MSAC Application 1743

Optical coherence tomography guided coronary stent insertion

Population

Describe the population in which the proposed health technology is intended to be used:

Ischemic heart disease (IHD), also called coronary heart disease (CHD) or coronary artery disease (CAD), reflect a large spectrum of clinical conditions caused by myocardial ischaemia due to narrowing of the coronary arteries. Most often the narrowing of the coronary arteries is caused by atherosclerosis, i.e. build-up of plaque. When blood to the heart muscle is completely blocked, the patient is experiencing a heart attack or myocardial infarction (MI). Patients may present with angina pectoris, a clinical syndrome characterised by pain or discomfort in the chest, jaw, shoulder, back or arms[1].

Angina can be stable (i.e., chronic), meaning it occurs when the heart is working harder than usual for example during exertion or high stress, with a regular and predictable pattern, and is relived with rest and medication. Unstable angina occurs suddenly, when the patient is at rest, and follows an unpredictable pattern. Unstable angina is less common than stable angina, and represents a more serious condition as the symptoms are not relieved by rest or medication, and may signal that a heart attack is forthcoming[2].

Coronary heart disease is the leading cause of disease burden and mortality in Australia. An estimated 571,000 adult Australians reported to have coronary heart disease in 2020-2021 (Australian Bureau of Statistics [ABS] 2020-21 National Health Survey [ABS 2022]) with prevalence increasing with age, affecting approximately one in nine patients aged 75 years or older. In 2020 coronary heart disease accounted for 16,600 deaths making it the leading single cause of death in Australia (AIHW 2022), representing 10% of all deaths, and 41% of cardiovascular disease deaths (AIHW 2021).

Diagnostic imaging and functional testing are used to identify patients with myocardial ischaemia, and further diagnostic testing is performed in patients with obstructive CAD to identify patients that are eligible for, and may benefit from myocardial revascularisation in conjunction with optimal medical therapy (Neumann 2019). The goal of treatment in patients with myocardial ischaemia is to improve myocardial blood flow. Revascularisation strategies include PCI (i.e., angioplasty and/or stent insertion) or coronary artery bypass graft surgery (CABG). The proposed patient population refer to those that require myocardial revascularisation and for whom the decision is to perform PCI with drug eluting stents (DES).

Coronary angiography is the mainstay, traditional imaging modality for visual evaluation of coronary anatomy and guidance of PCIs in patients with coronary artery disease (Räber 2018). However, angiography is limited by its two-dimensional representation of blood vessels, that are three dimensional structures, since it cannot depict the arterial vessel wall, evaluate vessel dimensions and plaque characteristics, or directly assess the results of stent implantation (Räber 2018). These limitations led to the development of intracoronary imaging technologies capable of accurately determining vessel size and plaque morphology. Two catheter based intracoronary imaging tools

[1] Institute of Medicine (US) Committee on Social Security Cardiovascular Disability Criteria. Cardiovascular Disability: Updating the Social Security Listings. Washington (DC): National Academies Press (US); 2010. 7, Ischemic Heart Disease. Available from: https://www.ncbi.nlm.nih.gov/books/NBK209964/ (accessed 12 October 2022)

[2] https://www.victorchang.edu.au/angina#:~:text=Stable%20(or%20chronic)%20angina%20%E2%80%93,and%20follows%20an%20irregular%20pattern (accessed 12 October 2022)

that are routinely available for coronary lesion assessment are intravascular ultrasound (IVUS) and OCT. IVUS uses ultrasound to create cross sectional images of the vessel wall while OCT uses infra-red light to obtain cross sectional images. Both techniques involve an intracoronary catheter to visualise vessel wall lumen morphology, endothelium, and microstructure (Lofti 2018). These techniques provide valuable information by identifying features that can be used to optimise stent implantation (i.e., expansion, apposition) and minimise stent-related problems (Räber 2018).

IVUS has some drawbacks including limited resolution, limited ability to identify plaque categorisation, and inability to pass through severely narrowed or blocked arteries. In contrast, OCT offers better resolution and rapid image acquisition, resulting in more accurate vessel and plaque measurements (Koganti 2016). More specifically, OCT provides 10 times better image resolution than IVUS, can determine vascular dimensions with a greater degree of accuracy than IVUS, and provides image acquisition that is 20 times faster than IVUS. The high-resolution, detailed visualisation of plaque components and morphology with OCT allows the ability to distinguish between fibrous, lipid, and calcified components of atherosclerotic plaque (Ali 2016). Thus, OCT can be applied in the pre-PCI setting to identify vessel and plaque morphology, as well in the post-PCI setting to detect optimal lesion coverage, stent expansion, and apposition (Meneveau 2016).

Whilst angiography is the main imaging modality for PCI with DES implantation procedures, in certain complex lesions IVUS adjunct to angiography has been recommended as an adjunct visualisation tool by MSAC (left main coronary artery and long lesions) (MSAC application 1354.1 public summary document [PSD]), noting IVUS is not yet listed on the MBS. Given the short comings of coronary angiography alone, the addition of OCT in patients with complex morphology lesions provide the opportunity to improve patient outcomes.

To note, the proposed patient population for OCT, as further discussed in the question to follow, reflect patients eligible for invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stent(s) as per the MBS items for this procedure (see Table 2) that have complex lesion morphology (specified below). Therefore, the tests required to determine the most appropriate treatment have already been conducted.

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

The proposed patient population is informed by the eligibility criteria of the ILUMIEN IV trial (see Table 1) coupled with expert advice sought from local experts, to ensure the defined population targets those for whom a clinical need for OCT exists.

The rationale for inclusion of complex target lesions in the ILUMIEN IV trial and hence the proposed population was to include a study population in whom the event rate after contemporary DES is still suboptimal despite angiography guidance. Complex lesions are associated with an increased risk of failed PCI and inferior clinical outcomes (Theuerle 2018).

Table 1 ILUMIEN IV eligibility criteria

General inclusion criteria (all must be present)
1. Subject must be at least 18 years of age. 2. Subject must have evidence of myocardial ischemia (e.g., stable angina, silent ischemia (ischemia in the absence of chest pain or other anginal equivalents), unstable angina, or acute myocardial infarction) suitable for elective PCI. 3. Subject must undergo planned XIENCE stent implantation during a clinically indicated PCI procedure. 4. Subject must provide written informed consent prior to any study related procedure.
Angiographic inclusion criteria
Either criterion 1 and/or 2 must be present: 1. Target lesions in subjects who are clinically deemed to be high-risk from medically treated diabetes, OR 2. Complex lesion(s) with at least one target lesion in each target vessel planned for randomization meeting at least one of the following criteria: i. Target lesion is the culprit lesion responsible for either: • NSTEMI, defined as a clinical syndrome consistent with an acute coronary syndrome and a minimum troponin of 1 ng/dL (may or may not have returned to normal), OR • STEMI >24 hours from the onset of ischemic symptoms ii. Long or multiple lesions (defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm), iii. Bifurcation intended to be treated with 2 planned stents, where the planned side branch stent is ≥2.5 mm in diameter by angiographic visual estimation. iv. Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion), v. Chronic total occlusion (randomization performed only after successful antegrade wire escalation crossing and pre-dilatation), vi. Diffuse or multi-focal pattern in-stent restenosis at or within the existing stent margin(s). Criteria 3-6 must all be present: 3. Target lesion(s) must be located in a native coronary artery with a visually estimated or quantitatively assessed %DS of ≥70% or ≥50% respectively, plus one or more of the following: i. An abnormal functional test (e.g., invasive physiological lesion assessment, stress test) signifying ischemia in the distribution of the target lesion(s) or ii. Biomarker positive acute coronary syndromes suggestive of plaque disruption or thrombus 4. 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. 5. Maximum 2 target lesions in any single vessel and in maximum 2 separate target vessels (including branches) can be included. Thus, up to 4 randomised target lesions per patient in maximum 2 target vessels are allowed. 6. Target lesions are amenable to OCT-guided PCI (i.e., no lesion-specific angiographic exclusion criteria are present

DS, diameter stenosis; NSTEMI, non–ST segment elevation myocardial infarction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction.

