

Medical Services Advisory Committee (MSAC) Public Summary Document

Application No. 1743 – Optical coherence tomography (OCT) guided coronary stent insertion for patients eligible for coronary revascularisation

Applicant: Abbott Medical Australia Pty Ltd

Date of MSAC consideration: 1-2 August 2024

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, [visit the MSAC website](#)

1. Purpose of application

An application requesting Medicare Benefits Schedule (MBS) listing of optical coherence tomography (OCT)-guided stent insertion for patients undergoing invasive coronary angiography, percutaneous angioplasty and transluminal insertion of stents, was received from Abbott Medical Australia Pty Ltd by the Department of Health and Aged Care (the department). The proposed populations for OCT-guided coronary stent insertion included patients with at least one of the following lesion types or complexity: long or multiple lesions, bifurcation lesion, angiographic severe calcification, or stent failure.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness, cost-effectiveness and total cost, MSAC considered OCT had acceptable safety and supported the creation of a new Medicare Benefits Schedule (MBS) item for the use of optical coherence tomography (OCT) guided coronary artery stent insertion for patients eligible for coronary revascularisation for the bifurcation and stent thrombosis subpopulations. MSAC considered there was high certainty evidence for the bifurcation subpopulation that found that OCT had superior effectiveness and acceptable cost-effectiveness against coronary angiography alone. MSAC noted patients with stent failure due to stent thrombosis were included despite a lack of evidence for superior effectiveness, however stent thrombosis is a rare event and MSAC considered that OCT addressed a high clinical need in this subpopulation. MSAC also supported the creation of a separate MBS item for the use of OCT in the long lesion (≥ 28 mm) subpopulation. In the long lesion subpopulation, MSAC considered that OCT had noninferior effectiveness and the cost-minimisation showed similar costs compared with intravascular ultrasound (IVUS). Additionally in the long lesion subpopulation, MSAC noted that there was moderate certainty evidence that OCT had superior effectiveness for the outcome risk of stent thrombosis at two years against coronary angiography alone. MSAC did not support the use of OCT in patients with severe calcification, or with stent failure due to in-stent restenosis, or multiple lesions and considered that clinical efficacy was not demonstrated in these subpopulations.

MSAC recommended that the new item for the use of OCT for long lesions should be considered and including alignment where clinically necessary with the existing IVUS item (MBS item 38325). MSAC advised the MBS item descriptor should contain provisions to prevent the dual

use of OCT and IVUS, to address concerns of overlapping indications/leakage and enable the use of a second modality in the case of failure of the first imaging technique. MSAC advised that for the long lesion subpopulation, either OCT or IVUS should only be billed per episode with the choice of modality determined by clinician preference. However, MSAC advised that the Department of Health and Aged Care consult with the Cardiac Society of Australia and New Zealand (CSANZ) regarding whether the indications should be the same for both OCT and IVUS modalities in an amalgamated MBS item and also credentialling for providers.

Proposed MBS item for bifurcation and stent thrombosis populations

Category 3 – Therapeutic procedures
<p>MBS item XXXX</p> <p>Use of optical coherence tomography (OCT) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition, for a patients documented with:</p> <ul style="list-style-type: none"> - one or more lesions located at a bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation, or - With this stent failure including stent thrombosis. <p>if performed in association with a service to which item 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, or 38323 applies.</p> <p>Applicable once per episode of care (for one or more lesions) (H).</p> <p><i>Multiple Operation Rule</i> (Anaes.)</p>
Fee: \$526.50 Benefit: 75% = \$394.90

Proposed MBS item for long lesion population.

Category 3 – Therapeutic procedures
<p>MBS item YYYY</p> <p>Use of optical coherence tomography (OCT) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition, for a patients documented with:</p> <ul style="list-style-type: none"> - one or more lesions at least 28mm in length <p>if performed in association with a service to which item 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, or 38323 applies.</p> <p>Other than a service associated with a service to which item 38325 applies.</p> <p>Applicable once per episode of care (for one or more lesions) (H).</p> <p><i>Multiple Operation Rule</i> (Anaes.)</p>
Fee: \$526.50 Benefit: 75% = \$394.90

Consumer summary

This is an application from Abbott Medical Australia Pty Ltd requesting Medicare Benefits Schedule (MBS) listing of optical coherence tomography (OCT) guided coronary stent insertion for patients eligible for coronary revascularisation.

The blood vessels that supply the heart with oxygen are called coronary arteries. These can become narrow over time, because of build-up of plaque and debris, which means the heart doesn't get enough blood. Coronary revascularisation is a group of treatments or procedures that restore blood flow through the arteries. Percutaneous coronary intervention (PCI) is one of these procedures and uses a catheter (a thin flexible tube) usually inserted via an artery in the arm or leg to place a small structure called a stent to open up the arteries.

A coronary angiogram is a test that uses X-rays to look at the coronary arteries, to see if a blood vessel is narrowed or blocked. A coronary angiogram is most often used to diagnose coronary artery disease. If a blockage is found, a balloon may be passed through the catheter and expanded to widen the artery. A mesh tube called a stent may be placed to keep the artery open. However, there are limitations as to what can be seen using X-rays.

Optical coherence tomography (OCT) is a new intravascular imaging technique that provides high-resolution, cross-sectional images of coronary artery anatomy. It uses near-infrared light to get a clearer look at blockages and plaque, and to make it easier to choose the appropriately sized stent and guide stent insertion, as well as to identify procedural complications. There is a similar technology available called intravascular ultrasound (IVUS) which is currently funded by the MBS. It is similar to OCT, except it uses ultrasound instead of near-infrared light.

In this application the request is to fund the use of OCT to guide stent insertion in people who have:

- long or multiple lesions (blockages or plaques), defined as intended total stent length (continuous or separated) in any single target vessel ≥ 28 mm
- a lesion located at a bifurcation and where the planned side branch is ≥ 2.5 mm in diameter, as estimated using angiography
- angiographic severe calcification (defined calcification on both sides of the vessel wall in the absence of cardiac motion, visible using angiography)
- stent failure (due to stent thrombosis [clot] or in-stent restenosis [re-accumulation of plaque] which is of diffuse or multi-focal pattern).

MSAC considered that OCT was safe. MSAC considered there was high certainty evidence for the bifurcation subpopulation and found that OCT had superior effectiveness and acceptable value for money. MSAC noted that stent failure due to stent thrombosis is a rare and serious event. Even though the evidence for this subpopulation wasn't as strong as for the bifurcation subpopulation, MSAC considered that the availability of funded OCT addressed a high clinical need for this subpopulation. MSAC did not support the use of OCT in patients with severe calcification, stent failure due to in-stent restenosis or multiple lesions, due to OCT not being shown to be effective in these subpopulations.

In the long lesion subpopulation, MSAC considered that OCT had similar effectiveness to IVUS and had similar costs. MSAC recommended that a new item for the use of OCT for long lesions should be considered and should be aligned where necessary with the existing IVUS item. MSAC recommended that only one or other procedure should be reimbursed for each episode of care.

Consumer summary

MSAC's advice to the Commonwealth Minister for Health and Aged Care

MSAC supported the creation of a new Medicare Benefits Schedule (MBS) item for the use of optical coherence tomography (OCT) guided coronary artery stent insertion for people eligible for coronary revascularisation for the bifurcation and stent failure due to stent thrombosis subpopulations. Additionally, MSAC supported the use of OCT guided coronary artery stent insertion for people eligible for coronary revascularisation in long lesions and recommended that this be created as a new MBS item number.

3. Summary of consideration and rationale for MSAC's advice

MSAC noted that this application from Abbott Medical Australia Pty Ltd requested Medicare Benefits Schedule (MBS) listing of optical coherence tomography (OCT)-guided stent insertion for patients undergoing invasive coronary angiography, percutaneous angioplasty and transluminal insertion of stents. The proposed populations for OCT-guided coronary stent insertion were patients with at least one of the following lesion types or complexity: long or multiple lesions, bifurcation lesion, angiographic severe calcification or stent failure.

MSAC recalled that it supported the MBS listing of intravascular ultrasound (IVUS)-guided coronary stent insertion in patients eligible for coronary revascularisation with complex anatomical characteristics (lesions associated with the left main coronary artery or other lesion locations with lesion length ≥ 28 mm) in April 2022 ([MSAC application 1354.1](#)), which resulted in MBS item 38325.

MSAC noted that the consumer feedback and consultation feedback was broadly supportive of the application. MSAC noted the consultation input included three (3) professional organisations, one (1) consumer organisation and twelve (12) individuals, all of whom were medical specialists. MSAC noted broad consensus was suggestive that OCT provided more detailed images and faster results than IVUS, however noted that it required a slightly longer procedure time compared with IVUS. Additionally, MSAC noted the consumer feedback was suggestive that OCT was a more costly procedure compared to coronary angiography (AG) alone or IVUS – both in terms of the costs for the equipment and consumables. MSAC considered that this may lead to equity issues, particularly in the case of availability of OCT in regional areas.

MSAC noted that the proposed population for OCT-guided coronary stent insertion were patients with myocardial ischaemia undergoing invasive AG, 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 (due to stent thrombosis or in-stent restenosis of diffuse or multi-focal pattern).

MSAC noted that in all subpopulations, the comparator included in the Applicant Developed Assessment Report (ADAR) to the proposed intervention (OCT+AG) was invasive coronary AG (AG alone). IVUS-guided coronary stent insertion as an adjunct to invasive coronary AG (IVUS+AG) was an additional comparator in the long/multiple lesion subpopulation. MSAC noted that the long

lesion subpopulation in the PICO is defined based on the trial definition from ILUMIEN IV: long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel of ≥ 28 mm. The MBS item descriptor for IVUS specifies its use for 'lesions ≥ 28 mm in length'. MSAC considered that this discrepancy, albeit minor, means that the long lesion subpopulation proposed for eligibility for OCT-guided PCI is broader than the approved population for IVUS-guided PCI. MSAC considered IVUS would not be a comparator for patients with multiple lesions who meet the definition specified in the ratified PICO for this subpopulation.

MSAC noted that three randomised control trials (RCT) met the pre-defined eligibility criteria and were included in the ADAR as pivotal evidence: OCTOBER compared OCT+AG-guided percutaneous coronary intervention (PCI) with AG-guided PCI in patients with complex bifurcation lesions; ILUMIEN IV:OPTIMAL PCI compared OCT+AG-guided PCI with AG-guided PCI in patients with medication-treated diabetes or complex coronary artery lesions (relevant to patients with bifurcation lesions, severely calcified lesions, stent failure due to in-stent restenosis, long diffuse lesions); and OCTIVUS compared OCT+AG-guided PCI with IVUS+AG-guided PCI in patients with significant coronary artery lesions (relevant to patients with long lesions). The comparative efficacy and safety claims made in the ADAR were based on these three RCTs.

MSAC noted that the primary composite outcome used in OCTOBER (major adverse cardiac events, or MACE) was not an outcome specified in the PICO. MACE was defined in OCTOBER as a composite of death from cardiac causes, target lesion myocardial infarction (MI), or ischaemia-driven target lesion revascularisation (TLR). By contrast, the PICO composite outcome of target vessel failure (TVF) was defined as the composite of cardiac death, target vessel MI, or ischaemia-driven target vessel revascularisation (TVR). Therefore, the OCTOBER definition of MACE was not aligned with the PICO and MSAC considered the outcomes too dissimilar to justify meta-analysis. MSAC noted that there were differences in the definitions of cardiac mortality, MI and revascularisation between the three trials. Additionally, MSAC noted that stent thrombosis (as an outcome measure) was also categorised differently between the trials.

MSAC noted that the OCTOBER trial (bifurcation lesions) was powered on the primary composite endpoint of MACE; however, all other proposed subpopulations relied on data from post hoc subgroup analyses from ILUMIEN IV and OCTIVUS, which lacked the statistical power to detect statistically significant differences in the primary composite endpoint and individual events.

For the purpose of guiding stent insertion in patients with myocardial ischaemia and lesions located at a bifurcation, MSAC considered that there was moderate certainty of evidence to suggest that OCT+AG was non-inferior to AG alone with respect to safety. On the basis of clinical evidence for the bifurcation lesion population, MSAC considered that there was high certainty evidence that found the use of OCT+AG had superior effectiveness compared with AG alone.

For the purpose of guiding stent insertion in patients with myocardial ischaemia and lesions with angiographic severe calcification, MSAC noted that results were based on a post hoc subgroup analysis as part of the ILUMIEN IV trial. MSAC considered that OCT+AG was non-inferior with respect to safety was supported by low certainty of evidence, although MSAC noted that procedural complications were not available specifically for this subpopulation. Additionally, MSAC considered that OCT+AG was non-inferior with respect to efficacy, based on low certainty of evidence. MSAC considered that the evidence supporting the use of OCT+AG compared to AG alone for the severe calcification population was not sufficient to demonstrate superior clinical effectiveness due to the low certainty of evidence.

For the purpose of guiding stent insertion in patients with myocardial ischaemia and stent failure due to stent thrombosis or in-stent restenosis of diffuse or multi-focal pattern, MSAC noted that evidence was only available for the in-stent restenosis subpopulation and results were based on a post hoc subgroup analysis as part of the ILUMIEN IV trial. MSAC considered that in relation to

safety, OCT+AG was non-inferior compared to AG alone in the stent failure due to in-stent restenosis subpopulation. MSAC noted that OCT can distinguish thrombus from other tissue components and is therefore generally the imaging modality of choice for stent failure due to stent thrombosis, except for in some cases when large amounts of thrombus is present, in which case IVUS may be preferred. MSAC considered that on the basis of clinical evidence, the use of OCT+AG compared to AG alone for stent failure due to in-stent restenosis was not supported. However, MSAC supported the use of OCT in the stent failure subgroup due to stent thrombosis, due to the high clinical need and expert opinion that OCT can provide increased imaging capability to distinguish thrombus from other tissue when compared to AG alone.

For the purpose of guiding stent insertion in patients with myocardial ischaemia and long or multiple lesions (total stent length, continuous or separate, in any single target vessel ≥ 28 mm), MSAC considered OCT+AG to be superior compared against AG alone but only for the outcome of stent thrombosis and with moderate certainty of evidence. MSAC considered that OCT+AG was non-inferior with respect to safety, compared to AG alone, although procedural complications were not available for this subpopulation.

For the purpose of guiding stent insertion in patients with myocardial ischaemia and long or multiple lesions (total stent length, continuous or separate, in any single target vessel ≥ 28 mm), MSAC considered OCT+AG is non-inferior in effectiveness, when compared to IVUS in long lesions and this is based on low certainty evidence. MSAC noted that the OCTIVUS trial post hoc subgroup analyses were not sufficiently powered – although acknowledged the challenges faced with trials being sufficiently powered when examining relatively rare events. MSAC considered that the clinical evidence for OCT+AG was non-inferior with respect to safety, compared with IVUS.

MSAC considered that the current evidence does not sufficiently demonstrate clinical superiority for the use of OCT in multiple lesions, compared with both AG and IVUS. MSAC noted that the source of the evidence for the IVUS comparator, the OCTIVUS trial, defined long coronary artery lesions as lesions > 28 mm or stent length > 32 mm of treated segment, and did not include multiple lesions. MSAC noted that OCT is probably non-inferior to IVUS for long lesions and recommended that multiple lesions be excluded from the proposed MBS item descriptor. MSAC considered that this would enable OCT or IVUS to be used for long lesions as there is sufficient clinical evidence in this subpopulation.

MSAC noted that both OCT and IVUS have overlapping indications – however, provide different information for the operator depending on the clinical situation. MSAC noted that the proposed MBS item descriptor in its current form would not prevent dual use of these technologies for particular lesions (such as for left main coronary artery bifurcation lesions or for long lesions). MSAC noted that a co-claiming restriction is proposed to prevent dual use of these technologies. MSAC noted that the applicant agreed to the introduction of a co-claiming restriction for OCT and IVUS in the pre-MSAC response. Additionally, MSAC noted that hybrid intracoronary imaging modalities are in development, including hybrid IVUS–OCT systems. MSAC considered that the use of a co-claiming restriction would be appropriate as this would prevent the MBS item from being billed twice due to overlapping indications.

Therefore, MSAC supported the use of OCT+AG in the long lesion population and recommended that this be created as a new MBS item and aligned with the IVUS MBS item.

MSAC noted that similar to IVUS, the OCT service is to be performed by trained interventional cardiologists. MSAC noted that the Cardiac Society of Australia and New Zealand (CSANZ) are developing guidelines to assist with implementation of IVUS on the MBS, which could encompass intravascular imaging using OCT. MSAC advised that the department should consult with the

CSANZ regarding whether the indications should be the same for OCT and IVUS modalities in an amalgamated MBS item and also provide advice on credentialling for providers.

MSAC noted that the cost of OCT catheter may be borne by the patient (~\$Redacted) and thus create a potential equity issue. In addition, there is an equity of access issue for patients in regional/remote areas because of the need for training and equipment.

MSAC noted the commentary asserted that the superiority claims for OCT+AG versus AG alone were not supported by the clinical evidence provided in the applicant-developed assessment report (ADAR) for the severe calcification and stent failure subpopulations. MSAC considered that if non-inferiority is justified, as per the Commentary's interpretation of the evidence, a cost-minimisation analysis would be more appropriate for these subpopulations. Although MSAC considered that cost minimisation would not be demonstrated due to the higher cost for OCT as an adjunct to coronary AG.

