**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

CEA=cost-effectiveness analysis, CMA=cost-minimisation analysis, CUA=cost-utility analysis.
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis
[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations
[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence
Yellow shading indicates OCT vs coronary angiography
Green shading indicates OCT vs IVUS

There are six published trials compiled by the applicant to support the claim of superior effectiveness of OCT vs coronary stent insertion guided by angiography alone and a claim of non-inferior effectiveness between OCT + coronary angiography vs IVUS + coronary angiography. Table 7 below provides a summary of how the trials are likely to cover the two comparators and the four specific components of the indication. Coronary angiogram was included as a comparator in 5 out of 6 trials with IVUS included in 3 out of 6 trials. 3 out of 6 trials provided intermediate outcomes and were not powered for clinical events. In terms of coverage of the proposed OCT indication, some aspects were explicitly excluded in some trials: long or multiple lesions are covered in all trials, bifurcation in 3 out of 6 trials, and calcification in 2 out of 6 trials. Stent failure with regards to at least one component of the PICO definition (i.e. either "stent thrombosis" or "in-stent restenosis") has been covered in 2 out of 6 trials.

Some of the trial evidence explicitly included only de novo patients which reduces the generalisability of these results for patients requiring repeat procedures. Some trials defined patient inclusion by a certain number of vessels or lesions. If a certain number of vessels or lesions is deemed more appropriate eligibility criteria for OCT this may have implications for alignment with existing MBS items for PCI where each MBS item specifies 1,2 or 3 vessel territories.

PASC noted that calcification as an indication for the intervention was not comprehensively covered in the literature, however, there was no evidence to suggest that this should be excluded. PASC noted that the ILUMIEN IV, OCTOBER and OCTIVUS trial have been published since the lodgement of the application. These trials include a priori *subgroups of the proposed subpopulations for OCT vs AG or vs IVUS (long lesions), see* Table 8.

Table 7 Characteristics of published trials comparing OCT with coronary angiography and/or IVUS

Study	OCT (n)	Coronary angiogram alone (n)	IVUS (n)	Long or multiple lesions defined as intended total stent length in any single target vessel ≥28mm	Bifurcation and where the planned side branch is ≥2.5mm in diameter by angiographic visual estimation	Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion)	Stent failure including stent thrombosis, in-stent restenosis of diffuse or multi-focal pattern
ILUMIEN III (RCT) Czech Republic	Yes (158)	Yes (146)	Yes (146)	Yes	Yes	Yes	Partial
OPINION (non-inferiority RCT) Japan	Yes (414)	-	Yes (415)	Yes	Yes	-	Excluded
DOCTORS (RCT) France	Yes (12)	Yes (120)	-	Partial (single)	-	Excluded	Excluded
OCTACS (RCT) Denmark	Yes (50)	Yes (50)	-	Yes	Excluded	-	Excluded
ROBUST (RCT) Czech Republic	Yes (105)	Yes (96)	-	Yes	-	-	-
RENOVATE (RCT) South Korea	Yes (278)	Yes (534)	Yes (813)	Yes	Yes	Yes	Partial (in stent stenosis)

IVUS = Intravenous ultrasound, OCT = Optical coherence tomography, RCT = Randomised controlled trial.

Table 8 Pivotal studies published after the application by subpopulation

Trial	Bifurcation	Severe calcification	Stent failure	Long lesion
Comparator	AG alone	AG alone	AG alone	IVUS + AG
Pivotal evidence				
OCTOBER (RTC) Europe	Yes	–	–	–
ILUMIEN IV	Yes	Yes	Yes	–
OCTIVUS	–	–	–	Yes

IVUS = Intravenous ultrasound.
Table provided by applicant prior to PASC demonstrating pivotal studies by lesion complexity.
Source: Lee 2023 Renovate, Ali 2023 Ilumien, Holm 2023 October, Kang 2023 Octivus

Proposal for public funding

The applicant has proposed funding for the use of OCT to guide coronary stent insertion under category 3 as a therapeutic procedure. Both the catheter and OCT system have been included on the Australian Register of Therapeutic Goods (ARTG).

Category (3) – Therapeutic procedures)
MBS item *XXXX Optical Coherence Tomography Use of optical coherence tomography (OCT) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients with: Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm), or Lesion located at a bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation, or Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion), or Stent failure (including stent thrombosis, in-stent restenosis of diffuse or multi-focal pattern). Being a service associated with items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323. Service is claimable once in a single episode of care (for one or more lesions). Fee only payable when the service is provided in association with insertion of coronary stent/s (items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323). (H)
Fee: $496.50

PASC agreed to remove myocardial ischaemia from the item descriptor as it is a requirement of PCI and therefore does not require specifying in the MBS listing for OCT.

The applicant has justified their proposed fee using the existing MBS item 38241 as a benchmark, which was used to form the basis of the proposed item for the comparator IVUS (Ratified PICO 1354.1). This basis was further supported by expert opinion consulted in preparing the application which noted that the duration of the procedure, the complexity, and the resources used of OCT to be similar to that of IVUS (and hence pressure wire [i.e. MBS item 38241]).

PASC queried whether the additional eligibility criteria of the ILUMIEN trial should be considered in the proposed MBS listing, particularly the limitation of stent insertion to 2 target vessels. The applicant's clinical expert suggested that this limitation in the trial was arbitrary and used only as part of the study

design. PASC noted there was no theoretical reason to limit the proposed intervention to 2 vessels per procedure, and also noted that such a limitation may incentivise some practitioners to perform multiple procedures in order to receive additional fees. However, PASC considered that a multi-disciplinary team should be consulted if 3 vessels require intervention because there are potential risks involved with increasing the duration of the procedure.