Source: ILUMIEN IV protocol, Ali (2020) Supplemental Table 1.

Based on correspondence from the Department of Health (DoH), it was advised that the proposed population should reflect 'lesion specific' criteria. To this end, local experts were consulted to inform the proposed population for OCT (refer to OCT Roundtable Meeting minutes attached). The resultant proposed population is provided in Text box 1.

Text box 1 Proposed population based on expert advice and ILUMIEN IV eligibility

The use of optical coherence tomography during invasive coronary angiogram percutaneous angioplasty or transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients documented with:

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

Provide a rationale for the specifics of the eligible population:

As noted above, the rationale for the proposed population was informed by local expert advice summarised as follows (for complete detail refer to the OCT Roundtable Meeting minutes, attached):

- Patients with diabetes have a higher risk of poor outcomes compared with those without diabetes. However, at present, the incremental benefit of using OCT adjunct to angiography in patients with diabetes relative to angiography alone is unclear, and as such diabetes should be removed from the proposed population (this criterion is not lesion specific). However, if the results from the ILUMIEN IV trial demonstrate superior outcomes with OCT relative to angiography alone, reimbursement should be considered for those with diabetes.
- The experts advised that non-ST-elevation myocardial infarction (NSTEMI) and ST-elevation myocardial infarction (STEMI) lesions be removed, as these are not reflective of 'lesion specific' high risk subpopulations, noting that STEMI lesions rarely present in the private setting. However, one expert noted that patients with acute coronary syndrome (ACS) with significant presentation and unclear culprit lesion would benefit from imaging with OCT as this would help optimise treatment strategy and hence outcomes.
- One expert expressed a need for 'multivessel lesions' to be included in the proposed population for OCT guided stent placement, to optimise treatment hence outcomes in these lesions, however, acknowledged that this was not a subgroup of the ILUMIEN IV trial, and as such limited data may be available to support efficacy of OCT in this subgroup.
- For bifurcation lesions, it is advised that 'intended to be treated with two planned stents (i.e., in both the main branch and side branch)' as per the ILUMIEN IV eligibility criteria be removed, because it is not always known at the planning stage that two stents are required.
- The indication for OCT in lesions with chronic total occlusion is unclear to date, and it is advised this subpopulation be removed.
- There is an unequivocally high clinical need for OCT in patients with stent failure. It is advised that stent failure be used, rather than the ILUMIEN IV criterion 'in-stent restenosis of diffuse or multi-focal 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).
- Whilst OCT may represent a suitable imaging choice in ostial left main lesions by some physicians, given scarcity of OCT evidence in these lesions to date, it is advised lesions in left main coronary artery be removed. The RENOVATE trial included lesions in left main, however,

the trial combined IVUS and OCT and the majority of left main lesions were supported by IVUS, hence, the RENOVATE trial alone will not support OCT use in left main lesions.

Are there any prerequisite tests?

No

Are the prerequisite tests MBS funded? (please highlight your response – only if you answered 'Yes' to the question above)

N/A

Please provide details to fund the prerequisite tests:

N/A

Intervention

Name of the proposed health technology:

Optical coherence tomography (OCT) guided coronary stent insertion as an adjunct to invasive coronary angiogram.

The proposed intervention, is intended for guiding percutaneous coronary intervention (PCI) with coronary stent insertion in patients that are eligible for coronary revascularisation. PCI and coronary stent implantation is the mainstay revascularisation intervention in patients with obstructive coronary artery disease. The intention of the proposed intervention is therapeutic.

Describe the key components and clinical steps involved in delivering the proposed health technology:

The proposed intervention involves the use of the OPTIS system (ILUMIEN™ OPTIS™ mobile system or OPTIS™ Integrated System, see Figure 1) and an imaging catheter (the Dragonfly OPTIS Imaging Catheter, see Figure 2). [Note, in addition to the systems displayed in Figure 1 the OPTIS Next system is also available, but not depicted]. The Dragonfly™ OPTIS™ Imaging Catheter consists of two main assemblies: the catheter body and the internal rotating fibre optic imaging core. The catheter has an insertable length of 135 cm with a diameter of 2.7 Fr. It is a rapid-exchange ('RX') design with a 'minirail' tip, having 20 mm of guide wire engagement length. The catheter has a hydrophilic coating and is designed for compatibility with 0.014" steerable guide wires used during coronary interventional procedures. Proximal to the minirail tip is the imaging area. During image acquisition the fibre optic core of the Dragonfly OPTIS Imaging Catheter rotates and is automatically retracted within the catheter to obtain a 360° image of the artery and obtain a continuous pullback image of an arterial segment.

The imaging catheter connects to the OCT imaging System through the drive-motor and optical controller (DOC). All fibre optic rotation and translational pullback is driven by the DOC and occurs inside the catheter.

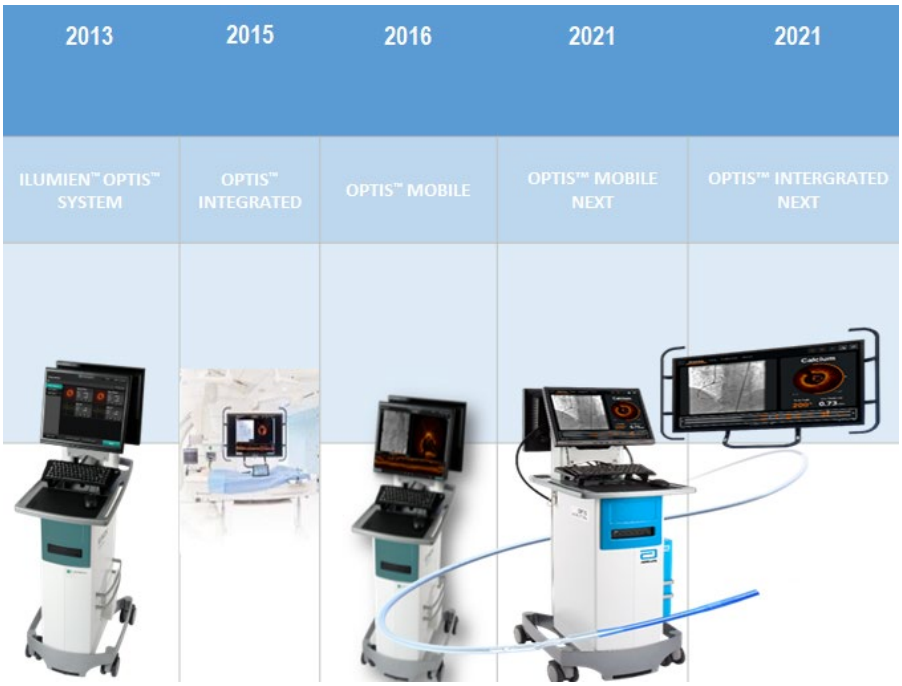

Figure 1 **Available OCT systems**

Figure 2 **OCT system imaging catheter**

The OCT procedure requires two operators: a sterile operator and a non-sterile operator. All steps requiring contact with the Dragonfly Imaging Catheter, or the outside of the sterile DOC cover must

be performed by the sterile operator. All steps performed within the sterile DOC cover or in direct contact with a keyboard or mouse must be performed by the non-sterile operator.