MSAC noted the economic evaluation for the subpopulation with bifurcation lesions consisted of a cost-utility analysis that resulted in an incremental cost-effectiveness ratio (ICER) of \$Redacted per quality-adjusted life year (QALY) gained, which increased to \$Redacted per QALY gained when a difference in cardiac death is removed.

MSAC noted that for the severe calcification subpopulation, the cost-utility analysis resulted in a base case ICER of \$Redacted per QALY gained. However, MSAC noted that the model was based on a post hoc subgroup analysis of a single RCT (ILUMIEN IV) that showed no statistically significant difference between the study arms for TVF. Rather than using direct event rates for this subpopulation, a relative rate compared to the long lesion subpopulation was used (due to uncertainty related to small event and patient numbers). For these reasons, the results of the analysis for this subpopulation are uncertain. MSAC noted that ESC's conclusion was that even if it is non-inferior, it is more expensive and probably would be dominated.

MSAC noted that for the economic evaluation for the subpopulation with long lesions, the clinical claim in the Commentary supports superiority for OCT in terms of the stent thrombosis outcome only. Including a difference only for this outcome yields an ICER of \$Redacted which is substantially higher than \$Redacted in the ADAR base case for this subpopulation.

MSAC noted that no formal cost-utility analysis was presented for the stent failure subpopulation due to the absence of reliable subgroup data.

MSAC noted that an epidemiological approach was taken in the ADAR to estimate the utilisation and financial impact to the MBS of the proposed listing. The ADAR assumed uptake of OCT would be gradual given the requirements for capital investment and infrastructure necessary for this technology, reaching Redacted% by Year 6.

For the long/multiple lesion subpopulation, the ADAR assumed that patients would otherwise receive IVUS, thus achieving cost neutrality from the perspective of the MBS (the proposed fee for the OCT service is the same as for IVUS). The Commentary noted that the assumed Redacted market share did not consider that the definition of long lesions was broader for OCT than for IVUS and there may be uncertainty in the way the IVUS and OCT eligibility for the long lesion subpopulation will be interpreted in clinical practice.

The financial implications to the MBS resulting from the proposed listing of OCT-guided PCI with stent insertion were \$Redacted in Year 1 and \$Redacted in Year 6. The analyses assumed 40% of all patients undergoing PCI stent insertion would meet at least one of the OCT eligibility criteria, acknowledging that many patients would satisfy multiple eligibility criteria. The net cost to the MBS would increase if OCT uptake was greater than Redacted% by Year 6, or if a lower proportion of patients satisfy multiple eligibility criteria. MSAC considered this to be a conservative estimate and acknowledged this uncertainty could be increased if OCT becomes widely used in clinical practice beyond its intended use. MSAC considered the department could

provide an explanatory note to the MBS item descriptor that details the correct usage and suggested this may reduce the uncertainty.

MSAC noted that the financial estimates did not include any potential cost savings to the MBS associated with reduced major cardiac events in patients who receive OCT-guided stent implantation.

MSAC noted that the MBS costs comprise a minor component of the overall financial costs. MSAC considered the majority of the costs of OCT would be borne by hospitals, health funds and/or patients. The capital equipment cost per procedure will occur on a per hospital basis, given that each hospital will be required to purchase its own OCT system. The OCT system currently costs **\$Redacted** per unit (plus **\$Redacted** annual maintenance) with an expected longevity of 10 years. MSAC noted that according to the application, there were **Redacted** OCT systems in private hospitals in Australia. MSAC acknowledged that there were no estimates for the number of OCT systems that would be purchased after listing on the MBS should OCT be supported and implemented.

MSAC noted that the OCT imaging catheter is a single use device, provided in a kit with other OCT-specific consumables at a cost of **\$Redacted** and that the applicant intends to seek inclusion of the catheter on Part C of the PL. However, MSAC noted that if the catheter is not listed on the PL, the cost of the OCT kit will need to be covered by patients (as an out-of-pocket expense), hospitals and/or private health insurance funds. MSAC noted advice from the department that the catheter is unlikely to be eligible for listing on the PL.

In summary, MSAC supported the creation of a new MBS item for the use of OCT guided coronary artery stent insertion for patients eligible for coronary revascularisation for the bifurcation and stent failure due to stent thrombosis subpopulations. Additionally, MSAC supported the use of OCT for the long lesion subpopulation and recommended that this could be either aligned with the pre-existing IVUS MBS item number 38325; or created as a new standalone MBS item. MSAC advised that for the long lesion subpopulation, either OCT or IVUS should only be billed per episode, with the choice of modality determined by clinician preference. MSAC recommended that the department consult with the CSANZ in the establishment of guidelines and credentialing for providers.

4. Background

MSAC has not previously considered OCT-guided coronary stent insertion for patients eligible for coronary revascularisation.

MSAC supported MBS listing of intravascular ultrasound (IVUS)-guided coronary stent insertion in patients eligible for coronary revascularisation with complex anatomical characteristics (lesions associated with the left main coronary artery or other lesion locations with lesion length ≥ 28 mm) in April 2022 ([MSAC application 1354.1](#)), which resulted in MBS item 38325.

5. Prerequisites to implementation of any funding advice

Regulatory approval status

Three coronary OCT systems and three coronary OCT system catheters are currently included on the Australian Register of Therapeutic Goods (ARTG) (see Table 1). All entries are sponsored by Abbott Medical.

The OCT imaging system and catheter are intended: 1. for qualitative and quantitative evaluation of vascular morphology in the coronary arteries; 2. as an adjunct to conventional angiographic procedure to provide an image of vessel lumen and wall structures; and 3. for the imaging of coronary arteries in patients who are candidates for transluminal interventional procedure.

Hybrid intracoronary imaging modalities are in development, including hybrid IVUS-OCT systems.

Table 1 OCT systems and imaging catheters listed on the ARTG

Name	ARTG ID	Product category	Start date
GMDN 47490 Coronary optical coherence tomography system			
Coronary OCT system	314829	Class IIa	26/02/2019
Coronary OCT system	370978	Class IIb	13/07/2021
Ilumien System - Coronary optical coherence tomography system	229311	Class IIa	14/10/2014
GMDN 47491 Coronary optical coherence tomography system catheter			
Dragonfly Optis Kit, Model C408646 - Coronary OCT system catheter	317614	Class III	16/05/2019
Dragonfly OpStar™ Imaging Catheter 1014652 - Coronary optical coherence tomography system catheter	384505	Class III	22/02/2022
Dragonfly OPTIS Kit Box, Model Number C408646 - Coronary optical coherence tomography system catheter	234447	Class III	5/03/2015

ARTG = Australian Register of Therapeutic Goods; GMDN = global medical device nomenclature; OCT = optical coherence tomography. Source: Adapted from Table 11 of MSAC 1743 ADAR+in-line commentary (current to 3 May 2024).

Funding of the device

The OCT imaging catheter is a single use device, provided in a kit with other OCT-specific consumables at a cost of **\$Redacted**. While the Department has advised the applicant that the catheter is not eligible for listing on the Prescribed List of Medical Devices and Human Tissue Products (PL), the applicant intends to seek inclusion of the catheter on Part C of the PL. If not listed on the PL, the cost of the OCT kit is to be met by patients (i.e. out-of-pocket expense) or by hospitals or private health insurance funds.

The OCT imaging system currently costs **\$Redacted** per unit and is a cost incurred by hospitals.

Training and certification

The Cardiac Society of Australia and New Zealand (CSANZ) is currently in the process of developing guidelines pertaining to accreditation and training for intravascular imaging to assist with implementation of IVUS on the MBS (listed 1 March 2024). The document is anticipated to be non-modality specific and would therefore also assist with the implementation of OCT on the MBS.

6. Proposal for public funding

The application requested a new MBS item under Category 3 (therapeutic procedures) for the use of OCT-guided coronary stent insertion as an adjunct to invasive coronary angiogram (AG) (referred to as OCT+AG) for patients undergoing percutaneous coronary intervention (PCI) with particular lesion types or complexity (long or multiple lesions, bifurcation lesion, angiographic severe calcification, or stent failure).

OCT is a catheter-based intravascular imaging technique that uses infrared light to obtain three-dimensional cross-sectional images of a coronary artery. The ADAR claimed that OCT technology allows physicians to visualise and measure vessel characteristics that are otherwise not visible or difficult to assess with angiography alone, which helps guide stent selection and deployment as well as assessment of stent placement.

OCT is delivered in the catheterisation laboratory setting where the PCI is performed. It is provided at public or private hospitals as an inpatient procedure, usually using local anaesthesia. During the procedure, the OCT imaging catheter is loaded onto a guide wire and advanced to the desired imaging region using a guide catheter. The imaging catheter connects to the OCT imaging system through the drive-motor and optical controller. The OCT procedure requires two operators (a sterile operator and a non-sterile operator). The use of OCT increases procedural time by approximately 15 minutes, including catheter preparation, setting up the system, image acquisition and image assessment.

Currently, OCT is not routinely used in Australia during percutaneous coronary stent insertion. According to the Victorian Cardiac Outcomes Registry (VCOR) [Annual Public Report 2022](#), OCT was used in 2.7% of PCI cases in Victoria in 2022 (3.4% of cases in the public sector and 1.7% of cases in the private sector).

Proposed MBS item descriptor

The proposed MBS item descriptor for OCT-guided coronary stent insertion is shown in Table 2. Edits proposed by the commentary for consistency with MBS item 38325 (IVUS-guided coronary stent insertion) are shown in strikethrough (deletions) and italics (additions).

Similar to IVUS, the proposed item for OCT does not mention concurrent invasive coronary AG, which is always performed with PCI, either just prior to stent insertion or separately (within three months of PCI).

Table 2 Proposed new MBS item descriptor for OCT-guided coronary stent insertion; with commentary amendments.

<p>Category 3 – Therapeutic procedures</p> <p>MBS item XXXX</p> <p>Optical Coherence Tomography (OCT)</p> <p>Use of <i>optical coherence tomography (OCT)</i> during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition, for a patients <i>documented</i> with:</p> <ul style="list-style-type: none"> – one or more Long or multiple lesions, defined as where the intended total stent length (continuous or separated) in any single target vessel is ≥28 mm), or – one or more Lesions located at a bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation, or – one or more lesions with 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 <i>or</i>, in-stent restenosis of diffuse or multi-focal pattern). <p>Being a service associated with if performed in association with a service to which items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, or 38323 applies.</p> <p>Service is claimable once in a single <i>Applicable once per episode of care (for one or more lesions) (H).</i></p> <p><i>Multiple Operation Rule</i> (Anaes.)</p> <p>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)</p> <p>Fee: \$516.90 <i>\$508.70</i> Benefit: 75% = \$387.70 <i>\$381.55</i> 85% = \$439.40</p>
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Source: adapted from Table 14 of MSAC 1743 ADAR+in-line commentary, with commentary amendments in strikethrough and italics.

PASC noted there was no theoretical reason to limit the proposed intervention to a particular number of target vessels but considered a multi-disciplinary team should be consulted if three or more vessels require intervention because there are potential risks involved with increasing the duration of the procedure. MSAC may wish to consider whether this should be included in an explanatory note.

MSAC may also wish to consider whether the service should be restricted to accredited providers or those with specific training. If so, the appropriate training standard needs to be confirmed and considered for inclusion in the item descriptor explanatory notes (noting, however, that MBS item 38325 for IVUS is not restricted to accredited providers and has no explanatory note specifying training requirements for IVUS).

Given that the indications for IVUS and OCT overlap, and the two modalities may provide different information for the operator, MSAC may wish to consider whether dual use of these intravascular imaging technologies would be appropriate without consideration of clinical evidence to support safe and effective use of the two modalities together. For example, OCT and IVUS could be used concurrently for left main coronary artery bifurcation lesions and for long lesions.

Proposed MBS schedule fee

The fee proposed by the applicant was informed by MBS item 38241, use of a coronary pressure wire (\$516.90 on 2 February 2024), that was used to form the basis of the proposed item for IVUS ([MSAC 1354.1 Public Summary Document](#) [PSD]). Expert opinion obtained by the applicant noted that the duration of the procedure, the complexity, and the resources used for OCT were similar to that for IVUS. On 1 March 2024, MBS item 38325 for use of IVUS during transluminal insertion of stents was listed on the MBS with a schedule fee of \$508.70 (see Table 3 for descriptor). The commentary has amended the proposed MBS fee in Table 2 for consistency.

7. Population

The ADAR included four subpopulations within the one PICO set. The intervention, primary comparator, and outcomes were the same for all four subpopulations. The long or multiple lesion subpopulation also had a second comparator.

The proposed population for OCT-guided coronary stent insertion was patients with myocardial ischaemia undergoing invasive coronary AG, 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 initial patient population is limited to patients who meet the eligibility criteria for the 12 MBS items used to claim stenting as part of primary PCI. This population is then further restricted based on whether patients meet one of the four lesion-specific or complexity criteria listed above.

Rationale

The proposed patient population was informed by the eligibility criteria of the ILUMIEN IV trial ([NCT03507777](#)) combined with advice sought by the applicant from five interventional cardiologists with experience using OCT.

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 drug eluting stent (DES) implantation is still suboptimal despite angiography guidance. Complex lesions have been shown to be associated with an increased risk of failed PCI and inferior clinical outcomes.

There were some differences in the wording of the proposed bifurcation lesion subpopulation compared to the ILUMIEN IV trial. In the ILUMIEN IV trial the bifurcation lesion must be intended to be treated with two planned stents, whereas the proposed population does not limit to two stent lesions. The clinicians consulted by the applicant 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.

Regarding the subpopulation 'stent failure', the experts consulted by the applicant advised that stent failure be used, rather than the ILUMIEN IV criterion 'in-stent restenosis of diffuse or multifocal pattern', to also allow use of OCT in patients with stent thrombosis consistent with the European Association of Percutaneous Cardiovascular Interventions ([EAPCI guidelines](#)) (Räber et al. 2018).¹

The long/multiple lesion and severe calcifications populations in the ADAR were consistent with the eligibility criteria used in the ILUMIEN IV trial.

8. Comparator

In all subpopulations, the comparator to the proposed intervention (OCT+AG) was invasive coronary AG (AG alone). IVUS-guided coronary stent insertion as an adjunct to invasive coronary AG (IVUS+AG) was an additional comparator in the long/multiple lesion subpopulation.

Coronary angiography is the mainstay traditional imaging modality for guidance of stent placement. It entails the use of x-ray, which is able to visualise the coronary arteries following the injection of an iodinated contrast medium. Coronary AG is limited by its two-dimensional representation of blood vessels, since it cannot depict the arterial vessel wall, evaluate vessel dimensions and plaque characteristics, or directly assess the results of stent implantation (Räber et al. 2018).

Coronary angiography for the purposes of guiding the transluminal insertion of stents is currently listed on the MBS under 12 PCI related items. PCI with stent insertion may be performed at the same time as invasive coronary angiography (MBS items 38307, 38308, 38310, 38311, 38313, 38314) or within 3 months of invasive coronary angiography (MBS items 38316, 38317, 38319, 38320, 38322, 38323).

¹ Räber L, Mintz GS, Koskinas KC, Johnson TW, Holm NR, Onuma Y, Radu MD, Joner M, Yu B, Jia H, Meneveau N, de la Torre Hernandez JM, Escaned J, Hill J, Prati F, Colombo A, di Mario C, Regar E, Capodanno D, Wijns W, Byrne RA, Guagliumi G, ESC Scientific Document Group (2018) 'Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions', *Eur Heart J*, 39(35), 3281-3300, doi: 10.1093/eurheartj/ehy285.

IVUS used as an adjunct to invasive coronary AG was recently listed on the MBS for lesions of the left main coronary artery or lesions at least 28 mm in length in other locations. The long lesion subpopulation proposed for OCT (long or multiple lesions with intended total stent length in any single target vessel at least 28 mm) was broader than for IVUS. The commentary noted that IVUS was therefore the comparator for a subset of patients with long lesions; coronary AG alone would be the appropriate comparator for the remainder of the proposed subpopulation. The ADAR acknowledged uncertainty around the way the IVUS and OCT eligibility for the long lesion subpopulation would be interpreted in practice.

Similar to OCT, IVUS-guided coronary stent insertion is used as an adjunct to invasive coronary AG. The MBS item for IVUS (38325, see Table 3) allows for IVUS to be performed in association with any of the 12 MBS items for PCI with coronary stent insertion, including where invasive coronary angiography was performed within 3 months prior to the PCI procedure.

PASC noted that the choice between IVUS and OCT for patients who have lesions with length ≥ 28 mm 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 due to the risk of contrast nephropathy with OCT).

Table 3 MBS item for IVUS during PCI with stent insertion

Category 3 – THERAPEUTIC PROCEDURES	
	Group T8 – Surgical Operations Subgroup 6 – Cardio-Thoracic
<p>38325</p> <p>Use of intravascular ultrasound (IVUS) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition, for a patient documented with:</p> <p>(a) one or more left main coronary artery lesions; or</p> <p>(b) one or more lesions at least 28mm in length in other locations;</p> <p>if performed in association with a service to which item 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies</p> <p>Applicable once per episode of care (for one or more lesions) (H)</p> <p>Multiple Operation Rule (Anaes.)</p> <p>Fee: \$508.70 Benefit: 75% = \$381.55</p>	

Source: MBS online, 1 March 2024.