As OCT is an adjunct of coronary angiography, the fee charged will be subject to the multiple operation rule. The multiple operation rule states that if two or more operations are performed on one patient on a single occasion, the given fee is equal to 100% of the item with the greatest schedule fee, plus 50% for the item with the second greatest schedule fee, and 25% for any other item. Using the fee proposed by the applicant, the cost of OCT will always be less than the fees listed for the 12 PCI items. And as these are adjunct therapies, under the multiple operation rule, OCT will either be performed at 50% or 25% of its scheduled cost, reducing the fee to $248.25 or $124.13 respectively.

PASC considered that OCT is suitable for adjunctive use across the 12 MBS item numbers for percutaneous coronary intervention (PCI). PASC considered that it was up to clinical judgement for clinicians to firstly apply the correct PCI item number and then apply the proposed item number for OCT (if the target lesion/s meet the OCT criteria) as an adjunct service.

Additionally, the applicant has indicated that the imaging catheter has a cost of REDACTED. During the PICO process the applicant clarified that the catheter is single use per patient only. In the pre-PASC period the department advised that this cost will not be covered under the Prescribed List of Medical Devices and Human Tissue Products (i.e., does not fit the criteria for the Prescribed List), which may have implications for out-of-pocket costs for patients.

PASC noted issues of equity and access due to the cost of the imaging catheter which was not considered likely to be eligible for listing on the Prescribed list of medical devices and human tissue products, and therefore may become an out of pocket expense for patients.

Summary of public consultation input

PASC noted and welcomed consultation input from 2 organisations and 8 individuals, all of whom were health professionals – mostly interventional cardiologists. The 2 organisations that submitted input were:

- Hearts4hearts
- Boston Scientific

The consultation feedback received was mostly supportive of public funding for optical coherence tomography (OCT) guided coronary stent insertion for patients eligible for coronary revascularisation.

Clinical need and public health significance

The main benefits of public funding received in the consultation feedback included improved patient care, clinical benefits from improved stent procedure outcomes, fewer repeat procedures, reduced risk of complications improving the safety and efficacy of the procedure, improved workflow for clinicians and reduced procedural times. Hearts4heart strongly supported the listing of OCT as a life-saving procedure for patients as it addresses a significant unmet need.

The main disadvantages of public funding received in the consultation feedback was the potential for increased radiographic contrast use and the cost of purchasing OCT equipment.

Indication(s) for the proposed medical service and clinical claim

With the exception of Boston Scientific, the consultation feedback strongly agreed with the proposed populations and noted that the four patient criteria listed in the application as the patient populations to benefit most from the use of OCT. Boston Scientific (a supplier of intravascular ultrasound (IVUS) products) questioned the proposed populations due to concerns with the clinical evidence. One individual stated there is a case for use of OCT guidance of proximal left anterior descending (LAD) artery as it is the number two in hierarchy of vessel compromise and appears more prone to restenosis.

The consultation feedback agreed with the proposed comparators. It was noted that the comparator is fluoroscopic guidance of percutaneous coronary intervention (PCI) is the standard of care and several individuals stated that IVUS was an appropriate secondary comparator in a subgroup of patients with long lesions. One individual stated that unlike IVUS, OCT can assess the depth of calcification and Hearts4heart stated that OCT provides better image resolution than IVUS, can determine vascular dimensions with a greater degree of accuracy than IVUS, and provides image acquisition that is faster than IVUS. Boston Scientific stated that OCT imaging often fails to demonstrate the media and that high definition (HD) IVUS has the advantage of much deeper tissue penetration and will often outline all the features of the vessel that are pertinent to subsequent treatment.

With the exception of Boston Scientific, the consultation feedback agreed with the clinical claim. Most of the individuals referred to the wealth of robust data including metanalysis and randomised controlled trials as the basis of the clinical claim. Boston Scientific stated that there has been a considerable shift in available evidence, much of which raises questions around how applicable OCT is as a technology in the patient populations as outlined in the application. Boston Scientific provided comment from a clinical expert outlining the limitations of the clinical evidence for OCT guided coronary stent insertion and the variable outcomes in clinical studies compared with IVUS.

Cost information for the proposed medical service

The consultation feedback ranged from disagreeing to strongly agreeing with the proposed service descriptor. Most of the consultation feedback stated that the item descriptor is in line with current clinical practice. Boston Scientific appeared to disagree with the patient criteria in the proposed service descriptor.

The consultation feedback ranged from agreeing to strongly agreeing with the proposed service fee with most individuals stating it is in line with physiology and IVUS which is to be listed on the MBS in 2024. Two individuals noted that imaging requires an increased skill set and that the fee should reflect the complexity and time of the procedure and the cost of purchasing OCT equipment.

Additional comments

One of the individuals is a specialist working in coronary intervention in a regional centre and stated that the use of OCT allows assessment of lesions to rule out major or life-threatening complications, and whether they can proceed to PCI or need to transfer the patient to a higher acuity centre which is two

hours away. The individual stated that restrictions in using this technology is impacting on patient care and that public funding of OCT will address an unmet need to improve the equity of care between public versus private and metro compared to regional care.

Consumer Feedback

Hearts4heart shared a patient journey where a patient had two separate admissions and stent procedures, and had OCT been used during the initial stent placement the second admission and procedure may not have been needed.

PASC noted concerns from Boston Scientific, the supplier of IVUS, over the limited evidence supporting OCT use as well as the use of extra dye required. The applicant's clinical expert stated that additional contrast use was not borne out in practice due to the reducing need for additional angiography.

Next steps

PASC noted the applicant has elected to progress its application as an ADAR (Applicant Developed Assessment Report).

Applicant Comments on Ratified PICO

The applicant had no comment.

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