Steps

Imaging catheter insertion and placement

- The Dragonfly OPTIS Imaging Catheter's rapid-exchange lumen is cack-loaded onto the guide wire and inserted via guide catheter.
- Under fluoroscopic guidance, the catheter is advanced so that the lens and proximal markers encompass the desired imaging region. For proximal imaging, when it is possible that the proximal marker may not exit the guide sheath, the lens marker is positioned just distal to the desired pullback initiation point. (*Note: There are three radiopaque markers. The most distal marker, the tip marker, is 4 mm proximal to the tip of the catheter and is affixed to the sheath. The lens marker is 2 mm proximal to the lens and indicates the location being imaged. The proximal marker is located 50 mm proximal to the lens marker and is used to help distinguish the imaging region).*
- It is ensured the guide catheter is oriented to preferentially direct contrast flow to the target lesion, and angiographically verify that adequate flow of contrast is delivered to the lesion.

(Source: Dragonfly™ OPTIS™ Imaging catheter Instruction for use)

OCT imaging overview

- Position – locating the Dragonfly imaging catheter relative to the target lesion/stent
- Purge – Clearing blood from the catheter lumen, if present, using the attached 3 mL syringe
- Puff – Injecting a small amount (~ 4 mL) of contrast through the guide catheter to evaluate clearance. If clarity is minimal, the orientation of the guide catheter and target vessel must be checked.
- Pullback – Selecting 'Enable' from the 'Live View' to start the imaging process

(Source: OPTIS™ Integrated System Instructions for Use)

Identify how the proposed technology achieves the intended patient outcomes:

The proposed intervention is OCT guided coronary stent insertion as an adjunct to invasive coronary angiogram for patients undergoing PCI. The OCT system is an intravascular imaging tools that use light to provide anatomical images of disease morphology and automated measurements. With OCT technology, physicians can visualise and measure important vessel characteristics that are otherwise not visible or difficult to assess with the older imaging technology. As a result, OCT can provide automated, highly accurate measurements that can help guide stent selection and deployment and assess stent placement to help ensure successful procedures. The proposed service will be delivered in the catheterisation laboratory setting where the PCI is performed.

OCT is a catheter-based intravascular imaging modality that provides rapid acquisition of high resolution images of the coronary arteries (Ha 2017). OCT uses infrared light to obtain 360° cross-sectional images of a coronary artery with a continuous pullback image of an arterial segment

(Sholfmitz 2018). The axial and lateral resolutions of OCT are 10-20 μm and 20 μm, respectively. and the maximum tissue penetration depth of OCT is 2 mm.[11] OCT has a rapid automated pullback (20-25 mm/s). Potential limitations of OCT include limited penetration, inability to see behind red thrombus, and the need for displacement of blood for clear visualisations of the artery wall which requires contrast medium (Koskinas 2016). Imaging from the OPTIS integrated system is provided in Figure 3, simultaneously showing the angiography imaging to the left and the OCT imaging to the right.

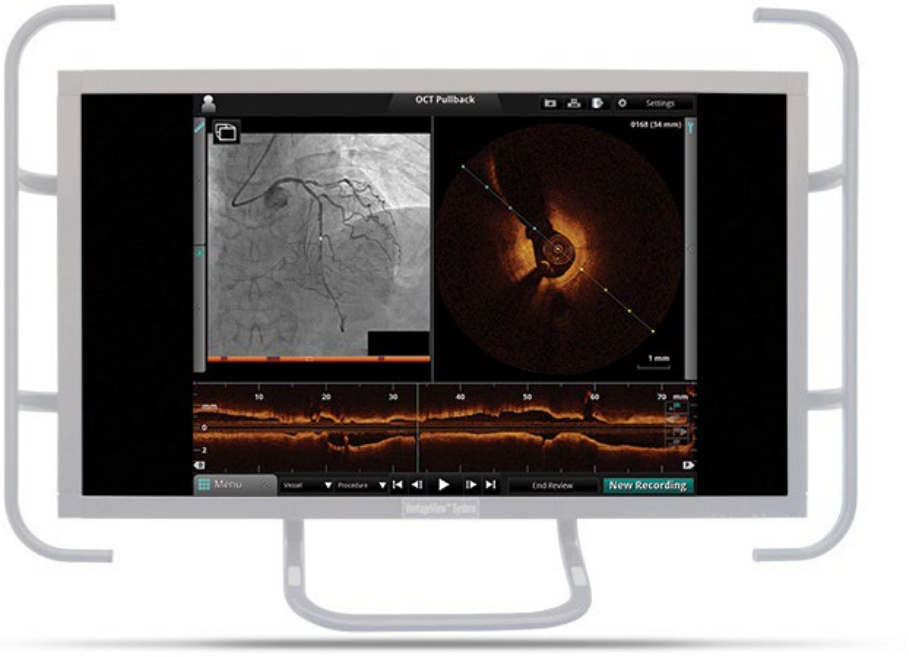

Figure 3 OPTIS integrated system

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?

No

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:

No

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):

Yes

Provide details and explain:

The limitation on the provision of the proposed medical service relates to access to the OCT system at the treatment centre. To date, there are REDACTED OCT systems used in the Private setting with a coverage of REDACTED% of all private hospitals used in Australia, however, this is expected to increase with listing of the procedure on the MBS. Further potential restrictions may relate to availability of a trained OCT cardiologist that may not necessarily be present at all centres where PCI is delivered (may increase over time with awareness).

If applicable, advise which health professionals will be needed to provide the proposed health technology:

The proposed service will be performed by an interventional cardiologist – the same health care professional delivering coronary angiography and IVUS.

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:

N/A

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:

N/A

Is there specific training or qualifications required to provide or deliver the proposed service, and/or any accreditation requirements to support delivery of the health technology?

Yes

Provide details and explain:

It is expected that similar training and accreditation for OCT will apply as per those required for IVUS. As per the public summary document (PSD) for IVUS, *"MSAC advised that issues needed to be satisfactorily addressed regarding physician training and credentialling (with CSANZ providing a credentialling guideline to the Department that can be referenced in the associated explanatory note) and the funding mechanism for specific consumables associated with the procedure (and possible out-of-pocket costs for patients) be completed before implementation"* (MSAC Application PSD 1354.1). It is expected that a similar consideration will be made regarding training and accreditation for OCT (and funding mechanisms for consumables associated with the procedure). Abbott will therefore take guidance from the implementation of IVUS when that is finalised to help inform any specific training and accreditation relevant to OCT.
The clinical experts consulted in the preparation of this application advised that to date, no Australian specific guidelines for intracoronary imaging for optimising guided stent placement in PCI exist, noting that CSANZ has endorsed the EAPCI Consensus statement.

Whilst CSANZ is working on consensus documents which will cover physiology assessment and image guidance, these documents are not yet drafted. It is unclear if credentialing will be covered. It would be reasonable for the Consensus documents with or without credentialling to be finalised in parallel with the reimbursement submission.

Indicate the proposed setting(s) in which the proposed health technology will be delivered: (select all relevant settings)

☐ Consulting rooms
☐ Day surgery centre
☐ Emergency Department
☒ Inpatient private hospital
☒ Inpatient public hospital
☐ Laboratory
☐ Outpatient clinic
☐ Patient's home
☐ Point of care testing
☐ Residential aged care facility
☐ Other (please specify)

The proposed medical service can be provided at a public or private hospital as an inpatient procedure, and may be performed as elective or emergency procedure.

Is the proposed health technology intended to be entirely rendered inside Australia? (please highlight your response)

Yes

Please provide additional details on the proposed health technology to be rendered outside of Australia:

N/A

Comparator

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

The primary comparator to OCT adjunct to coronary angiogram in the proposed population with high lesion risk as defined above, is placement of coronary stents under guidance of coronary angiography alone. IVUS was recommended for listing on the MBS for PCI guidance of either a left main coronary artery lesion (i.e. left main lesions) or lesion length of 28 mm or more (i.e. long lesions) (MSAC Application 1354.1 public summary document [PSD]). Whilst IVUS is not yet appearing on the MBS, it is nominated as a near to market, secondary comparator in the subgroup of patients with long lesions.