9. Summary of public consultation input

Consultation input was welcomed from three (3) professional organisations, one (1) consumer organisation and twelve (12) individuals, all of whom were medical specialists.

The four (4) organisations that submitted input were:

- Hearts4Heart
- Boston Scientific
- The Interventional Craft Group at the Victorian Heart Hospital
- Eastern Heart Clinic Group

The majority of consultation feedback received was generally supportive of the application, excluding feedback from Boston Scientific in relation to the proposed OCT population.

Benefits

- OCT is a superior modality when compared to coronary angiography and provides an alternative choice in intravascular imaging.
- OCT coupled with adjunct coronary angiography guided percutaneous coronary intervention (PCI) reduces target vessel failure, stent thrombosis and all-cause death.
- OCT allows the operator to accurately assess the size and length, as well as the optimal placement of the stent especially in cases of narrowed arteries. OCT can also identify the potential for stent failure that cannot be captured using coronary angiography alone.
- Reduction in the downstream cost of repeat intervention, i.e., repeat presentations to hospital and need for further PCI or surgery. Additionally, an increased ability to recommend same day procedures, avoiding need for admission for monitoring.
- OCT is useful for post-intervention assessment, detecting issues such as stent malposition, edge dissection, and tissue prolapse.
- OCT is useful for assessing the healing process post-stent implantation, as it can detect endothelial coverage and assess whether the stent is becoming incorporated into the vessel wall, which is critical for long-term outcomes.
- OCT will potentially provide effective treatment to a broader indication of high-risk coronary lesions not covered by currently funded MBS item numbers, such as calcification, bifurcation and stent complications.
- OCT can differentiate between different types of arterial plaque and enables targeted interventions by identifying the plaques that are prone to rupture and lead to heart attacks.
- Equity of access, as public funding for OCT may promote wider usage including in regional areas.

Disadvantages

- The use of OCT requires the use of a modest amount of additional radiographic contrast and a slightly longer procedure time.
- OCT use is limited in ostial lesions as contrast can't be expelled to obtain adequate imaging.
- The cost of the procedure and associated capital/equipment cost(s).
- In a subset of patient with abnormal kidney function, OCT may increase the risk of contrast induced nephropathy (reduction in kidney function), however this risk can be mitigated by injecting normal saline (NS) instead of contrast, noting NS is ineffective in left main and left anterior descending arteries (LAD).
- Risk of vessel dissection when a large volume of contrast or saline is injected into a vessel.
- Intra-coronary imaging marginally prolongs the time required for a stenting procedure.

Additional Comments

There was mixed feedback comparing OCT to (Intravascular Ultrasound) IVUS, with one respondent stating 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. Another respondent noted that a network comparison of OCT vs IVUS did not find any significant differences in outcomes between the 2 modalities, indirectly indicating that both are advantageous.

It was noted that if concurrent funding for OCT was implemented in line with the existing IVUS lesion type of long lesion from March 2024, this would provide increased clinician choice and address the unmet need whilst MSAC assesses this application for funding OCT in the broader population.

Boston Scientific raised concerns that MSAC will support public funding for the proposed OCT population while the evidence presented in MSAC 1743 Application Summary and PICO Set is limited, when compared to the evidence supporting the clinical utility of IVUS as submitted in [MSAC Application 1354.1](#).

The feedback from the Interventional Craft Group at the Victorian Heart Hospital noted that the proposed item descriptor would also permit the use of OCT during cases of stent failure which is their opinion is a critical component of the application. One medical specialist noted that 'stent failure' should also be on the item descriptor independent of stent insertion as in under expanded stents a further stent may not be required; rather optimisation of the already placed stent with OCT or IVUS guidance.

10. Characteristics of the evidence base

The literature search performed for the ADAR aimed to identify all randomised controlled trials (RCTs) of OCT+AG versus AG alone or IVUS+AG in patients undergoing PCI. To be eligible, RCTs were required to include patients representing the target population for the proposed listing, report stratified data informing the comparison of OCT+AG versus AG alone for at least one of the four subpopulations or OCT+AG versus IVUS+AG for the long lesion subpopulation, and report data for clinical outcomes specified in the PICO.

The commentary considered that the search strategy was sufficiently comprehensive. No additional pivotal studies were identified.

Three RCTs met the pre-defined eligibility criteria and were included in the ADAR as pivotal evidence: OCTOBER ([NCT03171311](#)) compared OCT+AG-guided PCI with AG-guided PCI in patients with complex bifurcation lesions; ILUMIEN IV:OPTIMAL PCI ([NCT03507777](#)) compared OCT+AG-guided PCI with AG-guided PCI in patients with medication-treated diabetes or complex coronary artery lesions; and OCTIVUS ([NCT03394079](#)) compared OCT+AG-guided PCI with IVUS+AG-guided PCI in patients with significant coronary artery lesions. The comparative efficacy and safety claims made in the ADAR were based on these three RCTs.

The approach to evidence synthesis used in the ADAR is summarised in Table 4. The publications for ILUMIEN IV and OCTIVUS did not provide baseline characteristics nor outcome data for the constituents of the primary endpoint for the subpopulations of interest. The ADAR presented additional post hoc analyses provided by the principal investigators (upon request).

The ADAR reported that safety data by subpopulation were only available for bifurcation lesions (OCTOBER). The OCTIVUS post hoc analyses for patients with diffuse long coronary artery lesions included data on procedural complications requiring active intervention. Safety data from the intention-to-treat (ITT) population of ILUMIEN IV and OCTIVUS were presented in lieu of data for the remaining subpopulations.

While the ADAR assumed that safety outcomes would unlikely be different between the subgroups and the ITT population, the commentary noted that this assumption may not be

justified for all subpopulations. For example, the baseline characteristics of the stent failure subgroup in the ILUMIEN IV trial suggested these patients may be at higher risk of adverse events. The use of safety data from the ITT population may underestimate these risks.

Table 4 Evidence matrix

Trial	Bifurcation	Severe calcification	Stent failure	Long lesion	
Comparator	AG alone	AG alone	AG alone	AG alone	IVUS + AG
Efficacy evidence					
OCTOBER	✓ ITT n = 1,201	✗ No data	✗ No data	✗ No data	✗ No data
ILUMIEN IV	✓ post hoc subgroup n = 83	✓ post hoc subgroup n = 286	✓ post hoc subgroup n = 268 (re-stenosis only)	✓ post hoc subgroup n = 1,677	✗ No data
OCTIVUS	✗ No data	✗ No data	✗ No data	✗ No data	✓ post hoc subgroup n = 1,169
Safety evidence					
OCTOBER	✓ ITT n = 1,201	✗ No data	✗ No data	✗ No data	✗ No data
ILUMIEN IV	✗ No data	✓ ITT n = 2,487	✓ ITT n = 2,487	✓ ITT n = 2,487	✗ No data
OCTIVUS	✗ No data	✗ No data	✗ No data	✗ No data	✓ ITT n = 2,008 ✓ post hoc subgroup n = 1,169
Clinical claims					
Efficacy	Superiority	Superiority	Superiority	Superiority	Non-inferiority
Safety	Non-inferiority	Non-inferiority	Non-inferiority	Non-inferiority	Non-inferiority

AG = angiogram; ITT = intention-to-treat, IVUS = intravascular ultrasound guided coronary.
Source: Table 18 of MSAC 1743 ADAR+in-line commentary.

The results from a recent network meta-analysis (NMA) including all relevant OCT+AG versus AG alone trials and the RENOVATE COMPLEX-PCI trial ([NCT03381872](#)) were presented as supportive evidence in the ADAR. Whilst the NMA (provided in the form of a conference presentation) was not directly applicable to the populations proposed for MBS listing for OCT, it supported the benefits of using OCT+AG more generally. Similarly, although the RENOVATE COMPLEX-PCI trial did not report subgroup data directly applicable to the proposed populations, it reflected a 'complex' population that was broadly relevant to the proposed populations for OCT+AG.

The key features of the pivotal evidence included in the ADAR is summarised in Table 5. While the ADAR assessed the three RCTs to be at low risk of bias overall, these assessments related to the ITT population. The post hoc subgroup analyses presented in the ADAR for the ILUMIEN IV and OCTIVUS trials were not prespecified in the statistical analysis plans and no separate sample size calculations were undertaken for the subgroups. The Evidence Profile Tables presented in the ADAR acknowledged that the ILUMIEN IV and OCTIVUS subgroup analyses were at moderate

risk of bias. Risk of bias assessments undertaken by the commentary determined the ILUMIEN IV subgroups to be at moderate to high risk of bias.

Table 5 Key features of the included evidence

Trial ID N	Study design Risk of bias	Population	Intervention Comparator	Key outcomes	Result used in economic model?
OCTOBER NCT03171311 N = 1,201	R (1:1), MC, OL trial at 38 centres in Europe Median follow up: 2 yr ^a Risk of bias: LOW	Adults (≥ 18 yr) with complex bifurcation lesions (main branch diameter of ≥ 2.75 mm by angiographic visual estimation, side branch diameter ≥ 2.5 mm) undergoing PCI	OCT+AG- guided PCI (N = 600) AG (± IVUS) ^b - guided PCI (N = 601)	Primary clinical (2 yr) MACE ^c Secondary clinical (2 yr) MI (any, target lesion) TVR, TLR Mortality (all cause, cardiac) Stent thrombosis Safety (over 2 yr) Procedure-related complications	Yes, informs the CUA for bifurcation lesions
ILUMIEN IV NCT03507777 N = 2,487	R (1:1), MC, SB trial at 80 centres in 18 countries including the US, Australia, and Europe Median follow up: 2 yr Risk of bias: LOW MODERATE (to HIGH) for efficacy subgroups	Adults (≥ 18 yr) with medication- treated diabetes or complex coronary artery lesions (including bifurcation, severely calcified lesions, in-stent restenosis, long or multiple lesions) undergoing PCI	OCT+AG- guided PCI (N = 1,233) AG-guided PCI (N = 1,254)	Primary clinical (2 yr) TVF ^d Secondary clinical (2 yr) Target vessel MI TVR Cardiac mortality Stent thrombosis HRQoL ^e Safety (over 2 yr) Procedure-related complications AEs	Yes, subgroup data for long lesions and for severely calcified lesions informs the CUAs
OCTIVUS NCT03394079 N = 2,008	R (1:1), MC, OL trial at 9 centres in South Korea Median follow up: 2 yr Risk of bias: LOW MODERATE for efficacy subgroup	Adults (≥ 19 yr) with significant coronary artery lesions (including diffuse long lesions) undergoing PCI	OCT+AG- guided PCI (N = 1,005) IVUS+AG- guided PCI (N = 1,003)	Primary clinical (1 yr) TVF ^d Secondary clinical (1 yr) MI (any, target vessel) TVR Cardiac mortality Stent thrombosis Safety (over 1 yr) Procedure-related complications	OCT+AG is non-inferior to IVUS+AG; OCTIVUS informs the CMA

AE = adverse event; AG = angiogram; CMA = cost-minimisation analysis; CUA = cost-utility analysis; HRQoL = health-related quality of life; IVUS = intravascular ultrasound; MACE = major adverse cardiac events; MC = multicentre; MI = myocardial infarction; N = total number of randomised patients; OCT = optical coherence tomography; OL = open label; PCI = percutaneous coronary intervention; R = randomised; SB = single blind; TLR = target lesion revascularisation; TVF = target vessel failure; TVR = target vessel revascularisation; US = United States; yr = year(s).

a The database for the primary end point was closed before the last 122 enrolled patients reached the 2-year follow-up point.

b The ADAR did not consider optional IVUS as part of the comparator; however, IVUS was allowed at the operators' discretion if the patient had a lesion located at a left main coronary artery bifurcation.

c MACE was defined as composite of death from a cardiac cause, target lesion MI, or ischemia-driven TLR.

d TVF was defined as composite of death from a cardiac cause, target vessel MI, or ischemia-driven TVR.

e EuroQoL EQ-5D-5L was completed at baseline and at 30-day, 1-yr and 2-yr follow-up. Results were not included in the primary publication but are planned for a future publication.

Source: Adapted from Table 19 of MSAC 1743 ADAR+in-line commentary.

Baseline demographics and characteristics

For the ILUMIEN IV and OCTIVUS trials, the benefits of randomisation in the ITT population were lost for the subgroup analyses, meaning that baseline characteristics were not always comparable between the OCT+AG and AG alone or IVUS+AG arms.

While the ADAR noted some differences in baseline characteristics between the OCT+AG and AG alone arms in the bifurcation, severe calcification and stent failure subgroups of the ILUMIEN IV trial, these differences generally did not reach statistical significance. This was likely in part due to the small sample sizes. The one exception to this was prior myocardial infarction (MI) in the stent failure subgroup, which was statistically significantly higher in the AG alone arm than the OCT+AG arm.

In the ILUMIEN IV long/multiple lesion subgroup, the OCT+AG arm had a higher proportion of male patients (81% vs. 76%, $p = 0.013$) than the AG alone arm. The OCTIVUS long lesion subgroup had a higher proportion of patients with congestive heart failure in the OCT+AG arm than the IVUS+AG arm (3.1% vs. 1.3%, $p = 0.035$).

In the absence of randomisation or other statistical adjustment in these subgroups it is also possible that the arms were not balanced for other important characteristics that were not measured or not reported.

Procedural details

The level of site experience with OCT in the OCTOBER trial was unclear. Sites were required to have completed at least one case of bifurcation stent implantation with OCT guidance and to have participated in an online feedback session before entering the study. Due to the limited training received by OCTOBER investigators before entering the study, investigators were given confidential “next day” case-by-case core laboratory feedback. The feedback was intended for continuous training in OCT-guided PCI and to maximise study protocol adherence. The trial was not designed to detect if the feedback sessions changed the treatment, and it is possible that this structured feedback could have introduced bias.

Applicability

Overall, relevant data from the OCTOBER, ILUMIEN IV and OCTIVUS trials were considered reasonably applicable to the Australian treatment setting in terms of population, intervention, comparator, and the healthcare system. However, the applicability information provided in the ADAR was not sufficient to determine whether the trial populations would be eligible for the MBS items for PCI for stent insertion.

Alignment with the PICO confirmation

Population

For the bifurcation subpopulation, the OCTOBER trial was directly applicable to the proposed population for OCT whereas the bifurcation subgroup in ILUMIEN IV represented only a subset of the proposed bifurcation population (those intended to be treated with two planned stents).

The proposed long/multiple lesion and severe calcification subpopulations were informed by the eligibility criteria of ILUMIEN IV, meaning the ILUMIEN IV subgroup data supporting these subpopulations were directly applicable.

The proposed stent failure subpopulation was broader than the ILUMIEN IV subgroup, which was restricted to in-stent restenosis of diffuse or multi-focal pattern. The data presented in the ADAR represented a subset of the population defined in the PICO (which included patients with stent thrombosis) and the commentary noted that it may not be an appropriate proxy.

The long lesion subgroup in the OCTIVUS trial was defined in a way that was broadly consistent with the definition of the proposed subpopulation for OCT. Data from this subgroup from OCTIVUS was broadly applicable to the proposed subpopulation for the OCT+AG versus IVUS+AG comparison.

Comparator

The commentary noted that it may be more appropriate to consider the comparator in the OCTOBER trial as AG ± IVUS-guided PCI, rather than AG-guided PCI as reported in the ADAR. Fifteen percent of patients randomised to AG-guided PCI underwent IVUS-guided PCI, which was not encouraged but allowed at the operators' discretion in patients with a lesion located at a left main coronary artery bifurcation (36% of cases where IVUS was used were protocol violations). The ADAR assumed that this was likely to have favoured the AG-guided PCI group and underestimated the true intervention effect of OCT+AG-guided PCI versus AG alone. However, a post hoc analysis showed higher rates of major adverse cardiac events (MACE) in IVUS-guided patients randomised to AG-guided PCI compared with AG-guided PCI alone (20.1% versus 13.0%). The commentary noted that this finding may reflect that these patients were more complex, hence requiring intravascular imaging.

Outcomes

The efficacy and safety outcomes included in the ADAR were generally consistent with the PICO. In-stent restenosis and health-related quality of life were not reported in any of the included publications and were therefore not reported in the ADAR.

Most notably, the primary composite outcome used in OCTOBER (MACE) was not an outcome specified in the PICO. MACE was defined in OCTOBER as death from cardiac causes, target lesion MI, or ischemia-driven target lesion revascularisation (TLR). By contrast, the PICO composite outcome of target vessel failure (TVF) was defined as the composite of cardiac death, target vessel MI, or ischemia-driven target vessel revascularisation (TVR). Therefore, the OCTOBER definition of MACE was not aligned with the PICO and the commentary considered the outcomes too dissimilar to justify meta-analysis.

There were differences in the definitions of cardiac mortality, MI and revascularisation between the three trials. Stent thrombosis was also categorised differently between the trials.

11. Comparative safety

OCT+AG versus AG alone

Key safety data from the OCTOBER ITT population for the bifurcation subgroup are presented in Table 6. The proportion of patients experiencing any procedural complication was similar between the OCT+AG and AG alone arms (6.8% vs 5.7%) (GRADE certainty of evidence was considered moderate in the ADAR and the commentary). There were no statistically significant differences in the individual procedural complications between arms; however, four complications occurred more frequently in the OCT+AG arm: major bleeding (0.5% vs. 0.2%), vessel occlusion non-recovered (1.5% vs. 1.0%), dissection (1.8% vs. 1.3%) and contrast-associated acute kidney injury (0.2% vs. 0.0%).

Table 6 Key safety data from OCTOBER: OCT+AG vs. AG alone

Event	OCT+AG n/N (%)	AG alone n/N (%)	OR [95% CI] ^a OR <1 favours OCT+AG	RR [95% CI] ^a RR <1 favours OCT+AG	RD [95% CI] ^a RD <0 favours OCT+AG
Any procedural complication	41/600 (6.8)	34/601 (5.7)	1.22 [0.76, 1.96]	1.21 [0.78, 1.88]	0.01 [-0.02, 0.04]
Contrast-associated acute kidney injury	1/600 (0.2)	0/601 (0)	NE	NE	0.00 [0.00, 0.00]

AG = angiogram; CI = confidence interval; ITT = intention-to-treat; OCT = optical coherence tomography; OR = odds ratio; RD = risk difference; RR = risk ratio.

^a OR, RR and RD with associated CIs were calculated from n/N event data.

Source: Table 41 of MSAC 1743 ADAR+in-line commentary.

Key safety data from the ILUMIEN IV ITT population are presented in Table 7. These data were included in the ADAR in the absence of subgroup-specific safety data for the severe calcification, stent failure, and long/multiple lesion subgroups to inform the comparison of OCT+AG versus AG alone. The commentary noted that the ITT population included an unspecified proportion of patients at high clinical risk (i.e. medication-treated diabetes) in the absence of complex coronary lesions (high angiographic risk), which raises applicability concerns.

Furthermore, a final set of OCT images was obtained after the PCI procedure in both arms in ILUMIEN IV (i.e. patients in the AG alone arm also received a final blinded OCT procedure). The commentary noted that the results from this trial were therefore not informative in terms of comparing the safety of OCT+AG versus AG with no OCT.

The incidence of OCT-related complications was low in both arms. At the completion of the procedure, a lower proportion of patients treated with OCT+AG experienced PCI-related angiographic complications (RD -1.7% [95% CI: -3.3, -0.1]) and procedure-related thrombotic events (RD -1.8% [95% CI: -3.1, -0.4]) compared with AG alone. Contrast induced nephropathy was not reported in the primary study publication.

Table 7 Key safety data from the ILUMIEN IV ITT population: OCT+AG vs. AG alone

Event	OCT+AG n/N (%)	AG alone n/N (%)	OR [95% CI] ^a OR <1 favours OCT+AG	RR [95% CI] ^a RR <1 favours OCT+AG	RD [95% CI] ^a RD <0 favours OCT+AG
OCT-related complications, n. patients ^b	1/1232 (<0.1)	2/1252 (0.2)	0.51 [0.05, 5.61]	0.51 [0.05, 5.60]	0.00 [0.00, 0.00]
PCI-related angiographic complications, n. lesions ^c	48/1320 (3.6)	74/1387 (5.3)	0.67 [0.46, 0.97]	0.68 [0.48, 0.97]	-0.02 [-0.03, 0.00]
Procedure-related thrombotic events	31/1320 (2.3)	57/1387 (4.1)	0.56 [0.36, 0.87]	0.57 [0.37, 0.88]	-0.02 [-0.03, -0.00]

AG = angiogram; CI = confidence interval; ITT = intention-to-treat; OCT = optical coherence tomography; OR = odds ratio; PCI = percutaneous coronary intervention; RD = risk difference, RR = risk ratio.

^a OR, RR and RD with associated CIs were calculated from n/N event data.

^b Data were adjudicated by the clinical events committee. The three OCT-related complications were a perforation treated with unplanned stent implantation, slow flow treated with hemodynamic support or pressor, and slow flow treated with unplanned stent implantation.

^c Angiographic complications were reported at the completion of the procedure and were the composite of slow flow, no reflow, main branch or side-branch closure, distal embolisation, new or worsening thrombus, or intraprocedural stent thrombosis; the events were assessed by the core laboratory. Data were available for 1,231 patients in the OCT+AG group and 1,252 patients in the AG alone group.

Note: Results in bold are statistically significant.

Source: Table 62 of MSAC 1743 ADAR+in-line commentary.

OCT+AG versus IVUS+AG

Key safety data from the OCTIVUS trial, including the ITT population, complex lesion subpopulation (published after the ADAR literature search), and long lesion subpopulation (post hoc analysis prepared for the ADAR) are summarised in Table 8.

For the ITT population, the incidence of procedural complications requiring active intervention during the index procedure was lower with OCT+AG (2.2%) than with IVUS+AG (3.7%). According to the p-value reported in the publication, the difference was statistically significant ($p = 0.047$). No statistically significant differences in the individual procedural complications between each arm were identified, with events either the same or numerically lower with OCT+AG. No deaths were reported.

In patients with complex coronary artery lesions² the incidence of procedural complications requiring active intervention was also significantly lower in the OCT+AG group than the IVUS+AG group (1.7% vs. 3.4%; $p = 0.03$). The difference in procedural complications requiring active intervention was not statistically significant in the subpopulation of patients with diffuse long coronary artery lesions (3.3% vs. 4.7%; $p = 0.22$).

No IVUS or OCT procedure related complications were observed in either treatment arm in the trial. The rate of contrast-induced nephropathy was similar between the OCT+AG and IVUS+AG arms in the ITT population (1.4% vs. 1.5%; HR=0.93, 95% CI 0.45, 1.92) and the complex lesion subgroup (1.9% vs. 1.5%).

Table 8 Key safety data for OCT+AG vs. IVUS+AG from the OCTIVUS trial

Event	OCT+AG n/N (%)	IVUS+AG n/N (%)	OR [95% CI] ^a OR <1 favours OCT+AG	RR [95% CI] ^a RR <1 favours OCT+AG	RD [95% CI] ^a RD <0 favours OCT+AG
Procedural complications requiring active intervention^b					
Any					
ITT	22/1005 (2.2)	37/1003 (3.7)	0.58 [0.34, 1.00]	0.59 [0.35, 1.00]	-0.01 [-0.03, -0.00]
Complex lesion subgroup	12/719 (1.7)	26/756 (3.4)	0.48 [0.24, 0.95]	0.49 [0.25, 0.95]	-0.02 [-0.03, -0.00]
Long lesion subgroup	19/575 (3.3)	28/594 (4.7)	0.69 [0.38, 1.25]	0.70 [0.40, 1.24]	-0.01 [-0.04, 0.01]
Contrast-induced nephropathy^c					
ITT ^d	14/1005 (1.4)	15/1003 (1.5)	0.93 [0.45, 1.94]	0.93 [0.45, 1.92]	0.00 [-0.01, 0.01]
Complex lesion subgroup	14/719 (1.9)	11/756 (1.5)	1.34 [0.61, 2.98]	1.34 [0.61, 2.93]	0.00 [-0.01, 0.02]

AG = angiogram; CI = confidence interval; ITT = intention-to-treat; IVUS = intravascular ultrasound; NE = not estimated; OCT = optical coherence tomography; OR = odds ratio; RD = risk difference; RR = risk ratio.

^a OR, RR and RD were calculated from n/N.

^b Procedural complications requiring active intervention (prolonged balloon inflations, additional stenting required, thrombus aspiration, pericardiocentesis, cardioversion, use of mechanical circulatory support devices) that were related to PCI or use of intravascular imaging.

^c Contrast-induced nephropathy was defined as either a greater than 25% increase of serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dL from baseline within 72 h after the index PCI procedure.

^d Evaluated during the entire follow up period (2 years).

Note: Results in bold are statistically significant.

Source: Table 64, Commentary Table 5 and Commentary Table 6 of MSAC 1743 ADAR+in-line commentary.

² Defined as unprotected left main disease, bifurcation disease, aorto-ostial lesion, chronic total occlusion, severely calcified lesion, in-stent restenotic lesion, long diffuse lesion (i.e. stent length >38 mm of treated segment), or multivessel PCI involving at least two major epicardial coronary arteries being treated at the index hospitalisation.

All trials excluded patients with renal disease (defined variably across trials) due to the increased risk of renal failure with the use of contrast media during PCI. As renal insufficiency is a risk factor for contrast-induced nephropathy, it is possible that this adverse effect would be seen more often in a non-trial selected population.

12. Comparative effectiveness

The OCTOBER trial (bifurcation lesions) was powered on the primary composite endpoint of MACE (similar to TVF); however, all other subpopulations relied on data from subgroup analyses from ILUMIEN IV and OCTIVUS, which lacked power to detect statistically significant differences in the primary composite endpoint and individual events.

Of note, for the ITT population of ILUMIEN IV, there was no apparent between-group difference in the percentage of patients with TVF at 2 years (HR 0.9, 95% CI 0.67, 1.19; $p = 0.45$), which was the primary clinical efficacy endpoint upon which the trial was statistically powered.

OCT+AG versus AG alone

Bifurcation subpopulation

The key effectiveness outcomes at 2 years for the bifurcation subpopulation are presented in Table 9 and Figure 1. OCTOBER was an appropriately powered trial dedicated to patients with bifurcation lesions applicable to the proposed listing and was considered the most applicable and informative to the bifurcation subpopulation. However, the composite outcome definition in OCTOBER (MACE) was not consistent with the PICO composite outcome (TVF).

Table 9 Key effectiveness outcomes at 2 years: OCT+AG versus AG alone – bifurcation subpopulation

Event	Evidence	OCT+AG n/N (%)	AG alone n/N (%)	HR [95% CI] HR <1 favours OCT+AG	GRADE certainty of evidence
TVF ^a /MACE ^b	ILUMIEN IV subgroup (TVF)	3/40 (7.5)	3/43 (7.0)	1.05 [0.21, 5.18]	NR
	OCTOBER ITT (MACE)	59/600 (10.1)	83/601 (14.1)	0.70 [0.50, 0.98]	High
Target lesion MI	OCTOBER ITT	46/600 (7.8)	51/601 (8.5)	0.90 [0.60, 1.34]	Moderate
Target vessel MI	ILUMIEN IV subgroup	1/40 (2.5)	0/43 (0)	NE	NR
Ischemia-driven TVR	OCTOBER ITT	17/600 (3.0)	27/601 (4.8)	0.62 [0.34, 1.13]	Moderate
	ILUMIEN IV subgroup	3/40 (7.5)	3/43 (7.0)	1.05 (0.21, 5.18]	NR
Ischemia-driven TLR	OCTOBER ITT	16/600 (2.8)	26/601 (4.6)	0.60 [0.32, 1.13]	Moderate
Cardiac death	OCTOBER ITT	8/600 (1.4)	15/601 (2.6)	0.53 [0.22, 1.25]	Moderate
	ILUMIEN IV subgroup	0/40 (0)	0/43 (0)	NE	NR
Stent thrombosis	OCTOBER ITT	12/600 (2.1)	17/601 (3.0)	0.70 [0.34, 1.47]	Moderate
	ILUMIEN IV subgroup	0/40 (0)	0/43 (0)	NE	NR

AG = angiogram; CI = confidence interval; HR = hazard ratio; ITT = intention-to-treat; MACE = major adverse cardiac events; MI = myocardial infarction; NE = not estimated; NR = not reported; OCT = optical coherence tomography; TLR = target lesion revascularisation; TVF = target vessel failure; TVR = target vessel revascularisation.

^a TVF, defined as a composite of death from a cardiac cause, target vessel MI, or ischemia-driven TVR.

^b MACE, defined as a composite of death from a cardiac cause, target lesion MI, or ischemia-driven TLR.

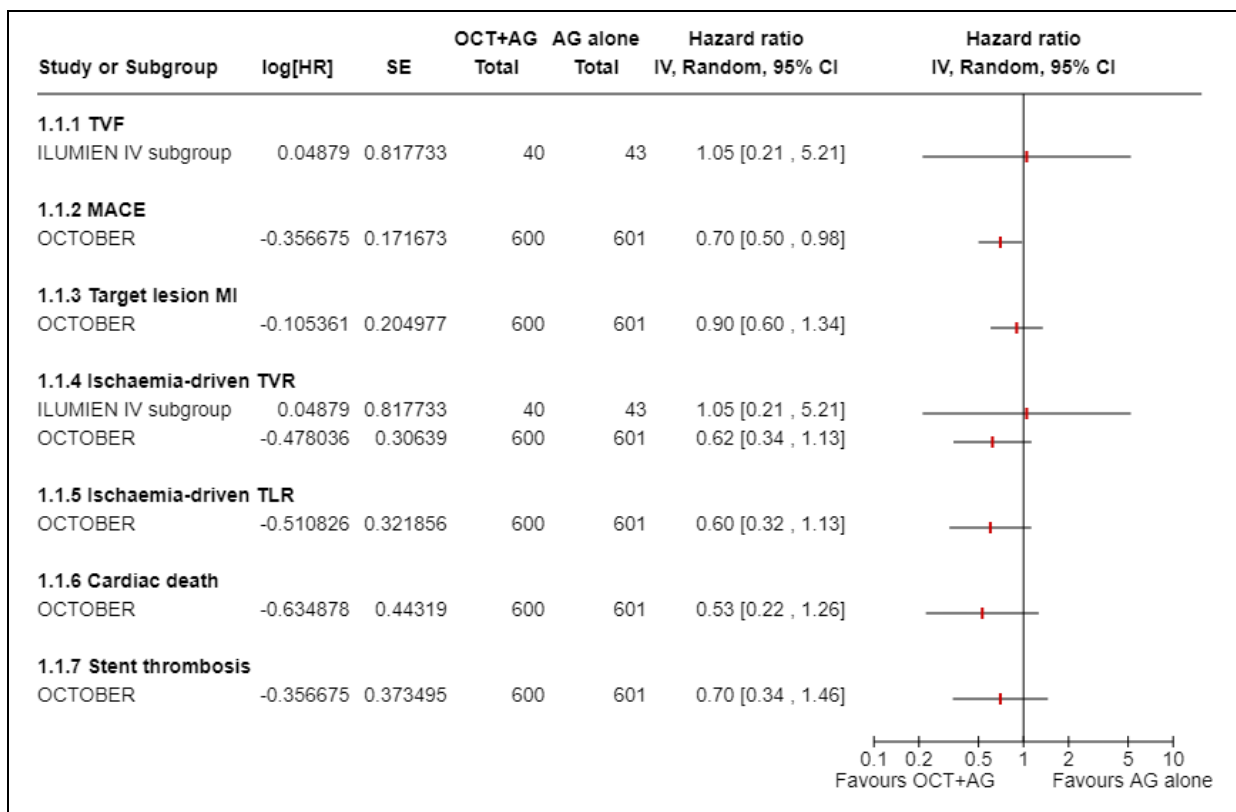
Notes: Results in bold are statistically significant. Estimated percentages were calculated from KM curves. The widths of the CIs have not been adjusted for multiplicity and should not be used to reject or not reject treatment effects.

Source: Compiled from Table 34, Table 35, Table 36, Table 37, Table 39 and Table 128 of MSAC 1743 ADAR+in-line commentary.

The numerical benefit in favour of OCT+AG versus AG alone in OCTOBER with respect to stent thrombosis was driven by a lower number of events classified as ‘possible’ stent thrombosis in the OCT+AG arm compared with the AG alone arm (7 vs. 12); both arms had five ‘definite’ or ‘probable’ stent thrombosis events. Notably, ILLUMIEN IV and OCTIVUS only captured ‘definite’ or ‘probable’ stent thrombosis events.

For completeness, the ADAR conducted indicative meta-analyses of OCTOBER and ILUMIEN IV bifurcation subgroup data where possible. The commentary considered that differences in outcome definitions and populations introduced uncertainty and the meta-analyses are not shown in Table 9 or Figure 1.

Figure 1 Forest plot of key effectiveness outcomes for the bifurcation subpopulation



AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; MACE = major adverse cardiac events; MI = myocardial infarction; OCT = optical coherence tomography; SE = standard error; TLR = target lesion revascularisation; TVF = target vessel failure; TVR = target vessel revascularisation.

Notes: Some CIs may vary slightly from those in the ADAR due to calculations being performed in RevMan Web. The small differences do not change the interpretation of the data. Data are not shown for ILUMIEN IV for target lesion MI, cardiac death and stent thrombosis because there were no cases of cardiac death or stent thrombosis in either arm, and only one case of target lesion MI in the OCT+AG arm. Source: Commentary Figure 1 of MSAC 1743 ADAR+in-line commentary.

Severe calcification subpopulation

The key effectiveness outcomes at 2 years for the severe calcification subpopulation are presented in Table 10 and Figure 2. The ILUMIEN IV severe calcification subgroup was not adequately powered to show a statistically significant difference between groups.