List any existing MBS item numbers that are relevant for the nominated comparators:

Coronary angiography

Following the changes to MBS Cardiac Surgical Services including selective coronary angiogram and PCI related items in July 2021, coronary angiography is now incorporated as part of the relevant PCI items to provide one complete service. A total of 12 MBS items are available for transluminal insertion of coronary stents, split according to whether PCI has been completed or has not been completed within the previous 3 months of selective coronary angiography.

Then, each category is further split based on whether patients meet the clinical indications for acute coronary syndrome (ACS) or not, in which case they have a stable PCI indication with documented ischaemia, and finally, by number of territories treated, as shown in Table 2.

Table 2 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.

The associated MBS explanatory notes provide details of the indications for selective coronary angiography (TR.8.2) and stable PCI indications (TR.8.4) as summarised below. Furthermore, MBS explanatory notes provide details on documentation requirements (TR.8.5), Heart Team conferences (TR.8.6 & TR.8.7) as well as staging rules and disease definitions (TN.8.217, TN.8.218, TN.8.219, TN.8.225 & TN.8.226). Where percutaneous transluminal coronary rotational atherectomy is considered prior to stenting, MBS item 38309 is appropriate.

Note TR.8.2 – Selective coronary angiography indications

Clause 5.10.17A Items 38244, 38247, 38307, 38308, 38310, 38316, 38317 and 38319—patient eligibility and timing

(1) A patient is eligible for a service to which item 38244, 38247, 38307, 38308, 38310, 38316, 38317 or 38319 applies if:

(a) subclause (2) applies to the patient; and

(b) a service to which the item applies has not been provided to the patient in the previous 3 months, unless:

(i) the patient experiences a new acute coronary syndrome or angina, as described in paragraph (2)(a), (b) or (c), in that period; or

(ii) for a service to which item 38316, 38317 or 38319 applies—the service was provided to the patient in that period as a subsequent stage following an initial primary percutaneous coronary intervention procedure.

(2) This subclause applies to a patient who has:

(a) an acute coronary syndrome evidenced by any of the following:

(i) ST segment elevation;

(ii) new left bundle branch block;

(iii) troponin elevation above the local upper reference limit;

(iv) new resting wall motion abnormality or perfusion defect;

(v) cardiogenic shock;

(vi) resuscitated cardiac arrest;

(vii) ventricular fibrillation;

(viii) sustained ventricular tachycardia; or

(b) unstable angina or angina equivalent with a crescendo pattern, rest pain or other high-risk clinical features, such as hypotension, dizziness, pallor, diaphoresis or syncope occurring at a low threshold; or

(c) either of the following, detected on computed tomography coronary angiography:

(i) significant left main coronary artery disease with greater than 50% stenosis or a cross-sectional area of less than 6 $mm^{2;}$

(ii) severe proximal left anterior descending coronary artery disease (with stenosis of more than 70% or a cross-sectional area of less than 4 mm2 before the first major diagonal branch).

Note TR.8.4 – Stable - Percutaneous Coronary Intervention Indications

Clause 5.10.17C Items 38311, 38313, 38314, 38320, 38322 and 38323—patient eligibility

1) A patient is eligible for a service to which item 38311, 38313, 38314, 38320, 38322 or 38323 applies if:

(a) subclause (2) applies to the patient; or

(b) the patient is recommended for the service as a result of a heart team conference that meets the requirements of subclause (4).

(2) This subclause applies to a patient if:

(a) the patient has any of the following:

(i) limiting angina or angina equivalent despite an adequate trial of optimal medical therapy;

(ii) myocardial ischaemia demonstrated on functional imaging;

(iii) high risk features such as ST segment elevation, sustained ST depression, hypotension or a Duke treadmill score of minus 11 or less, demonstrated by stress electrocardiogram testing; and

(b) the patient has either of the following in a vascular territory treated:

(i) a stenosis of 70% or more;

(ii) a fractional flow reserve of 0.80 or less, or non-hyperaemic pressure ratios distal to the lesions of 0.89 or less; and

(c) for items 38314 and 38323—either:

(i) the patient does not have diabetes mellitus and the multi-vessel coronary artery disease of the patient meets the criterion in subclause (3); or

(ii) despite a recommendation that surgery is preferable, the patient has expressed a preference for catheter-based intervention.

(3) For the purposes of subparagraph (2)(c)(i), the criterion for the multi-vessel coronary artery disease is that the disease does not involve any of the following:

(a) stenosis of more than 50% in the left main coronary artery;

(b) bifurcation lesions involving side branches with a diameter of more than 2.75 mm;

(c) chronic vessel occlusions for more than 3 months;

(d) severely angulated or calcified lesions;

(e) a SYNTAX score of more than 23.

(4) For the purposes of paragraph (1)(b), the requirements for a heart team conference are as follows:

(a) the conference must be conducted by a team of specialists or consultant physicians practising in the speciality of cardiology or cardiothoracic surgery, including each of the following:

(i) an interventional cardiologist;

(ii) a specialist or consultant physician;

(iii) for items 38314 and 38323—a cardiothoracic surgeon;

(iv) for items 38311, 38313, 38320 and 38322—a cardiothoracic surgeon or a non-interventional cardiologist; and

(b) the team must:

(i) assess the patient's risk and technical suitability to receive the service; and

(ii) make a recommendation about whether or not the patient is suitable for percutaneous coronary intervention; and (c) a record of the conference must be created, and must include the following: (i) the particulars of the assessment of the patient during the conference; (ii) the recommendations made as a result of the conference; (iii) the names of the members of the team making the recommendations.

IVUS (near to market comparator)

IVUS is not yet listed on the MBS but has been recommended for listing for the following populations:

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

Please provide a rationale for why this is a comparator:

Placement of coronary stents under guidance of coronary angiography alone is the primary comparator to OCT adjunct to angiography because it is the standard of care imagining for stent placement.

Whilst not yet appearing on the MBS, IVUS has been recommended for PCI guidance of either a left main coronary artery lesion (i.e. left main lesions) or lesion length of 28 mm or more (i.e. long lesions) (MSAC Application 1354.1 PSD). It is not clear if / when IVUS will be listed on the MBS. Therefore, in the proposed subgroup of patients with long lesions, IVUS represents a near to market comparator to OCT.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator? (please select your response)

☒ None – used with the comparator
☐ Displaced – comparator will likely be used following the proposed technology in some patients
☒ Partial – in some cases, the proposed technology will replace the use of the comparator, but not in all cases
☐ Full – subjects who receive the proposed intervention will not receive the comparator

Please outline and explain the extent to which the current comparator is expected to be substituted:

OCT will be used in addition to angiography, the primary comparator.

In the subgroup where IVUS is a near to market comparator to OCT (patients with long lesions ≥28 mm), OCT will be used as a replacement of IVUS, noting that IVUS has been recommended but is not yet listed on the MBS.

Outcomes

List the key health outcomes (major and minor – prioritising major key health outcomes first) that will need to be measured in assessing the clinical claim for the proposed medical service/technology (versus the comparator): (please select your response)

The main outcomes relevant to the assessment of OCT adjunct to angiography versus angiography alone, along with descriptions are provided in the table below.

Type	Outcome	Outcome claim
Health benefit	Target vessel failure (TVF: Defined as the composite of: • cardiac death, • target vessel myocardial infarction, or • ischemia-driven target vessel revascularization	OCT is expected to reduce TVF as a composite outcome, relative to AG alone. (Additionally, it is expected that OCT will improve outcomes for the individual constituents of the composite).
Health benefit	All-cause mortality / cardiac mortality	OCT is expected to reduce mortality relative to AG alone
Health benefit	Myocardial infarction	OCT is expected to reduce myocardial infarction relative to AG alone
Health benefit	Revascularisation	OCT is expected to reduce revascularisation relative to AG alone
Health harm	Procedural complications / adverse events	Given OCT is used adjunct to AG, it is expected that OCT will increase some procedural complications relative to AG alone

Health benefit	Quality of life	OCT is expected to improve quality of life relative to AG alone
Health benefit	Stent thrombosis	OCT is expected to decrease stent thrombosis relative to AG alone

AG, angiography; OCT, optical coherence tomography.

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:

N/A

Proposed MBS items

How is the technology/service funded at present? (for example: research funding; State-based funding; self-funded by patients; no funding or payments):

OCT guided coronary stent insertion is not funded at present.

Please provide at least one proposed item with their descriptor and associated costs, for each population/Intervention: (please copy the below questions and complete for each proposed item)

Proposed item details

MBS item number (where used as a template for the proposed item)	N/A
Category number	3
Category description	Therapeutic Procedures
Proposed item descriptor	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 documented with: • Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm), or • 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). Multiple Operation Rule (Anaes.) [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).
Proposed MBS fee	$496.50
Indicate the overall cost per patient of providing the proposed health technology	$REDACTED
Please specify any anticipated out of pocket expenses	0.0
Provide any further details and explain	A likely incremental cost per procedure (i.e., over the current standard practice without the availability of OCT) would be $REDACTED = $248.25 (adjusted for MOR at 50%) plus $REDACTED (based on an assumed caseload of REDACTED per machine per year) plus $REDACTED. In the IVUS application, the IVUS MBS item fee was benchmarked to MBS item 38241 for use of a coronary pressure wire to measure fractional flow reserve (FFR). "MSAC considered that despite differences in complexity and resource use, the fee was reasonable" (MSAC Application 1354.1 PSD). The experts consulted in preparing this Application confirmed 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). As such, the proposed MBS item fee benchmarked to IVUS / pressure wire MBS item 38241 is justified. Anticipated out of pocket expenses are unknown at this stage; it may reflect 25% of the fee for patients with private health funds that do not cover this part of the arrangement.

Algorithms

Preparation for using the health technology

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, before patients would be eligible for the proposed health technology:

To be eligible for the proposed health technology, patients must meet one or more of the complex lesion criteria:

- Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm)
- 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, in-stent restenosis of diffuse or multi-focal pattern

These complex lesion morphologies will be identified and diagnosed via pre-PCI coronary angiography imaging at a prior consultation or just prior to stent insertion.

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology? (please highlight your response)

No

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:

There are no differences in the clinical management algorithm of the proposed patient population with complex lesions as defined above prior to the use of OCT versus use of coronary angiography alone.

Use of the health technology

Explain what other healthcare resources are used in conjunction with delivering the proposed health technology:

The proposed service will be performed in addition to PCI with DES guided by coronary angiography, claimed via one of 12 available MBS codes (38316, 38317, 38319, 38320, 38322, 38323, 38307, 38308, 38310, 38311, 38313, 38314). A number of coronary DESs are listed on the Prostheses List (PL) (subcategory coronary stent; product group: 08.12.01 drug eluding) at a benefit amount of $1699. Anaesthesia is also used during the PCI procedure.

Explain what other healthcare resources are used in conjunction with the comparator health technology:

The health care resources used with the comparator technology, coronary angiography alone, include the PCI with DES guided by coronary angiography, claimed via one of 12 available MBS codes (38316, 38317, 38319, 38320, 38322, 38323, 38307, 38308, 38310, 38311, 38313, 38314). A number of coronary DESs are listed on the PL (subcategory coronary stent; product group: 08.12.01 drug eluding) at a benefit amount of $1699. Anaesthesia is also used during the PCI with DES procedure.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:

The only difference in the healthcare resources used in conjunction with OCT versus the comparator, coronary angiography, is the use of OCT per se in addition to other resources used for the comparator.

When compared to IVUS, the only difference in healthcare resource use is the use of IVUS versus OCT to guide the PCI with DES procedure.

Clinical management after the use of health technology

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the proposed health technology:

Patients who have undergone PCI with DES implantation will be treated with antithrombotic therapy post procedure to optimise outcomes. The type of antithrombotic therapy, combinations, duration and dose is individualised based on patient characteristics, comorbidities and the clinical setting (elective revascularisation vs acute coronary syndrome) (Neuman 2019).

After elective PCI with DES, dual antiplatelet therapy (DAPT) consisting of clopidogrel and aspirin is typically recommended for 6 months with the duration of standard DAPT shortened (<6 months) or extended (>12 months) in specific clinical scenarios. Subsequent to management with DAPT, it is recommended the patient remain on single antiplatelet (usually aspirin) for life. Patients are advised not to discontinue oral antiplatelet therapy prematurely post stenting given the risks of stent thrombosis and recurrent myocardial infarction (Neuman 2019)

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the comparator health technology:

Management of patients after the comparator health technology is identical to after the proposed technology.

Describe and explain any differences in the healthcare resources used *after* the proposed health technology vs. the comparator health technology:

There are no differences in the healthcare resources used after the proposed health technology versus the comparator health technology.

Algorithms

Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:

The current clinical management pathway is broadly based on the algorithm in the PICO for IVUS (Application 1354.1) and amended to accommodate the proposed population, see Figure 4.

Coronary angiography is the gold standard imaging modality used for placement of coronary stents in patients with acute coronary syndrome or stable angina with documented ischaemia. IVUS was recommended for listing on the MBS for PCI stent guidance in patients with complex lesions, defined as having a left main coronary artery lesion (i.e. left main lesions) or lesion length of 28 mm or more (i.e. long lesions) (MSAC Application 1354.1 public summary document [PSD]). Whilst IVUS is not yet appearing on the MBS, it represents a near to market, additional imaging modality in the recommended subgroups (left main lesions and long lesions), with coronary angiography alone used in patients not meeting either criterion. It is expected that IVUS will be used with angiography in most patients with left main and long lesions, given the superiority of IVUS when used adjunct to angiography relative to angiography alone. However, there may be some patients with either left main or long lesions that are not suitable for IVUS, in whom angiography alone would be used. [Note, the algorithm in the PICO for Application 1354.1 did not include angiography alone in the

proposed populations, however, the algorithm in Figure 4 does for completeness]. Whilst IVUS is recommended, it is not yet listed on the MBS as indicated in grey text in the figure. It is expected that IVUS will be listed in the future.