Table 10 Key effectiveness outcomes at 2 years: OCT+AG versus AG alone – severe calcification subpopulation

Event	Evidence	OCT+AG n/N (%)	AG alone n/N (%)	HR [95% CI] HR <1 favours OCT+AG	GRADE certainty of evidence
TVF ^a	ILUMIEN IV subgroup	9/140 (6.4)	18/146 (12.3)	0.50 [0.23, 1.12]	Low
Target vessel MI	ILUMIEN IV subgroup	3/140 (2.1)	7/146 (4.8)	0.44 [0.11, 1.69]	Low
Ischemia-driven TVR	ILUMIEN IV subgroup	6/140 (4.3)	10/146 (6.8)	0.61 [0.22, 1.69]	Low
Cardiac death	ILUMIEN IV subgroup	3/140 (2.1)	4/146 (2.7)	0.79 [0.18, 3.51]	Low
Stent thrombosis	ILUMIEN IV subgroup	1/140 (0.7)	0/146 (0)	NE	Low

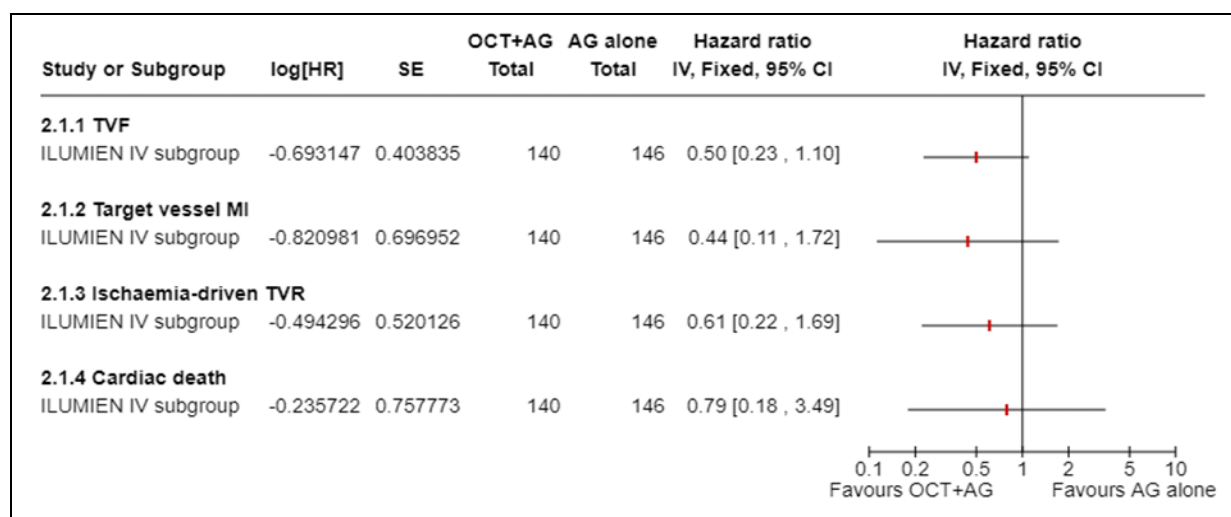
AG = angiogram; CI = confidence interval; HR = hazard ratio; MI = myocardial infarction; OCT = optical coherence tomography; TVF = target vessel failure; TVR = target vessel revascularisation.

^a TVF, defined as a composite of death from a cardiac cause, target vessel MI, or ischemia-driven TVR.

Note: Estimated percentages were calculated from KM curves. The widths of the CIs have not been adjusted for multiplicity and should not be used to reject or not reject treatment effects.

Source: Table 42, Table 43, Table 44, Table 45, Table 46 and Table 129 of MSAC 1743 ADAR+in-line commentary.

Figure 2 Forest plot of key effectiveness outcomes for the severe calcification subpopulation



AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; MI = myocardial infarction; OCT = optical coherence tomography; SE = standard error; TVF = target vessel failure; TVR = target vessel revascularisation.

Note: Some CIs may vary slightly from those reported in the ADAR due to calculations being performed in RevMan Web. The small differences do not change the interpretation of the data. Data are not shown for stent thrombosis because there was only one event.

Source: Commentary Figure 2 of MSAC 1743 ADAR+in-line commentary.

Stent failure subpopulation

The key effectiveness outcomes at 2 years for the stent failure subpopulation are presented in Table 11 and Figure 3. The ILUMIEN IV subgroup included patients with in-stent restenosis of diffuse or multifocal pattern (which is a subset of the stent failure subpopulation) and was not adequately powered to show a statistically significant difference between groups.

No clinical evidence was provided for OCT+AG versus AG alone in patients with stent thrombosis. A pragmatic review of the literature did not identify observational data of OCT+AG used for guiding stent placement in patients with stent thrombosis.

Table 11 Key effectiveness outcomes at 2 years: OCT+AG versus AG alone – stent failure subpopulation^a

Event	Evidence	OCT+AG n/N (%)	AG alone n/N (%)	HR [95% CI] HR <1 favours OCT+AG	GRADE certainty of evidence
TVF ^b	ILUMIEN IV subgroup	18/130 (15.2)	18/138 (13.5)	1.06 [0.55, 2.04]	Low
Target vessel MI	ILUMIEN IV subgroup	3/130 (2.3)	5/138 (3.7)	0.64 [0.15, 2.70]	Low
Ischemia-driven TVR	ILUMIEN IV subgroup	15/130 (12.9)	15/138 (11.4)	1.05 [0.52, 2.16]	Low
Cardiac death	ILUMIEN IV subgroup	2/130 (1.6)	2/138 (1.5)	1.09 [0.15, 7.75]	Low
Stent thrombosis	ILUMIEN IV subgroup	2/130 (1.6)	2/138 (1.5)	1.08 [0.15, 7.65]	Low

AG = angiogram; CI = confidence interval; HR = hazard ratio; MI = myocardial infarction; OCT = optical coherence tomography; TVF = target vessel failure; TVR = target vessel revascularisation.

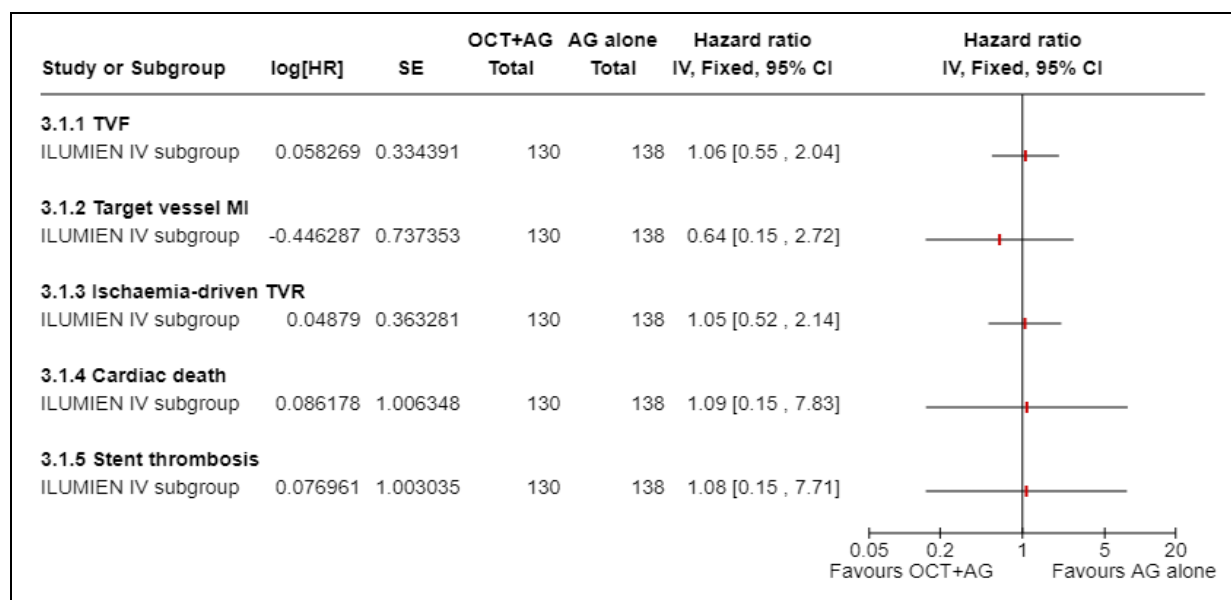
a Data were from patients with in-stent restenosis, which is a subset of the proposed stent failure subpopulation.

b TVF, defined as a composite of death from a cardiac cause, target vessel MI, or ischemia-driven TVR.

Note: Estimated percentages were calculated from KM curves. The widths of the CIs have not been adjusted for multiplicity and should not be used to reject or not reject treatment effects.

Source: Table 47, Table 48, Table 49, Table 50, Table 51 and Table 130 of MSAC 1743 ADAR+in-line commentary.

Figure 3 Forest plot of key effectiveness outcomes for the stent failure subpopulation^a



AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; MI = myocardial infarction; OCT = optical coherence tomography; SE = standard error; TVF = target vessel failure; TVR = target vessel revascularisation.

a Data were from patients with in-stent restenosis, which is a subset of the proposed stent failure subpopulation.

Note: Some CIs may vary slightly from those reported in the ADAR due to calculations being performed in RevMan Web. The small differences do not change the interpretation of the data.

Source: Commentary Figure 3 of MSAC 1743 ADAR+in-line commentary.

According to the European Association of Percutaneous Cardiovascular Interventions (EAPCI) guidelines (Räber et al. 2018), OCT can distinguish thrombus from other tissue components and is generally the imaging modality of choice for stent thrombosis, except for some cases when large amounts of thrombus is present, which may make the assessment of stent struts and the outer vessels challenging by OCT given light attenuation, in which case IVUS may be preferred.

Long/multiple lesion subpopulation

The key effectiveness outcomes at 2 years for the long/multiple lesion subpopulation comparing OCT+AG versus AG alone are presented in Table 12 and Figure 4. The post hoc subgroup analysis

showed a statistically significant difference in favour of OCT+AG compared with AG alone for time to stent thrombosis at 2 years.

Table 12 Key effectiveness outcomes at 2 years: OCT+AG versus AG alone – long/multiple lesion subpopulation

Event	Evidence	OCT+AG n/N (%)	AG alone n/N (%)	HR [95% CI] HR <1 favours OCT+AG	GRADE certainty of evidence
TVF ^a	ILUMIEN IV subgroup	53/853 (6.2%)	63/824 (7.7%)	0.81 [0.56, 1.16]	Moderate
Target vessel MI	ILUMIEN IV subgroup	23/853 (2.7%)	31/824 (3.8%)	0.71 [0.42, 1.22]	Low
Ischemia-driven TVR	ILUMIEN IV subgroup	38/853 (4.5%)	37/824 (4.5%)	0.99 [0.63, 1.56]	Low
Cardiac death	ILUMIEN IV subgroup	5/853 (0.6%)	12/824 (1.5%)	0.40 [0.14, 1.14]	Low
Stent thrombosis	ILUMIEN IV subgroup	5/853 (0.6%)	15/824 (1.8%)	0.32 [0.12, 0.88]	Moderate

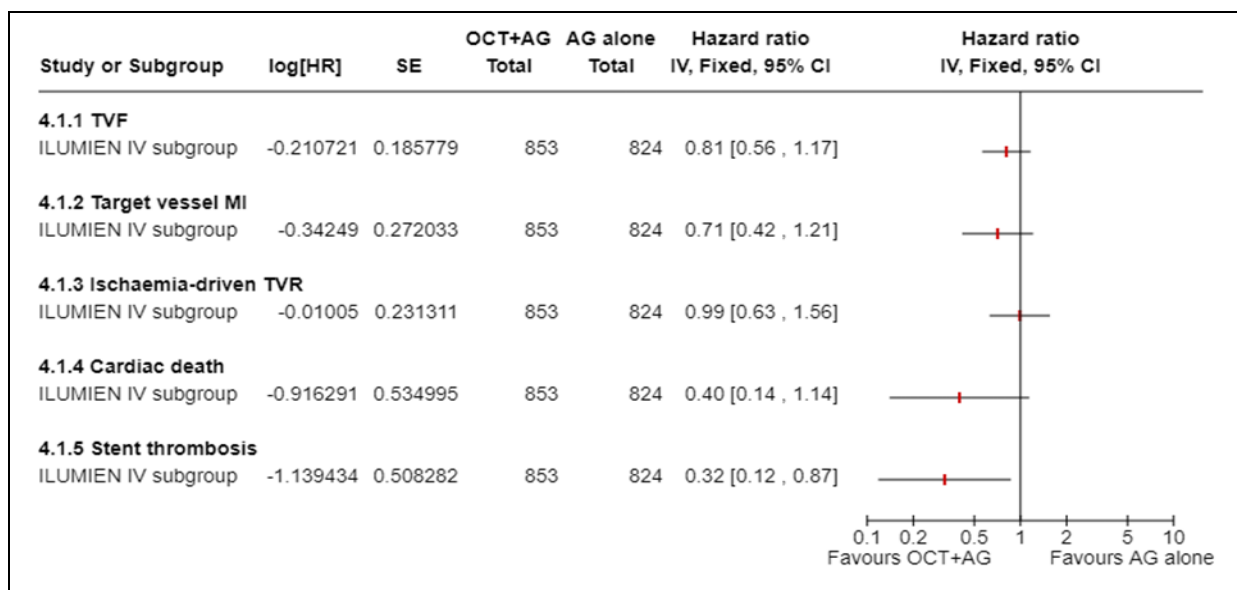
AG = angiogram; CI = confidence interval; HR = hazard ratio; MI = myocardial infarction; OCT = optical coherence tomography; TVF = target vessel failure; TVR = target vessel revascularisation.

a TVF, defined as a composite of death from a cardiac cause, target vessel MI, or ischemia-driven TVR.

Notes: Results in bold are statistically significant. Estimated percentages were calculated from KM curves.

Source: Table 52, Table 53, Table 54, Table 55, Table 56 and Table 132 of MSAC 1743 ADAR+in-line commentary.

Figure 4 Forest plot of key effectiveness outcomes for the long/multiple lesion subpopulation, versus AG alone



AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; MI = myocardial infarction; OCT = optical coherence tomography; SE = standard error; TVF = target vessel failure; TVR = target vessel revascularisation.

Note: some CIs may vary slightly from those reported in the ADAR due to calculations being performed in RevMan Web. The small differences do not change the interpretation of the data.

Source: Commentary Figure 4 of MSAC 1743 ADAR+in-line commentary.

OCT+AG versus IVUS+AG

Long lesion subpopulation

The key effectiveness outcomes at 2 years for OCT+AG versus IVUS+AG in the long lesion subpopulation are presented in Table 13 and Figure 5. The evidence presented in the ADAR was from post hoc subgroup analyses from the OCTIVUS trial.

Table 13 Key effectiveness outcomes at 2 years: OCT+AG versus IVUS+AG – long lesion subpopulation^a

Event	Evidence	OCT+AG n/N (%)	IVUS+AG n/N (%)	HR [95% CI] HR <1 favours OCT+AG	GRADE certainty of evidence
TVF ^b	OCTIVUS subgroup	35/575 (6.1)	36/594 (6.1)	0.99 [0.62, 1.59]	Low
Target vessel MI	OCTIVUS subgroup	6/575 (1.0)	9/594 (1.5)	0.69 [0.25, 1.97]	Low
Ischemia-driven TVR	OCTIVUS subgroup	22/575 (3.8)	20/594 (3.4)	1.16 [0.63, 2.13]	Low
Cardiac death	OCTIVUS subgroup	7/575 (1.2)	9/594 (1.5)	0.70 [0.25, 1.97]	Low
Stent thrombosis ^c	OCTIVUS subgroup	0/575 (0.0)	2/594 (0.3)	NE	Low

AG = angiogram; CI = confidence interval; IVUS = intravascular ultrasound; HR = hazard ratio; MI = myocardial infarction; NE = not estimated; OCT = optical coherence tomography; TVF = target vessel failure; TVR = target vessel revascularisation.

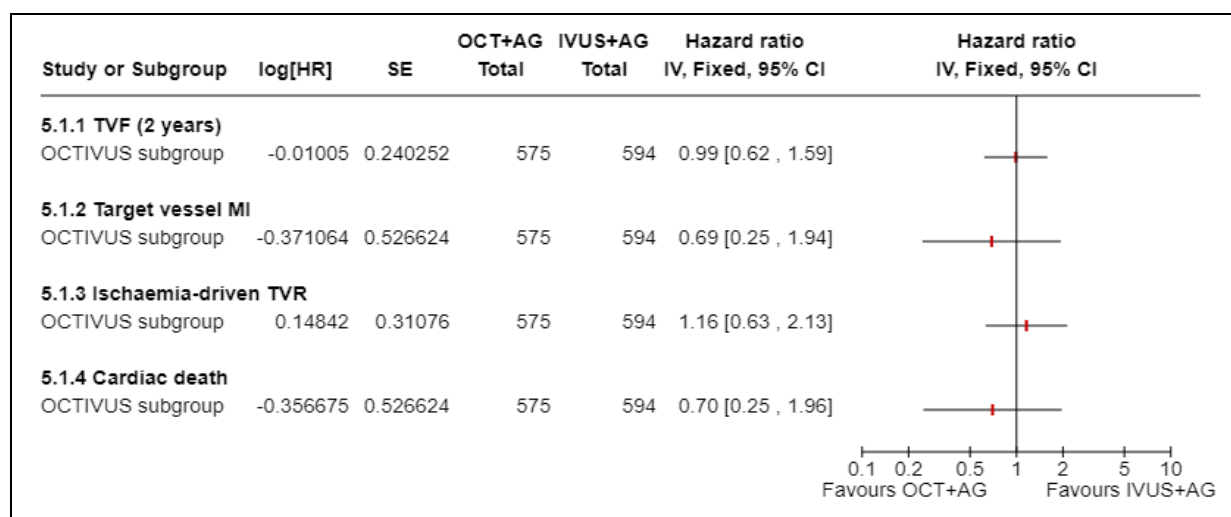
a Diffuse long coronary artery lesion was defined as lesion length \geq 28 mm or stent length \geq 32 mm of treated segment.

b TVF, defined as a composite of death from a cardiac cause, target vessel MI, or ischemia-driven TVR.

c Definite or probable stent thrombosis.