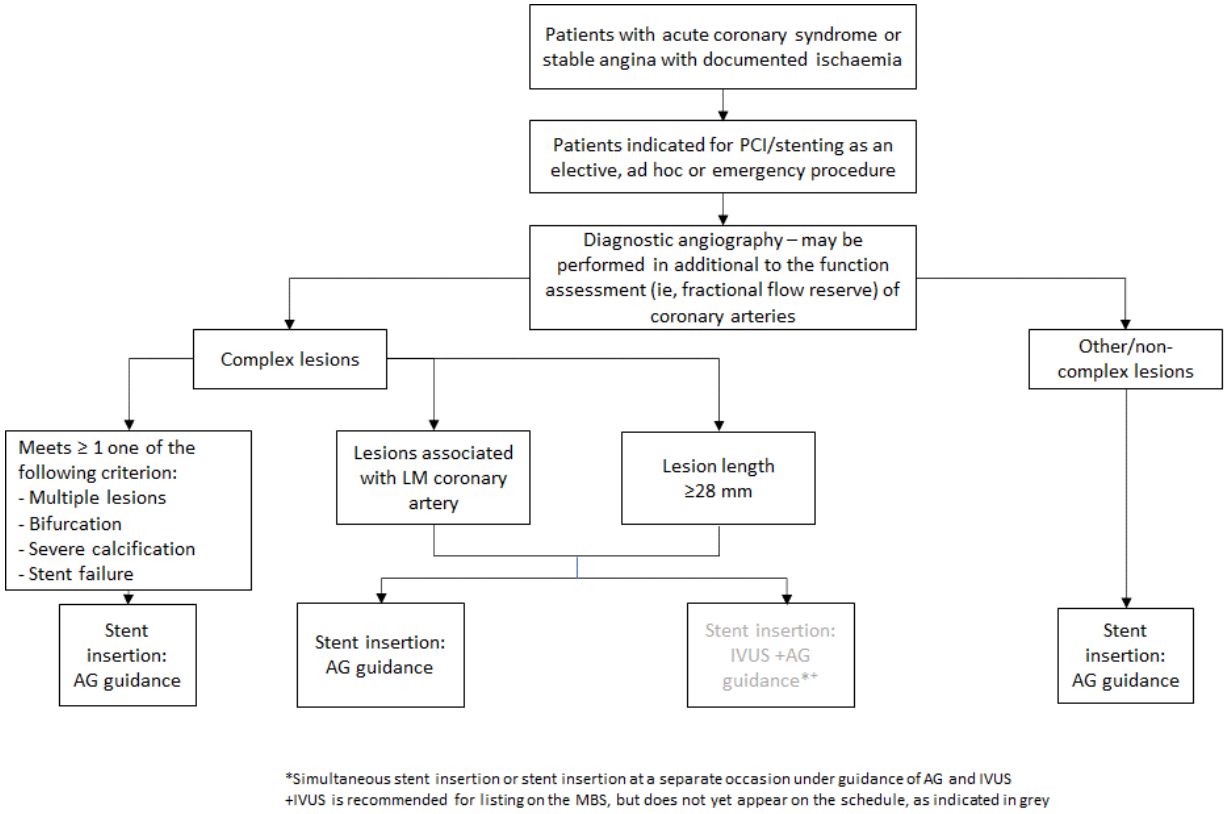

Figure 4 Current management algorithm of the proposed patient population

The proposed clinical algorithm with the introduction of OCT in the proposed patient populations is depicted in Figure 5.

OCT guidance represents an alternative intravascular imaging modality to IVUS for patients with long lesions. OCT guidance represents an additional imaging modality to angiography alone in the remining proposed patient populations with complex lesions including those with multiple lesions, bifurcation, severe calcification and stent failure.

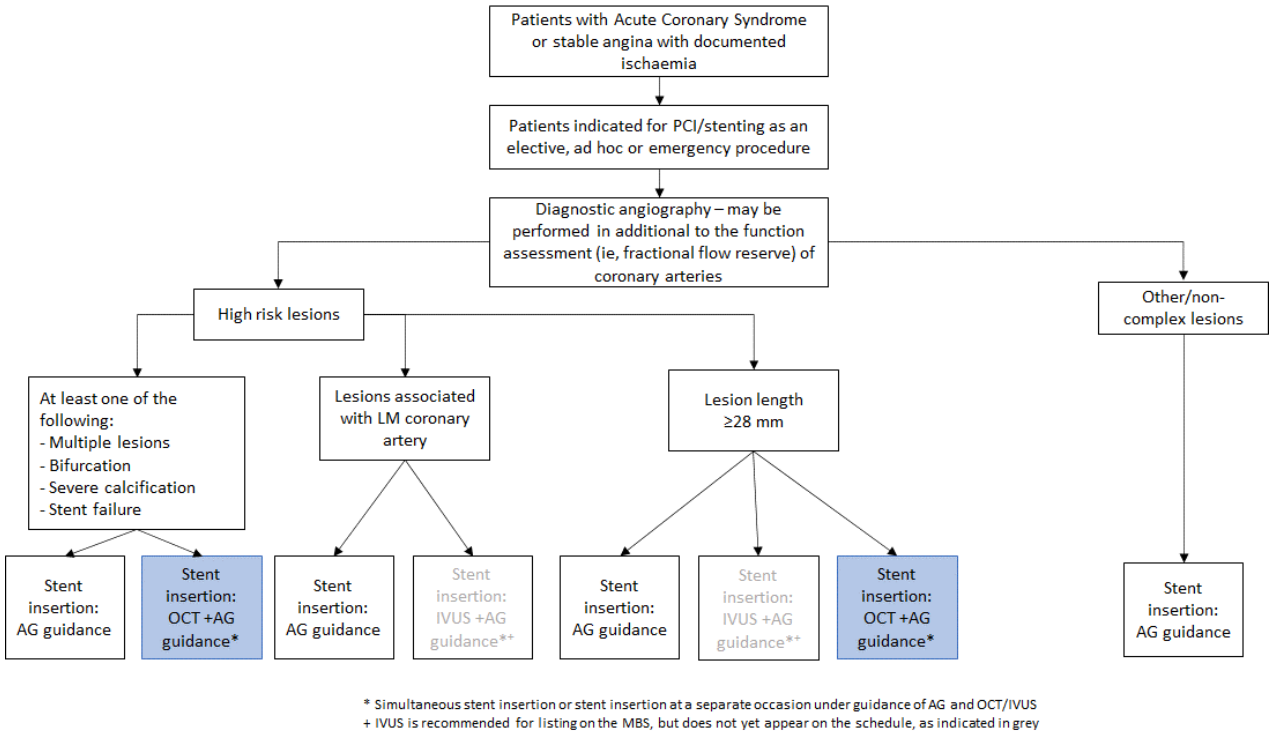

Figure 5 **Proposed management algorithm of the proposed patient population including OCT**

Claims

In terms of health outcomes (comparative benefits and harms), is the proposed technology claimed to be superior, non-inferior or inferior to the comparator(s)?

(please select your response)

☒ Superior
☐ Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:

OCT with adjunct coronary angiography is superior to adjunct coronary angiography alone with respect to target vessel failure, which as per the main forthcoming trial ILUMIEN IV, is defined as a composite outcome of cardiac death, target vessel myocardial infarction, or ischaemia driven target vessel revascularization (NCT03507777). As per the completed ILUMIEN III study, OCT with adjunct coronary angiography was found to be safe with few procedural and 30 day major adverse cardiovascular events (MACE) observed at rates similar to angiography with adjunct IVUS or angiograph alone (Ali 2016).

The results from the recently published RENOVATE trial, comparing intravascular imaging including IVUS / OCT adjunct to coronary angiography versus coronary angiography alone (Lee 2023) demonstrated statistically significantly superior outcomes with intravascular imaging with respect to target lesion failure (a composite of death from cardiac causes, target-vessel myocardial infarction, or clinically driven target-vessel revascularisation) compared to coronary angiography alone (hazard

ratio [HR] [95% confidence interval (CI)]: 0.64 [0.45–0.89]). When stratified by type of intravascular imaging device, OCT performed numerically better than IVUS relative to angiography alone (HR [95%CI]: 0.47 [0.27–0.83] versus 0.66 [0.46–0.95], respectively).

Furthermore, on the basis of the results from ILUMIEN III and OPTIMUM, whilst not being adequately powered on clinical outcomes, demonstrated that OCT-guided PCI resulted in similar minimum stent area to that of IVUS-guided PCI (Ali 2016), and both approaches to PCI guidance resulted in excellent angiographic and clinical results with low rates of angiographic binary restenosis at 8-months and target vessel failure at 12-month (Kubo 2017). These results may suggest non-inferiority of OCT and IVUS, albeit not specifically in the proposed subgroups of patients for whom IVUS has been recommended (i.e., long lesion).

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?

N/A

Identify how the proposed technology achieves the intended patient outcomes:

Relative to coronary angiography alone, imaging with OCT allows for better morphologic lesion characterisation, superior procedural planning, and enhanced DES optimisation (correcting suboptimal results and major procedural complications) resulting in improved acute procedural results and superior long-term clinical outcomes

Angiography is limited by its two-dimensional representation of blood vessels, that are three dimensional structures, since it cannot depict the arterial vessel wall, evaluate vessel dimensions and plaque characteristics, or directly assess the results of stent implantation (Räber 2018). OCT uses infra-red light to obtain cross sectional images and is therefore capable of accurately determining vessel size and plaque morphology. OCT allows for the visualisation of the vessel wall lumen morphology, endothelium, and microstructure (Lofti 2018), which in turn helps to identify features that can be used to optimise stent implantation (i.e., expansion, apposition) and minimise stent-related problems (Räber 2018).

For some people, compared with the comparator(s), does the test information result in: (please highlight your response)

N/A

A change in clinical management?	Yes	No
A change in health outcome?	Yes	No
Other benefits?	Yes	No

Please provide a rationale, and information on other benefits if relevant:

N/A

In terms of the immediate costs of the proposed technology (and immediate cost consequences, such as procedural costs, testing costs etc.), is the proposed technology claimed to be more costly, the same cost or less costly than the comparator?
(please select your response)

☒ More costly
☐ Same cost
☐ Less costly

Provide a brief rationale for the claim:

OCT adjunct to coronary angiography will be more costly compared to angiography alone, given the OCT procedure requires additional equipment, consumables and procedure time compared to when PCI guidance is performed without OCT.

Compared with IVUS, it is expected that OCT will be associated with similar costs.

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology.

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	**ILUMIEN III** RCT vs IVUS & AG	Ali (2016). Optical coherence tomography compared with intravascular ultrasound and with angiography to guide coronary stent implantation (ILUMIEN III: OPTIMIZE PCI): a randomised controlled trial	*Population: PCI with* DES to a one or more target lesions located in a native coronary artery with vessel diameter of 2·25–3·50 mm and a length of < 40 mm). *Excluded left main (LM) lesions.* The study included 450, randomised to OCT+AG (n=158), IVUS+AG (n=146) or AG alone (n=146). The primary outcome was post-PCI minimum stent area; the primary safety objective was procedural MACE. The study was not powered on clinical events. The final median minimum stent area was 5.79 mm² (IQR 4.54–7.34) with OCT guidance, 5.89 mm² (4.67–7.80) with IVUS guidance, and 5.49 mm² (4.39–6.59) with AG guidance. OCT guidance was non-inferior to IVUS, but not superior (p=0·42). OCT guidance was also not superior to AG guidance (p=0·12). Over 30 days, procedural MACE were observed in 3% of patients in the OCT group, 1% in the IVUS group, and one 1% AG group (OCT vs IVUS p=0·37; OCT vs angiography p=0·37).	https://pubmed.ncbi.nlm.nih.gov/27806900/	2016
		Ali (2021). Outcomes of Optical Coherence Tomography Compared With Intravascular Ultrasound and With Angiography to Guide Coronary Stent Implantation: One-Year Results from the ILUMIEN III: OPTIMIZE PCI trial.	Over 12 months in the ILUMIEN III study, there were no significant differences in the rates of target lesion failure (2.0% OCT, 3.7% IVUS, 1.4% angiography), MACE (9.8% OCT, 9.1% IVUS, 7.9% angiography), or any of the individual components of these outcomes between groups. To note, the study was not powered to show differences on these events.	https://pubmed.ncbi.nlm.nih.gov/32540793/	2021

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
2.	**OPINION** RCT, non-inferiority trial vs IVUS	Kubo (2017). Optical frequency domain imaging vs. intravascular ultrasound in percutaneous coronary intervention (OPINION trial): one-year angiographic and clinical results. NCT01873027	*Population: PCI with DES to a de novo native coronary artery lesion. Excluded LM lesions.* Patients were randomised to PCI stent placement with OCT (n=414) or IVUS (n=415) guidance adjunct to AG, with the study powered to detect non-inferiority on TVF at 12 months (defined as a composite of cardiac death, target-vessel related myocardial infarction, and ischaemia-driven target vessel revascularisation). A similar proportion of patients undergoing OCT and IVUS guided PCI experienced TVF (5.2% vs 4.9%), demonstrating non-inferiority (HR=1.07, upper limit of one-sided 95% CI=1.80; $p_{non\text{-}inferiority}$=0.042). With 89.8% angiographic follow-up, the rate of binary restenosis was comparable between OCT and IVUS guided PCI (in-stent: 1.6% vs. 1.6%, p = 1.00; and in-segment: 6.2% vs 6.0%, p = 1.00), further supporting non-inferiority. The rate of procedure-related complications in patients undergoing OCT guided PCI was low (0.7%), and was similar to the rate observed in those undergoing IVUS-guided PCI (0.3%), with no patients experiencing contrast-induced nephropathy.	https://pubmed.ncbi.nlm.nih.gov/29121226/	2017

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	**DOCTORS** RCT vs AG	Meneveau 2016 Optical Coherence Tomography to Optimize Results of Percutaneous Coronary Intervention in Patients with Non–ST-Elevation Acute Coronary Syndrome Results of the Multicenter, Randomized DOCTORS Study (Does Optical Coherence Tomography Optimize Results of Stenting) NCT01743274	*Population:* *PCI with DES in patients with non–ST-segment elevation acute coronary syndromes; Excluded LM lesions.* Patients were randomised to OCT+AG (n=120) or AG alone (n=120); primary endpoint was fractional flow reserve (FFR) post-PCI. The study was not powered on clinical events. OCT use led to a change in procedural strategy in 50% of the patients in the OCT-guided group vs 22.5% in AG alone. The OCT-guided group had significantly greater FFR value compared with the AG-guided group (0.94±0.04 vs 0.92±0.05, p=0.005). There was no significant difference in the rate of type 4a myocardial infarction between OCT and AG groups (33% vs 40%; p=0.28) and the incidences of procedural complications (5.8%) and acute kidney injury (1.6%) were identical in each group despite longer procedure time and use of more contrast medium in the OCT-guided group,	**https://pubmed.ncbi.nlm.nih.gov/27573032/**	2016

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
4.	**OCTACS** RCT vs AG	Antonsen (2015) Optical Coherence Tomography Guided Percutaneous Coronary Intervention With Nobori Stent Implantation in Patients With Non–ST-Segment–Elevation Myocardial Infarction (OCTACS) Trial NCT02272283	*Population:* *PCI with DES in patients with STEMI with lesion in native vessel-segment elevated myocardial infarction; Excluded LM lesions.* Patients were randomised to OCT+AG (n=50) or AG alone (n=50); primary endpoint was the difference in percentage of uncovered struts between groups at 6-month follow-up. The results showed that OCT guidance improves strut coverage relative to AG alone meaning healing is improved. The study was not powered on clinical events. At 6-month follow-up, the proportion with uncovered struts was statistically significantly lower with OCT guidance than AG alone (4.3% vs 9.0%; p<0.001), and OCT-guided patients had significantly more completely covered stents (17.5% vs 2.2%, p=0.02). OCT guidance significantly reduced the percentage of acutely malapposed struts, the post-procedure total malapposition area, and malapposition volume. One patient in both groups had in-stent restenosis at follow up. During the 6-month follow-up, 2 (4%) patients from the AG group had a MACE; whereas no cardiac events were registered in the OCT arm.	https://pubmed.ncbi.nlm.nih.gov/26253735/	2015
5.	**ROBUST** RCT vs AG	Kala (2018) OCT guidance during stent implantation in primary PCI: A randomized multicenter study with nine months of optical coherence tomography follow-up NCT 00888758	*Population:* *PCI with DES in patients with non–ST-segment elevated myocardial infarction; Excluded LM lesions.* Patients were randomly assigned to AG (n=96) or OCT+AG guidance (n=105). The study was not powered on clinical events. At nine months, significantly less in-segment area of stenosis was observed with OCT vs AG (6% vs 18%; p = 0.0002). The rates of MACEs were comparable at nine months between OCT and AG groups (3% vs 2%; p= 0.87). One stent thrombosis was found in each group.	https://pubmed.ncbi.nlm.nih.gov/29079414/	2018