Source: Table 57, Table 58, Table 59, Table 60, Table 61 and Table 131 of MSAC 1743 ADAR+in-line commentary.

Figure 5 Forest plot of key outcomes for the long lesion subpopulation, versus IVUS+AG



AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; IVUS = intravascular ultrasound; MI = myocardial infarction; OCT = optical coherence tomography; SE = standard error; TVF = target vessel failure; TVR = target vessel revascularisation.

Note: Some CIs may vary slightly from those reported in the ADAR due to calculations being performed in RevMan Web. The small differences do not change the interpretation of the data. Stent thrombosis is not shown because there were no events in the OCT+AG arm and 2 events in the IVUS+AG arm.

Source: Commentary Figure 5 of MSAC 1743 ADAR+in-line commentary.

Clinical claims

Regarding the clinical claims, the ADAR concluded that:

- OCT+AG versus AG alone for the purpose of guiding stent insertion in patients with myocardial ischemia and prior stent failure or one of 3 documented lesion types (long/multiple, bifurcation, severe calcification) is **superior** with respect to efficacy and **non-inferior** with respect to safety.
- OCT+AG versus IVUS+AG for the purpose of guiding stent insertion in patients with myocardial ischaemia and long/multiple lesions is **non-inferior** with respect to efficacy and safety.

Many of the ADAR claims of superiority were based on numerical differences/“trends” rather than statistically significant differences.

Based on the evidence presented in the ADAR, the commentary proposed the clinical claims presented in Table 14 with respect to OCT+AG for the purpose of guiding stent insertion in patients with myocardial ischemia in the subpopulations of interest.

Table 14 Summary of commentary conclusions of the clinical claims in the subpopulations of interest

Subpopulation	Efficacy	Safety
OCT+AG vs. AG alone		
Bifurcation	Superior (MACE at 2 years; HIGH certainty evidence)	Non-inferior (procedural complications; MODERATE certainty evidence)
Severe calcification	Non-inferior (TVF and its individual constituents at 2 years; LOW certainty evidence) Further trials are required to confirm the applicant's claim of superiority	Non-inferior (although procedural complications were not available specifically for this subpopulation; LOW certainty evidence)
Stent failure		
In-stent restenosis	Non-inferior (TVF and its individual constituents at 2 years; LOW certainty evidence)	Non-inferior (although procedural complications were not available specifically for this subpopulation; LOW certainty evidence)
Stent thrombosis	No evidence presented in the ADAR	No evidence presented in the ADAR
Long/multiple lesion ^a	Superior (risk of stent thrombosis at 2 years; MODERATE certainty evidence)	Non-inferior (although procedural complications were not available specifically for this subpopulation; LOW certainty evidence)
OCT+AG vs. IVUS+AG		
Long lesion	Non-inferior (TVF and its individual constituents at 2 years; LOW certainty evidence)	Non-inferior (procedural complications; MODERATE certainty evidence).

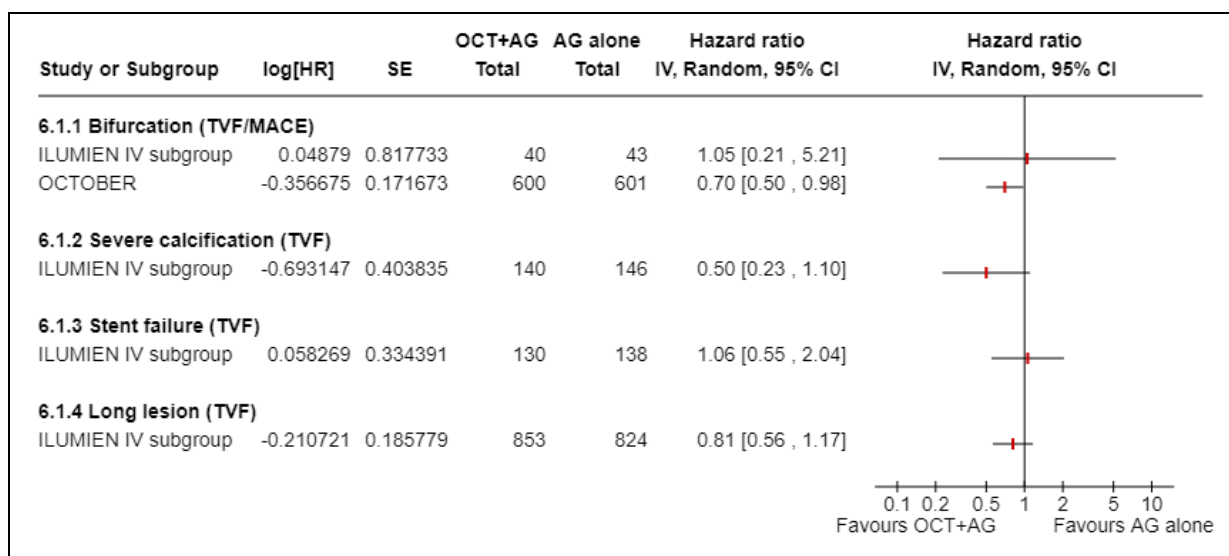
AG = angiogram; IVUS = intravascular ultrasound; MACE = major adverse cardiac events; OCT = optical coherence tomography; TVF = target vessel failure.

^a Note that if stent thrombosis was considered a safety outcome, as per PICO Confirmation 1354.1 for IVUS, the clinical claim for the long or multiple lesion subpopulation would be non-inferior with respect to efficacy (TVF and its individual constituents at 2 years) and superior for safety (stent thrombosis).

Source: Compiled from Section 2A.5 of MSAC 1743 ADAR+in-line commentary.

Figure 6 and Figure 7 summarise the primary composite outcome across the subpopulations for the OCT+AG versus AG alone and OCT+AG versus IVUS+AG comparisons, respectively.

Figure 6 Forest plot of the primary composite outcome (TVF/MACE) by subpopulation for OCT+AG versus AG alone

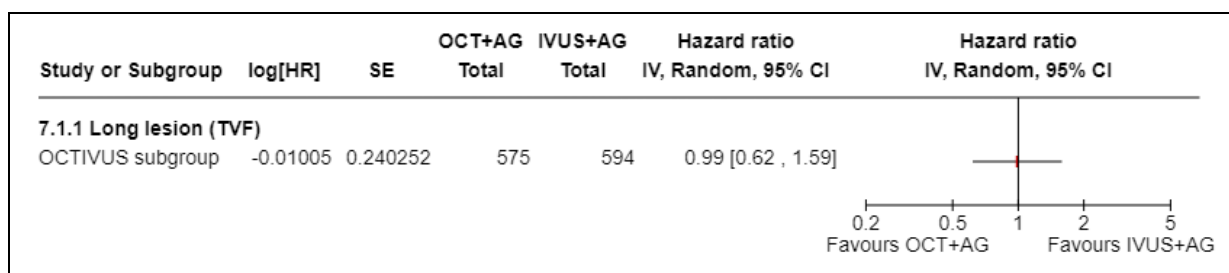


AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; MACE = major adverse cardiac event; OCT = optical coherence tomography; SE = standard error; TVF = target vessel failure.

Note: Some CIs may vary slightly from those reported in the ADAR due to calculations being performed in RevMan Web. The small differences do not change the interpretation of the data.

Source: Commentary Figure 6 of MSAC 1743 ADAR+in-line commentary.

Figure 7 Forest plot of the primary composite outcome (TVF) for OCT+AG versus IVUS+AG for the long/multiple lesion subpopulation



AG = angiogram; CI = confidence interval; HR = hazard ratio; IV = inverse variance; OCT = optical coherence tomography; SE = standard error; TVF = target vessel failure.

Source: Commentary Figure 7 of MSAC application 1743 ADAR+in-line commentary.

13. Economic evaluation

Three cost-utility analyses (CUAs) and one cost-minimisation analysis (CMA) were presented in the ADAR (Table 15). No formal CUA was presented for the stent failure subpopulation due to the absence of reliable subgroup data.

Table 15 Economic analyses presented in the ADAR for OCT+AG, by patient subpopulation

Eligibility group	Applicant's clinical claim	Economic analysis in ADAR	Comparator	Supporting clinical data (efficacy)
Bifurcation	Superiority	CUA	AG alone	OCTOBER RCT ITT population
Severe calcification	Superiority	CUA	AG alone	ILUMIEN IV RCT post hoc subgroup
Stent failure	Superiority	Not formally explored	AG alone	ILUMIEN IV RCT post hoc subgroup
Long/multiple lesion	Superiority	CUA	AG alone	ILUMIEN IV RCT post hoc subgroup
	Non-inferiority	CMA	IVUS+AG	OCTIVUS RCT post hoc subgroup

AG = angiogram; CMA = cost minimisation analysis; CUA = cost-utility analysis; ITT = intention-to-treat; IVUS = intravascular ultrasound; OCT = optical coherence tomography; RCT = randomised control trial.
 Source: Table 74 of MSAC 1743 ADAR+in-line commentary.

The commentary asserted that the superiority claims for OCT+AG versus AG alone were not supported by the clinical evidence provided in the ADAR for the severe calcification and stent failure subpopulations. If non-inferiority is justified, as per the commentary interpretation of the evidence, a CMA would be more appropriate, though cost minimisation would not be demonstrated due to the higher cost for OCT as an adjunct to coronary AG.

OCT+AG versus AG alone

A summary of the cost-utility economic evaluation is provided in Table 16. The three patient subpopulations (bifurcation, severe calcification, long/multiple lesion) were considered in separate analyses.

Table 16 Summary of the cost-utility economic evaluation

Component	Description
Perspective	Health care system perspective
Population	Patients undergoing angiography-guided PCI for DES insertion
Prior testing	Not applicable
Comparator	Angiography guidance alone (= the current standard practice)
Type(s) of analysis	Modelled cost-utility analysis
Outcomes	Quality-adjusted life years (QALYs)
Time horizon	Lifetime: the duration of OCT efficacy is limited to 2 years to match the trial data availability
Computational method	Markov cohort analysis
Generation of the base case	Markov cohort model: the duration of OCT efficacy is limited to 2 years to match the trial data availability
Health states	Alive with no event Alive post-MI Alive post-revascularisation Dead
Cycle length	0-1 month (= 30 days), 2-12 months, then annual cycle thereafter
Transition probabilities	Bifurcation subpopulation: OCTOBER RCT, ITT data Long lesion / severe calcification subpopulations: ILUMIEN IV RCT, post hoc subgroup data Other cause death as per the Australian life table
Discount rate	5%
Software	Excel

DES = drug eluting stent; ITT = intention-to-treat; OCT = optical coherence tomography; MI = myocardial infarction; PCI = percutaneous coronary intervention; RCT = randomised controlled trial.

Source: Table 76 of MSAC 1743 ADAR+in-line commentary.

The model considered differential risks between the two treatment arms in terms of: 1. death from a cardiac cause; 2. MI; 3. ischemia-driven revascularisation; and 4. stent thrombosis. Long-term sequelae of MI and revascularisation were also captured in terms of elevated subsequent risks of recurrent MI (only relevant to those with prior MI) and death.

The model was designed to closely resemble the IVUS model considered by MSAC at its April 2022 meeting (MSAC application 1354.1 PSD), thereby facilitating consideration of OCT on a consistent basis with IVUS in application 1354.1. While this approach has some merit, the commentary raised concerns about the applicability of the model to the clinical evidence presented in support of superiority of OCT+AG versus AG alone. In particular, the clinical trials for OCT were powered for composite efficacy outcomes rather than the individual components, and no statistically significant between-group differences were shown for cardiac death, MI or revascularisation. Furthermore, crude percentages from the trial data were used as model inputs and did not account for competing risks (i.e. secondary outcomes were not mutually exclusive and the sum exceeded that of the primary composite outcome). The commentary noted that this could bias the incremental cost-effectiveness ratio (ICER) to be more favourable because the benefit for some people in the model (and the associated quality-adjusted life year [QALY] gain and complication cost averted) could be incurred more than once.

Bifurcation subpopulation

The primary outcome for the bifurcation subpopulation was a composite outcome (MACE, comprised of death from a cardiac cause, target-lesion MI and ischaemia-driven TLR at a median

of 2 years follow-up). The OCTOBER study supported superiority based on this primary outcome with the addition of OCT to AG alone. These outcomes were disaggregated for the economic evaluation, with the addition of stent thrombosis and other death outcomes. While this matches the natural history of patients better than simulating a composite outcome, the commentary noted the major limitation to this approach is that the secondary endpoints had no data supporting a statistically significant difference between groups.

The base case results for the bifurcation subpopulation are shown in Table 17.

Table 17 Incremental cost-effectiveness ratio for OCT+AG versus AG alone – bifurcation subpopulation

Treatment strategy	OCT+AG	AG alone	Difference
Costs – Total	\$Redacted	\$17,888	\$Redacted
Intervention	\$Redacted	\$13,423	\$Redacted
Management of complications	\$4,008	\$4,465	-\$457
QALYS	9.6659	9.5373	0.1286
Incremental cost-effectiveness ratio			\$Redacted per QALY gain

AG = angiogram; OCT = optical coherence tomography; QALY = quality-adjusted life year.

Source: Table 91 of MSAC 1743 ADAR+in-line commentary.

The results for the bifurcation subpopulation were most sensitive to the time horizon (base = lifetime), as shown in Table 18.

When removing the differential effect for each component of the primary outcome in-turn, the ICER was highest when no difference in death from a cardiac cause was considered (\$Redacted per QALY gained, Table 18). Removing a difference based on target lesion MI, ischaemia-driven TLR, or stent thrombosis had a much less pronounced effect on the ICERs (range \$Redacted to \$Redacted per QALY gained).

Table 18 Selected sensitivity analyses – bifurcation subpopulation

Tested variable	Input	Incremental cost	Incremental QALYs	ICER
Base case analysis	-	\$Redacted	0.1286	\$Redacted
Model duration	2-year analysis	\$Redacted	0.0219	\$Redacted
	5-year analysis ^a	\$Redacted	0.0481	\$Redacted
	10-year analysis ^a	\$Redacted	0.0821	\$Redacted
Secondary endpoint inclusion	No difference in MI (risk equal to AG only)	\$Redacted	0.1123	\$Redacted
	No difference in TLR (risk equal to AG only)	\$Redacted	0.1270	\$Redacted
	No difference in ST (risk equal to AG only)	\$Redacted	0.1263	\$Redacted
	No difference in CV death (risk equal to AG only)	\$Redacted	0.0195	\$Redacted

AG = angiogram; CV = cardiovascular; ICER = incremental cost-effectiveness ratio; MI = myocardial infarction; QALY = quality-adjusted life year; ST = stent thrombosis; TLR = target lesion revascularisation.

Note: Duration of OCT benefits limited to the availability of trial data (= 2 years) under all scenarios.

^a Elevated risks of MI and/or death for 'Alive post-MI' and 'Alive post-revascularisation' applied to 5 years (= base case).

Source: Table 96 and Table 97 of MSAC 1743 ADAR+in-line commentary, with commentary additions (sensitivity analyses relating to secondary endpoint inclusion).

Severe calcification subpopulation

Due to the small sample size and low event rates for the severely calcified lesion subpopulation of ILUMIEN IV (a total of 9 events were observed for the three component outcomes of TVF in the OCT arm), the ADAR used an alternative approach to generate event rates, whereby a ratio of the reported TVF rates between the long/multiple lesion and severe calcification subpopulations was calculated and applied to the available long/multiple lesion data. The ADAR acknowledged that this approach is pragmatic, and primarily aimed at providing an ‘indicative ICER’ that is reflective of the favourable effect size observed for this subgroup on the primary endpoint.

The base case results for the severely calcified lesion subpopulation are shown in Table 19. The commentary noted that the ICER was subject to considerable uncertainty given the direction of any association was not statistically robust.

Table 19 Incremental cost-effectiveness ratio for OCT+AG versus AG alone – severe calcification subpopulation

Treatment strategy	OCT+AG	AG alone	Difference
Costs – Total	\$Redacted	\$22,229	\$Redacted
Intervention	\$Redacted	\$13,423	\$Redacted
Management of complications	\$7,575	\$8,806	-\$1,231
QALYS	9.7357	9.4818	0.2538
Incremental cost-effectiveness ratio			\$Redacted per QALY gain

AG = angiogram; OCT = optical coherence tomography; QALY = quality-adjusted life year.
Source: Table 95 of MSAC 1743 ADAR+in-line commentary.

Stent failure subpopulation

No formal CUA was presented therefore no quantitative comments can be made on the likely cost-effectiveness for this subpopulation.

Long/multiple lesion subpopulation

The base case results for the long/multiple lesion subpopulation are shown in Table 20. The clinical inputs were taken from the ILUMIEN IV post hoc subgroup analysis. The available evidence supported a claim of superiority for stent thrombosis only, whereas other endpoints of cardiac death, target vessel MI and TVR were included in the model with no statistically significant evidence for a between-group difference.

Table 20 Incremental cost-effectiveness ratio for OCT+AG versus AG alone – long/multiple lesion subpopulation

Treatment strategy	OCT+AG	AG alone	Difference
Costs – Total	\$Redacted	\$18,859	\$Redacted
Intervention	\$Redacted	\$13,423	\$Redacted
Management of complications	\$5,071	\$5,436	-\$365
QALYS	9.7755	9.6559	0.1196
Incremental cost-effectiveness ratio			\$Redacted per QALY gain

AG = angiogram; OCT = optical coherence tomography; QALY = quality-adjusted life year.
Source: Table 93 of MSAC 1743 ADAR+in-line commentary.

The results for the long/multiple lesion subpopulation were most sensitive to the time horizon (base = lifetime), as shown in Table 21. When only a difference in stent thrombosis was included

in the model (other transition probabilities were equal to that of the AG group alone), the resulting ICER was **\$Redacted** per QALY gained.

Table 21 Selected sensitivity analyses – long/multiple lesion subpopulation

Tested variable	Input	Incremental cost	Incremental QALYs	ICER
Base case analysis	-	\$Redacted	0.1196	\$Redacted
Model duration	2-year analysis	\$Redacted	0.0156	\$Redacted
	5-year analysis ^a	\$Redacted	0.0412	\$Redacted
	10-year analysis ^a	\$Redacted	0.0745	\$Redacted
Secondary endpoint inclusion	Difference applied only for ST. No difference in MI, TVR or CV death (risk equal to AG only)	\$Redacted	0.0203	\$Redacted

AG = angiogram; CV = cardiovascular; ICER = incremental cost-effectiveness ratio; MI = myocardial infarction; QALY = quality-adjusted life year; ST = stent thrombosis; TVR = target vessel revascularisation.

Note: Duration of OCT benefits limited to the availability of trial data (= 2 years) under all scenarios.

a Elevated risks of MI and/or death for 'Alive post-MI' and 'Alive post-revascularisation' applied to 5 years (= base case).

Source: Table 94 and Table 98 (commentary sensitivity analysis relating to secondary endpoint inclusion) of MSAC 1743 ADAR+in-line commentary.

OCT+AG versus IVUS+AG

Long lesion subpopulation

A summary of the cost-minimisation economic evaluation is provided in Table 22. The premise for cost neutrality assumes that OCT is substituted for IVUS, and not used in addition to IVUS.

Table 22 Summary of the cost-minimisation economic evaluation

Component	Description
Therapeutic claim: effectiveness	Effectiveness is non-inferior between OCT+AG and IVUS+AG
Therapeutic claim: safety	Safety is non-inferior between OCT+AG and IVUS+AG
Evidence base	OCTIVUS RCT, post hoc subgroup data
Direct health technology costs	Proposed MBS fee for OCT is same as that for IVUS (with no additional cost implications; cost-neutrality for MBS has been achieved) Costs of other resource use, including consumables and imaging equipment, are expected to be comparable
Other costs or cost offsets	Not considered; not expected to meaningfully differ between OCT and IVUS

AG = angiogram; IVUS = intravascular ultrasound; MBS = Medicare Benefits Schedule; OCT = optical coherence tomography; RCT = randomised controlled trial.

Source: Derived from Table 100 of MSAC 1743 ADAR+in-line commentary.

The delivery of OCT services requires the OCT imaging system, the cost of which is currently **\$Redacted** per unit with an expected longevity of 10 years, and the likely cost of maintenance each year estimated at **\$Redacted**. Translating the annualised capital cost to a per-procedure equivalent required an estimated number of procedures provided per OCT system, noting that the same system could be shared to treat patients managed under the public system or privately paying patients for any indications (including diagnostic and interventional). The analysis assumed that each OCT system would on average deliver **Redacted** services each year, noting that caseload intensity is difficult to reliably derive.

Table 23 presents the results of the cost comparison of OCT+AG versus IVUS+AG. The ADAR acknowledged the cost minimisation premise was not achieved in the strict sense with an additional cost of **\$Redacted** per procedure, which should be considered as negligible given the costs for IVUS were based on 2014 information included in MSAC application 1354.

The commentary provided a revised analysis using a lower cost for the IVUS catheter and consumables. Leaving aside the capital cost per procedure, which is highly uncertain because it depends on the number of machines available and total caseload, the revised analysis suggests that cost neutrality may not be established with the current cost proposed for OCT consumables, with OCT+AG resulting in an additional cost in excess of **\$Redacted** compared with IVUS+AG. To achieve cost minimisation, the cost for OCT consumables would need to be lower.

Table 23 Cost comparison of OCT+AG versus IVUS+AG for use in angiography-guided PCI procedure

Resource use	OCT+AG	IVUS+AG	Source / note
ADAR analysis			
Professional fee	\$258.45	\$258.45	Requested fee (\$516.90), 50% MOR factor Benchmarked to MBS item 38241 (coronary pressure wire)
Catheter and other consumables	\$Redacted	\$1,500	Proposed price for OCT IVUS cost based on MSAC application 1354, quoted range \$1,000-\$1,500
Capital cost and maintenance			
Imaging system	\$Redacted	\$150,000	IVUS cost based on MSAC application 1354
Maintenance (annual)	\$Redacted	\$1,940	IVUS cost based on MSAC application 1354
Annualised capital cost (including maintenance)	\$Redacted	\$26,690	Expected longevity 10 years for OCT, 8 years for IVUS (based on MSAC application 1354) 4% annual foregone capital return based on MSAC application 1354
Cost per procedure	\$Redacted	\$69	Calculated, assuming an average of 500 OCT and 388 IVUS procedures per machine per year
Total per service	\$Redacted	\$1,827.31	Calculated
Commentary revised analysis			
Professional fee	\$254.35	\$254.35	MBS item 38325 Schedule fee (\$508.70), 50% MOR factor
Catheter and other consumables	\$Redacted	\$1,250	IVUS cost based on MSAC application 1354.1 PSD, quoted range \$1,000-\$1,500 Zhou et al. 2021 ³ reported additional cost of \$1,170 for IVUS consumables based on costs at the Alfred Hospital, Melbourne Assume \$1,250 per procedure (mid of range in PSD for MSAC application 1354.1).
Capital cost and maintenance	-	-	Cost per procedure not included due to uncertainty in the assumed MBS caseload per machine per year
Total per service	\$Redacted	\$1,504.35	Calculated

AG = angiogram; IVUS = intravascular ultrasound; MBS = Medicare Benefits Schedule; MOR = multiple operation rule; MSAC = Medical Services Advisory Committee; OCT = optical coherence tomography; PSD = Public Summary Document.

Note: ADAR costs and assumptions for IVUS were taken from MSAC application 1354 (2014) Final Protocol, assuming costs remain unchanged.

Source: Compiled from Table 102, Table 104 and Table 106 of MSAC 1743 ADAR+in-line commentary.

³ Zhou J, Liew D, Duffy SJ, Shaw J, Walton A, Chan W, Gerber R, Stub D (2021) 'Intravascular ultrasound versus angiography-guided drug-eluting stent implantation: A health economic analysis', *Circ Cardiovasc Qual Outcomes*, 14(5):e006789, doi: 10.1161/CIRCOUTCOMES.120.006789.

14. Financial/budgetary impacts

An epidemiological approach was taken in the ADAR to estimate the utilisation and financial impact to the MBS of the proposed listing. The estimates were informed by the current MBS service data for the relevant PCI services, together with patient demographics / disease characteristics data from Australian registries (primarily VCOR) to inform eligibility rates for each lesion type (long/multiple, bifurcation, severely calcified and stent failure). The ADAR assumed uptake of OCT would be gradual given the requirements for capital investment / infrastructure necessary for this technology, reaching **Redacted**% by Year 6.

For the long/multiple lesion subpopulation, the ADAR assumed that patients would otherwise receive IVUS, thus achieving cost neutrality from the perspective of the MBS (the proposed fee for the OCT service is the same as for IVUS). The commentary noted that the assumed **Redacted** market share did not take into account that the definition of long lesions was broader for OCT than for IVUS and there may be uncertainty in the way the IVUS and OCT eligibility for the long lesion subpopulation will be interpreted in clinical practice.

The commentary noted that in practice, uptake of OCT, and substitution with IVUS, may be dependent on the availability of OCT capital equipment as well as patients' accessibility to OCT-trained cardiologists. Given that OCT and IVUS provide different information for the operator, the commentary raised concerns that OCT and IVUS may be used together for long lesions if both modalities were available (the proposed MBS item descriptor does not prohibit dual use).

The financial implications to the MBS resulting from the proposed listing of OCT-guided PCI with stent insertion are summarised in Table 24. The analyses assumed **Redacted**% of all patients undergoing PCI stent insertion would meet at least one of the OCT eligibility criteria, acknowledging many patients would satisfy multiple eligibility criteria. The net cost to the MBS would increase if OCT uptake was greater than **Redacted**% by Year 6, or a lower proportion of patients satisfy multiple eligibility criteria.

The financial estimates did not include any potential cost savings to the MBS associated with reduced major cardiac events in patients who receive OCT-guided stent implantation (modelled in the economic evaluation).

Table 24 Net financial implications of OCT-guided stent insertion to the MBS

Parameter	Year 2025	Year 2026	Year 2027	Year 2028	Year 2029	Year 2030
Estimated use and cost of the proposed health technology						
Number of PCI procedures with stent insertion ^a	23,031	23,652	24,291	24,947	25,620	26,312
Uptake of intravascular imaging ^b	Redacted%	Redacted%	Redacted%	Redacted%	Redacted%	Redacted%
Number of PCI procedures meeting proposed eligibility criteria ^c						
Long/multiple lesion	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
Bifurcation lesion	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
Severe calcification	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
Stent failure	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
At least one of the above (assuming overlap) ^d	Redacted	Redacted	Redacted	Redacted	Redacted	Redacted
Cost to the MBS at 75% benefit ^e						
Long/multiple lesion	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Bifurcation lesion	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Severe calcification	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Stent failure	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
At least one of the above (assuming overlap) ^d	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Change in use and cost of other health technologies						
Change in use of IVUS for long lesion only	-Redacted	-Redacted	-Redacted	-Redacted	-Redacted	-Redacted
Total cost offset to the MBS at 75% benefit ^e	-\$Redacted	-\$Redacted	-\$Redacted	-\$Redacted	-\$Redacted	-\$Redacted
Net financial impact to the MBS^e						
Long/multiple lesion	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Bifurcation lesion	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Severe calcification	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Stent failure	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
At least one of the above (assuming overlap) ^d	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted

IVUS = intravascular ultrasounds; MBS = Medical Benefits Schedule; OCT = optical coherence tomography; PCI = percutaneous coronary intervention.

a Based on usage of 12 PCI MBS items in 2023, growth rate of 2.7% per annum, and 93.3% stent deployment.

b For long lesions, uptake refers to OCT/IVUS. Assumed market share was Redacted.

c Assumed that for all PCI procedures, prevalence of long/multiple lesions is 30%, bifurcation lesions is 10%, severely calcified lesions is 8% and for stent failure is 6.9%.

d Assumed 40% of all patients undergoing PCI stent insertion meet at least one of the OCT eligibility criteria, acknowledging many patients would satisfy multiple eligibility criteria.

e Costed at 75% of \$258.45 per service, after applying a 50% multiple operation rule (MOR) factor to the requested fee of \$516.90.

Source: Compiled from Tables 112, Table 113, Table 115 and Table 117 of MSAC 1743 ADAR+in-line commentary.

MBS costs comprise a minor component of the overall financial costs. The majority of the costs of OCT are borne by hospitals, health funds and/or patients. The capital equipment cost per procedure will occur on a per hospital basis, given that each hospital will be required to purchase its own OCT system. The OCT system currently costs \$Redacted per unit (plus \$Redacted annual maintenance) with an expected longevity of 10 years. According to the application, there were Redacted OCT systems in private hospitals in Australia. No estimate was provided for the number of OCT systems that would be purchased after listing on the MBS.

Each OCT procedure requires a single-use catheter, which is provided as a kit including other OCT-specific consumables. Depending on the funding arrangement, the cost of the OCT kit (\$Redacted per procedure) is to be met by patients (i.e. out-of-pocket expense) or by hospitals or private health insurance funds. Table 25 estimates the total catheter / consumable costs based on the utilisation estimates presented above.

Table 25 Net financial implications of OCT in terms of catheter / consumables

Parameter	Year 2025	Year 2026	Year 2027	Year 2028	Year 2029	Year 2030
Total cost for OCT catheter / consumables^a, by eligibility group						
Long/multiple lesion	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Bifurcation lesion	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Severe calcification	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Stent failure	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
At least one of the above	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted
Change in cost for IVUS catheter / consumables^b (substitution)						
For long lesion only	-\$Redacted	-\$Redacted	-\$Redacted	-\$Redacted	-\$Redacted	-\$Redacted
Net financial impact to patients / PHIs / hospitals						
Total	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted	\$Redacted

IVUS = intravascular ultrasounds; OCT = optical coherence tomography; PHI = private health insurance.

a Assumes OCT catheter / consumables cost \$Redacted per procedure.

b Assumes IVUS catheter / consumables cost \$1,500 per procedure. The commentary noted that the cost of the IVUS catheter / consumables may be lower.

Source: Table 118 of MSAC 1743 ADAR+in-line commentary.

No meaningful changes in other healthcare resource use (for example, hospital stay) are expected because OCT will be added onto the current standard practice of invasive coronary angiography to guide stent placement (i.e. adjunct setting).

15. Other relevant information

While the ADAR noted existing equity of access issues for OCT, particularly for privately insured patients in regional and remote areas, it is unclear if listing OCT on the MBS would address this issue given the training and accreditation requirements of the proposed service, the high capital cost of the OCT system, and the requirement for the service to be provided in-hospital only.

As noted by PASC, inequity in access may also arise due to the cost of the imaging catheter, which may become a patient out-of-pocket expense.

16. Committee-in-confidence information

The cost of the IVUS system was redacted from the PSD for MSAC application 1354.1. The IVUS consumables (including the imaging catheter) was estimated by the applicant (Boston Scientific) to be \$Redacted per procedure. The disclosed cost for the IVUS generator was \$Redacted. Redacted the cost of OCT consumables (\$Redacted) and the OCT imaging system (\$Redacted).

17. Key issues from ESC to MSAC

Main issues for MSAC consideration

Clinical issues:

- The safety evidence is based on intention to treat (ITT) data for the whole trial population rather than for specified MBS indications. Safety appears to be non-inferior to coronary angiography (AG), notwithstanding the data limitations.
- The clinical evidence is mostly from underpowered subgroup (potentially biased) analyses. Evidence supports optical coherence tomography (OCT) use in bifurcation lesions but is inconclusive for other indications compared to AG.
- Patients with stent thrombosis were included in the stent failure group despite a lack of evidence. However, stent thrombosis is a rare event and therefore the evidence base supporting this subgroup is likely to be small. There is a high clinical need for stent thrombosis treatments.
- The intravascular ultrasound guided coronary (IVUS) comparison for the long lesion subgroup was based on a trial subgroup and thus not powered for non-inferiority, but results are suggestive of non-inferiority.

Economic issues:

- Separate cost-utility analyses were performed for OCT+AG versus AG alone in the bifurcation, severe calcification and long/multiple lesion subgroups (the stent failure subgroup was not formally explored). Statistically significant differences in the primary outcome of major adverse cardiac events (MACE) were observed for the bifurcation group only. MACE is a composite outcome of death from cardiac cause, MI and target lesion revascularisation (TLR). However, transition probabilities for the secondary outcomes of myocardial infarction (MI), revascularisation and cardiac death were used in the ADAR's model when there were no statistically significant between-group differences observed in the trials.
- Key drivers: Removing a difference between groups in cardiac death increased the incremental cost-effectiveness ratio (ICER) for the bifurcation subpopulation from \$Redacted to \$Redacted per quality adjusted life year (QALY) gained; removing a difference based on MI, revascularisation or stent thrombosis had a much less pronounced effect (range \$Redacted to \$Redacted per QALY gained).
- For the comparison of OCT+AG versus IVUS+AG in the long lesion subgroup, the cost-minimisation analysis showed similar costs, assuming that OCT is substituted for IVUS.
- The costs of consumables are the main driver of a cost difference as there was uncertainty about the capital cost component (which depends on the number of imaging systems available). For OCT to meet cost minimisation, the consumables would need to be equivalent in cost to IVUS, although information from the MSAC 1354.1 PSD and a published Australian economic analysis indicate that IVUS consumables may be less costly.