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
6	**RENOVATE** RCT of intravascular imaging guidance (IVUS/OCT) vs AG	Intravascular Imaging-Versus Angiography-Guided Percutaneous Coronary Intervention For Complex Coronary Artery Disease NCT03381872	This is a large-scale (N~1620), MC, designed to investigate whether PCI under guidance of intravascular imaging devices (IVUS or OCT) chosen by operators would improve clinical outcomes compared with angiography-guided PCI in patients with complex lesions*, powered on TVF at 12 months. *Defined as: i) True bifurcation lesion ii) Chronic total occlusion iii) Unprotected LM disease PCI iv) Long coronary lesions (implanted stent ≥38 mm in length) v) Multi-vessel PCI (≥2 vessels treated at one PCI session) vi) Multiple stents needed (≥3 more stent per patient) vii) In-stent restenosis lesion as target lesion viii) Severely calcified lesion ix) Ostial coronary lesion (LAD, LCX, RCA)	https://www.nejm.org/doi/full/10.1056/NEJMoa2216607	2023

AG, angiography; DES, drug eluting stent; IVUS, intravascular ultrasound; LM, left main; MACE, major adverse cardiovascular events; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RCT, randomised controlled trial; TVF, target vessel failure.
* Categorise study design, for example meta-analysis, randomised trials, non-randomised trial or observational study, study of diagnostic accuracy, etc.
**Provide high level information including population numbers and whether patients are being recruited or in post-recruitment, including providing the trial registration number to allow for tracking purposes.
*** If the publication is a follow-up to an initial publication, please advise.

Identify yet-to-be-published research that may have results available in the near future (that could be relevant to your application).

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
1.	**ILUMIEN IV** RCT vs AG	ILUMIEN IV: OPTIMAL PCI NCT03507777	This is a large-scale (N~2500), MC, RCT designed to demonstrate the superiority of OCT versus angiography-guided stent implantation in patients with high risk clinical characteristics (diabetes) and/or complex angiographic lesions* in achieving larger post-PCI lumen dimensions and improving clinical outcomes (TVF). *Defined as: i) A target lesion responsible for either NSTEMI or STEMI ii) Long or multiple lesions (intended stent length ≥28 mm) iii) A bifurcation lesion iv) Angiographic severe calcification v) A chronic total occlusion. vi) Diffuse or multifocal pattern in-stent restenosis with lesion at or within the existing stent margin(s). Exclusion: Lesion in LM	Protocol: https://pubmed.ncbi.nlm.nih.gov/32863246/	Results will be presented at the European Society of Cardiology (ESC) Congress in Amsterdam 25-28 August 2023. Study findings from 24 months follow up will be shared with DoH by end of August 2023.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
3.	**OPTIMAL** Prospective, non-RCT, MC, registry, vs AG	OPTical Coherence Tomography IMAging in Patients With Acute myocardiaL Infarction (OPTIMAL) NCT03084991	This is a prospective, MC (20 cites in China), non-randomised, observational registry study of patients with AMI that require catheterisation. The purpose of this registry is to investigate the clinical outcomes, safety and cost-effectiveness of OCT imaging in patients with AMI undergoing PCI. Expected duration of the study is 5 years Approximately 4500 subjects (1500 with OCT imaging and 3000 without OCT imaging) will be enrolled. The primary outcome is major cardiovascular adverse events (re-infarction, re-hospitalisation, revascularisation by PCI or CABG, cardiac death, stroke, and major bleeding). Inclusion: Patients presenting with: a) Symptoms of myocardial ischemia lasting for ≥ 30 minutes. b). Definite ECG changes indicating STEMI c). NSTEMI Referred for primary PCI. Exclusion: LM occlusion	NA	Recruitment status: Unknown
4.	**OCTIVUS** RCT vs IVUS	Optical Coherence Tomography Versus Intravascular Ultrasound Guided Percutaneous Coronary Intervention (OCTIVUS) NCT03394079	This aim of this large RCT (N~2000), MC (Korea) study is to establish the primary hypothesis that OCT guided PCI is non-inferior to IVUS guided PCI regarding the target vessel failure at 1 year. Eligibility is designed to capture a broad range of real-world patients ('all comers) with stable angina or acute coronary syndrome. Inclusion: Coronary artery disease undergoing PCI Exclusion: STEMI	https://pubmed.ncbi.nlm.nih.gov/32871327/	Results will be presented at the ESC Congress in Amsterdam 25-28 August 2023. Study findings from 24 months follow up will be shared with DoH by end of August 2023.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
5.	**OCTOBER** RCT vs AG	The OCTOBER Trial - European Trial on Optical Coherence Tomography Optimized Bifurcation Event Reduction (OCTOBER) NCT03171311	The aim of this large RCT (N~1200), MC (Europe) study is to demonstrate that OCT guided revascularisation of patients with bifurcation lesions requiring complex stent implantation provides superior two-year clinical outcome compared to standard revascularization by PCI using AG. The primary outcome is MACE, defined as cardiac death, target lesion myocardial infarction, ischaemic driven target lesion revascularisation. Inclusion: • Stable angina pectoris, unstable angina pectoris, clinically stable non-STEMI • Native coronary bifurcation de novo lesion • 50% diameter stenosis in the main vessel (MV) • >50% diameter stenosis in the side branch (SB) within 5 mm of the ostium • Reference size ≥2.75 mm in the MV and ≥2.5 mm in the SB. Exclusion: STEMI within 72 hours; massive thrombus in LM	NA	Results will be presented at the ESC Congress in Amsterdam 25-28 August 2023. Study findings from 24 months follow up will be shared with DoH by end of August 2023.

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
6.	**OCCUPI** RCT vs AG	Optical CoherenCe Tomography-gUided Coronary Intervention in Patients With Complex lesIons: a Randomized Controlled Trial (OCCUPI Trial) NCT03625908	In this large RCT (N~1600), conducted in Korea, eligible patients will be randomly assigned to either OCT guided PCI arm or angiography guided PCI with routine high pressure non-compliant (NC) ballooning arm in 1:1 ratio. Within OCT-guided PCI arm, the use of OCT will be also assigned to full OCT-guidance arm and postprocedural OCT only arm, and comparison of stent implantation with and without preprocedural OCT will be evaluated by postprocedural OCT (OCT defined stent optimisation will be assessed). In angiography-guided PCI arm, PCI for complex lesion will be performed without guidance of intravascular imaging, and routine use of high pressure post-dilation with NC balloon will be also recommended. Primary endpoint, MACE, will be evaluated at 12 months. Inclusions: Patients with ischaemic heart disease (including stable angina, unstable angina and AMI) presenting with typical chest pain or objective evidence of myocardial ischaemia. Complex coronary stenotic lesions (>50% based on visual estimate) considered for DES, defined as at least one of the following: • AMI • Chronic total occlusion • Long lesion: expected stent length ≥28mm based on angiographic estimation • Calcified lesion • Bifurcation (including all techniques, one- or two-stent) • Unprotected LM disease • Small vessel diseases with reference vessel diameter less than 2.5 mm • Intracoronary thrombus visible on the angiography • Stent thrombosis • In-stent restenosis	NA	Recruitment status: recruiting Expected completion: July 30, 2023 This is an independent study conducted in Korea, hence details pertaining to completion are informed by the NCT record. It is understood results will be presented at the American College of Cardiology (ACC) conference in 2024.

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

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

*** If the publication is a follow-up to an initial publication, please advise. For yet to be published research, include the date of when results will be made available (to the best of your knowledge).