Financial issues:

- The financial forecasts are sensitive to uptake assumptions. A conservative uptake rate was assumed for OCT and may underestimate usage if OCT is listed on the MBS. In practice, uptake of OCT, and substitution with IVUS, may depend on the availability of OCT capital equipment as well as patients' accessibility to OCT-trained cardiologists.
- MBS costs comprise a minor component of the overall financial costs. Most of the costs of OCT relate to capital equipment and consumables, which are borne by hospitals, health funds and/or patients.

Other relevant information:

- Service providers may need to be accredited. ESC considered there may be access/equity implications for regional/remote/rural areas that may have access to the device, but not an adequately accredited clinician to perform the service.
- If the cost of the OCT catheter and consumables (\$Redacted per procedure) is to be incurred as an out-of-pocket expense to patients, this has potential equity implications. There is a pending application of consumables on Part C of the Prescribed List (PL).

ESC discussion

ESC noted that this application from Abbott Medical was for Medicare Benefits Schedule (MBS) listing of optical coherence tomography- (OCT-) guided stent insertion for patients undergoing invasive coronary angiography (AG), percutaneous angioplasty and transluminal insertion of stents for the management of high-risk lesions which includes long or multiple lesions, bifurcation lesions angiographic severe calcification or stent failure. ESC noted the applicant has removed lesions in the left main coronary artery from the population, due to a lack of evidence for this patient group.

ESC noted that OCT is a catheter-based intravascular imaging technique that uses infrared light to obtain three-dimensional cross-sectional images of a coronary artery. The applicant-developed assessment report (ADAR) claimed that OCT technology allows physicians to visualise and measure vessel characteristics that are otherwise not visible or difficult to assess with angiography alone, which helps guide stent selection and deployment as well as assess stent placement. ESC noted that the European Guidelines recommend OCT for complex lesion morphology.⁴

ESC noted that three coronary OCT systems and three OCT system catheters are currently listed on the Australian Register of Therapeutic Goods (ARTG).

ESC noted and welcomed consultation input from one (1) professional organisation, one (1) consumer organisations and nine (9) individuals, all of whom were medical specialists. ESC noted the consultation feedback from 11 individuals or organisations, which overall was supportive of the technology. Specialists claimed that it will allow more accurate decisions about which intervention to go forward with, and that patients are at increased risk if OCT is not available. ESC noted that a number of specialists noted that OCT would take 5–10 minutes longer than IVUS – however, justified that this increased time is warranted due to the clinical benefit(s). Consultation feedback concerns included the need for accreditation and how this will affect access in regional, rural, and remote areas, as well as the issue of out-of-pocket costs and the uncertainty of what these costs would be. ESC considered the accreditation issue and determined that it would be flagged for MSAC consideration.

⁴ Räber et al. (2018). Clinical use of intracoronary imaging. Part 1: guidance and optimization of coronary interventions. An expert consensus document of the European Association of Percutaneous Cardiovascular Interventions. Eur Heart J 39(35):3281–3300.

ESC noted the proposed MBS item descriptor and fee and agreed with the suggested changes (see Table 2).

ESC also considered that the fee should be \$508.70, not \$516.90, to align with the fee for IVUS ([MBS item 38325](#)).

ESC noted that OCT and IVUS have overlapping indications and provide different information for the operator. The proposed MBS item descriptor would not prevent dual use of these technologies for some lesions (e.g. for left main coronary artery bifurcation lesions or for long lesions). ESC considered this would have financial and economic implications, without clinical evidence to support safe and effective use of the two modalities together. However, ESC noted that hybrid IVUS–OCT systems are in development. Additionally, ESC noted that the applicant raised no issues in the pre-ESC response in relation to the possibility of a co-claiming restriction being included on the proposed MBS item descriptor. ESC considered that a co-claiming restriction to prevent dual use of these technologies is appropriate however, the use of a second imaging technique should be possible in the event that there is a failure with the use of the first imaging technique.

ESC noted there is no evidence of patient safety issues with repeat procedures, but increasing duration of the procedure may pose risks. ESC considered the presence of a multidisciplinary team (MDT) may need to be consulted for ≥ 3 vessels and queried whether this should be included as an explanatory note.

ESC also noted that stent thrombosis (ST) is included in stent failure within the proposed MBS item descriptor – however, there is no trial evidence to support this use.

ESC noted the Cardiac Society of Australia and New Zealand (CSANZ) is currently developing accreditation guidelines and training for intravascular imaging to assist with implementing IVUS on the MBS, and CSANZ should also assist with the implementation of OCT. Additionally, ESC noted smaller hospitals may only have access to either IVUS or OCT and not provide both. ESC considered there may be equity of access issues for patients in regional/remote areas, given the need for specialised training and equipment.

ESC noted the comparator for the transluminal insertion of stents alone was coronary angiogram (AG) and percutaneous angioplasty. For the subgroup of patients with long or multiple lesions (total stent length ≥ 28 mm), IVUS-guided coronary stent insertion + AG was the comparator.

ESC considered the ≥ 28 mm threshold for long lesions was appropriate, as this is recommended in the European Guidelines.

ESC noted the proposed clinical management algorithm where OCT + AG would be offered as an option for patients with high-risk lesions which includes long or multiple lesions, bifurcation lesions, lesions with severe calcification or stent failure. ESC also noted that OCT + AG would be an alternative option with IVUS + AG for patients with long lesions.

ESC noted the clinical evidence was derived from three randomised clinical trials (RCTs):

- The Holm (OCTOBER) trial ($n = 2,487$), evaluated patients with complex bifurcation lesions with a median of 2 years follow-up, compared with AG guided PCI.
- The Ali (ILUMIEN IV) trial ($n = 1,201$), evaluated patients with medication-treated diabetes or complex coronary artery lesions with 2 years follow-up, compared with AG guided PCI.
- The Kang (OCTIVUS) trial ($n = 2,008$), evaluated patients with significant coronary artery lesions with 2 years follow-up, compared with IVUS-guided PCI.

ESC noted the comparative safety data for all the groups and considered that OCT to be non-inferior, compared to both AG and IVUS. However, ESC noted that the safety analysis was for the

intention-to-treat (ITT) population and was not analysed by subgroup, which is potentially problematic because the clinical-effectiveness analysis was separated into subgroups.

For the bifurcation lesion population, ESC considered that OCT + AG appeared to be superior to AG alone when examining major adverse cardiac events (MACE) – hazard ratio (HR) = 0.70 [0.50, 0.98]; $p = 0.035$; target vessel failure (TVF) – HR = 1.05 [0.21, 5.18]; and meta-analysis – HR = 0.71 [0.51, 0.99]. ESC noted that the adverse events (AEs) were similar across treatment arms in the OCTOBER trial with 6.8% for OCT and 5.7% in AG.

ESC noted that the ILUMIEN IV trial did not demonstrate superiority on the primary endpoint in the intention to treat (ITT) population.

For the severe calcification population, ESC noted the results were based on subgroup analysis from the ILUMIEN IV trial, which demonstrated a HR = 0.50 [0.23, 1.12] for TVF. ESC considered that although the HR favours the intervention, the results were not statistically significant and such ESC concluded that OCT superiority to AG alone for lesions with severe calcification was not clearly demonstrated.

For the stent failure population, ESC noted the results from the ILUMIEN IV trial were based on a subgroup analysis that included diffuse or multifocal in-stent stenosis and did not include patients with ST as per the PICO. ESC noted that the results demonstrated a HR = 1.06 [0.55, 2.04] for TVF – however, did not suggest a statistically significant benefit. ESC noted the pre-ESC response, which stated that there is a lack of evidence for ST. However, ESC considered the high clinical need in this rare group (as per expert opinion) and OCT may be better at distinguishing thrombus from other tissue compared to AG. ESC concluded that these results did not demonstrate OCT had superiority to AG alone for the stent failure subgroup.

For the long lesions population, ESC noted the results from the ILUMIEN IV trial were based on a subgroup analysis and revealed a HR = 0.81 [0.56, 1.16] for TVF. ESC considered that OCT superiority to AG alone for long lesions was not clearly demonstrated.

For OCT compared to IVUS in the long lesions population, the OCTIVUS trial was based on a subgroup analysis that evaluated 2-year data provided in the ADAR as a post hoc analysis that demonstrated a HR = 1.15 [0.60, 2.22] for TVF; after 1-year follow-up and HR = 0.99 [0.62, 1.59] for TVF after 2-years follow-up. ESC noted that these results are based on subgroup analyses that were not sufficiently powered. ESC agreed with the pre-ESC response that there are challenges with trials being sufficiently powered when looking at relatively rare events. ESC considered that OCT is non-inferior in effectiveness to IVUS for long lesions.

ESC noted additional evidence from a network meta-analysis that demonstrated intravascular-guided percutaneous coronary stent insertion (PCI) (using IVUS or OCT) reduced most adverse outcomes compared to AG-guided PCI.⁵ Additionally, this meta-analysis demonstrated minimal clinical difference between IVUS and OCT (noting most point estimates suggested slight benefit for IVUS and estimates for target vessel revascularisation [TVR] were statistically significant in favour of IVUS).

ESC noted that ST was a rare event (<1%) in the trials. The European Guidelines state that OCT is mostly superior in its ability to distinguish thrombus when compared to IVUS, although no evidence was available to demonstrate this benefit in the three RCTs considered in the ADAR.

ESC considered the main safety issue to be the use of contrast and the potential for contrast-induced nephropathy. OCT is a longer procedure than, for example, IVUS, and thus requires the use of more contrast. ESC noted that the RCTs excluded those with significant renal disease, and

⁵ Stone et al. (2024). [Intravascular imaging-guided coronary drug-eluting stent implantation: an updated network meta-analysis](#). *Lancet* 403(10429):824–837.

ESC acknowledged that clinical judgement would be used for patients with renal disease before recommending OCT.

ESC noted that, for the economic evaluations, the ADAR presented three cost-utility analyses (CUAs) and one cost-minimisation analysis (CMA). No formal CUA was presented for the stent failure subgroup due to the absence of reliable subgroup data. ESC noted that the evidence for bifurcation (OCTOBER trial) had low risk of bias and that the evidence supported the claim of superiority. The subgroup analysis for severe calcification (ILUMIEN IV trial) and long lesions (ILUMIEN IV and OCTIVUS trials) were not prespecified in analysis plans and no separate sample size calculations were undertaken. The benefits of randomisation to the ITT population were consequently lost (there was an underlying difference in the observed and unobserved baseline characteristics), which introduces bias. ESC agreed with the commentary that there was a moderate to high risk of bias for these trials, which makes the translation uncertain. Therefore, ESC considered the clinical claims of superiority compared to AG for severe calcification and long lesions were unsupported by the evidence. The claim of non-inferiority for long lesions compared to IVUS (using a CMA) was supported by the evidence.

ESC noted that the CUA was similar to that used for [MSAC Application 1354.1](#) (IVUS) and was based on Zhou 2021 for IVUS-guided PCI.⁶ As a lifetime model, the clinical benefits directly attributable to OCT are assumed to be fully absorbed within 2 years post-baseline. The probability estimates for events at each branch differed, based on crude event rates from trials for bifurcation, severe calcification and long/multiple lesions. ESC considered the transition probabilities for the secondary outcomes of MI, revascularisation and cardiac death were problematic as there were no statistically significant difference between groups observed in the trials, although underpowered for these outcomes.

ESC noted the separate subgroup analyses for the economic evaluation. In the pre-ESC response, the applicant stated that this is valid and appropriate because each event is associated with very different clinical sequela and quality-adjusted life year (QALY)/cost implications. ESC considered that this is a valid approach, but found the trials were not powered for these subgroups and thus the issue of statistical non-significance remains.

For the bifurcation subgroup, the incremental cost-effectiveness ratio (ICER) for the base case analysis was **\$Redacted** per QALY gained. ESC noted from the sensitivity analysis that the key driver was removing a difference between groups in cardiac death, which increased the ICER for this subgroup to **\$Redacted**/QALY gained. ESC noted removing the secondary endpoints produced a much less pronounced effect on the ICER resulting in **\$Redacted** per QALY gained for no difference in myocardial infarction (MI); **\$Redacted** per QALY gained for no difference in TLR; and **\$Redacted** per QALY gained for no difference in ST. ESC noted that the multivariate sensitivity analysis removing difference in MI, TLR, ST and CV resulted in OCT dominated. ESC noted that MACE was the only statistically significant outcome but was not explicitly included in the ADAR's economic evaluation. ESC noted that the clinical trials for OCT were powered for composite efficacy outcomes rather than the individual components. ESC noted the commentary considered that the crude percentages used as model inputs did not account for competing risks (i.e. secondary outcomes were not mutually exclusive and the sum exceeded that of the primary composite outcome) and could bias the ICER in favour of OCT.

The pre-ESC response stated that the commentary's ICER for the bifurcation subgroup of **\$Redacted**/QALY gained reflected a hypothetical scenario where there are no mortality benefits

⁶ Zhou J, Liew D, Duffy SJ, Shaw J, Walton A, Chan W, Gerber R, Stub D. [Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation: A Health Economic Analysis. Circ Cardiovasc Qual Outcomes. 2021 May;14\(5\):e006789.](#) doi: 10.1161/CIRCOUTCOMES.120.006789. Epub 2021 May 18. PMID: 34003686.

directly attributable to the use of OCT. The applicant presented a different two-step analysis for the bifurcation subgroup – a combined event risk based on MACE (OCTOBER trial) and assumed mortality rate of 2.9% and 4.1% for each disease sequela. This resulted in ICERs ranging from **\$Redacted** to **\$Redacted/QALY** gained. ESC considered that this approach required several assumptions which appeared reasonable, however ESC noted that because there was no between group difference in cardiac death in the OCTOBER trial so the issue of non-significance remained.

For the severe calcification subgroup, the base case ICER was **\$Redacted/QALY** gained. ESC noted that, due to the small sample size and low event rates for the severely calcified lesion subgroup of ILUMIEN IV (a total of nine events were observed for the three component outcomes of TVF in the OCT arm), the ADAR used an alternative approach to generate event rates, whereby a ratio of the reported TVF rates between the long/multiple lesion and severe calcification subgroups was calculated and applied to the available long/multiple lesion data. ESC noted the ADAR acknowledged that this approach is pragmatic, and primarily aimed at providing an 'indicative ICER' that reflects the favourable effect size observed for this subgroup on the primary endpoint. ESC considered that on the basis of assuming non-inferiority, OCT is more expensive, with no difference in quality of life.

ESC noted that for the long/multiple lesions subgroup, the base case ICER was **\$Redacted/QALY** gained. Additionally, ESC noted that when the ST difference was applied – being the only statistically significant variable secondary endpoint – the ICER increased to **\$Redacted/QALY** gained.

ESC noted that the proposed MBS fee for OCT is the same as that for IVUS, which the ADAR claimed cost neutrality due to no additional cost implications. ESC noted that the ADAR considered that costs of other resource use, including consumables and imaging equipment, are expected to be comparable to IVUS as well.

ESC noted the ADAR's net financial implications of OCT-guided stent insertions to the MBS. ESC noted the total cost offset to the MBS at 75% benefit would result in cost savings to the MBS of **\$Redacted** in Year 1 and **\$Redacted** in Year 6. ESC noted that the MBS costs comprise a minor component of the overall financial costs, as most of the costs associated with OCT are borne by hospitals, health funds and/or patients. ESC noted the capital equipment cost per procedure will occur on a per hospital basis, given that each hospital will be required to purchase its own OCT system. The OCT system currently costs **\$Redacted** per unit (plus **\$Redacted** annual maintenance), with an expected longevity of 10 years. ESC noted the ADAR specified that there were **Redacted** OCT systems in private hospitals in Australia – however, no estimate was provided for the number of OCT systems that would be purchased after listing on the MBS.

ESC noted that each OCT procedure requires a single-use catheter, which is provided as a kit including other OCT-specific consumables. ESC noted that the commentary identified that cost neutrality may not be achieved based on the current cost of OCT consumables being approximately **\$Redacted** more than compared with IVUS (OCT is **\$Redacted** and IVUS is \$1,250 per procedure respectively) as calculated by the commentary from the range presented in [MSAC Application 1354.1](#). ESC considered that depending on the funding arrangement, the **\$Redacted** cost per OCT procedure will be met by patients (i.e., as an out-of-pocket expense), hospitals and/or private health insurance funds (subject to approval on the Prescribed List [PL]). ESC noted that the applicant intends to lodge a submission to the PL seeking listing of the consumables on Part C of the PL list. ESC considered that there are potential equity implications, if the cost of the OCT catheter and consumables is to be incurred as an out-of-pocket cost to patients, rather than as an ancillary service cost borne by hospitals as suggested in the pre-ESC response.

ESC noted that, in 2022, OCT was used in 2.7% of PCI cases in Victoria, with public use higher than in private hospitals. The ADAR estimated that **Redacted**% of these PCI cases would meet the PICO population definition, which ESC considered to be conservative, and that actual uptake may be higher and influence the economic and financial modelling.

18. Applicant comments on MSAC's Public Summary Document

Abbott Australasia Pty Ltd. (Abbott) is pleased with the advice made by MSAC for public funding of OCT for bifurcation, long lesion and stent thrombosis subpopulations. Abbott is committed to working with all relevant stakeholders to enable equitable access to OCT across Australia.

19. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website: [visit the MSAC website](#)