



**Australian Government**  

---

**Medical Services Advisory Committee**

## **Public Summary Document**

### ***Application No. 1354.1 – Intravascular Ultrasound (IVUS) Guided Coronary Stent Insertion***

**Applicant:** Boston Scientific Pty Ltd

**Date of MSAC consideration:** 31 March – 1 April 2022

#### **1. Purpose of application**

An application requesting Medicare Benefits Schedule (MBS) listing of intravascular ultrasound (IVUS)-guided coronary stent insertion as an adjunct to invasive coronary angiogram for patients undergoing percutaneous coronary intervention (PCI) was received from Boston Scientific Pty Ltd. by the Department of Health.

#### **2. MSAC's advice to the Minister**

After considering the strength of the available evidence in relation to comparative safety, clinical effectiveness and cost-effectiveness, MSAC supported the creation of a new Medicare Benefits Schedule (MBS) item for intravascular ultrasound (IVUS) guided coronary stent insertion as an adjunct to invasive coronary angiogram for patients undergoing percutaneous coronary intervention (PCI) in patients with complex anatomical characteristics (lesions associated with the left main coronary artery or other lesion locations with lesion length  $\geq 28$  mm). MSAC accepted that in this population IVUS had superior effectiveness and acceptable cost-effectiveness and financial impact. MSAC did not support public funding for generalised use in the all-comers population as the evidence did not satisfactorily demonstrate clinical effectiveness or acceptable cost-effectiveness and was associated with significant financial implications.

MSAC advised that IVUS training and accreditation programs should be in place prior to implementation.

The MSAC supported item descriptor and draft explanatory note for IVUS as an adjunct to invasive coronary angiogram for patients undergoing PCI with complex anatomical characteristics are summarised below:

MBS XXXXX

Use of Intravascular Ultrasound (IVUS) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients documented with:

- a) Left main coronary artery lesions; or
- b) Other lesion locations with lesion length  $\geq 28$ mm.

Being a service associated with items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323.

Service is claimable once in a single episode of care (for one or more lesions).

Multiple Operation Rule

(Anaes.)

Fee: \$488.70 Benefit: 75% = \$366.550 85% = \$415.40

[Relevant explanatory notes]

Fee only payable when the service is provided in association with insertion of coronary stent/s (items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323).

**Acute Coronary Syndromes (ACS – items 38307, 38308, 38310, 38316, 38317, 38319)**

Item XXXXX (IVUS) can only be claimed in association with items **38307, 38308, 38310, 38316, 38317 or 38319** if;

- The patient meets one or more of the indications in subclause 2 of explanatory note TR.8.2; and
- The patient meets one of the indications listed in item XXXXX for the lesion being treated.

**Stable Coronary Syndromes (items 38311, 38313, 38314, 38320, 38322, 38323)**

Item XXXXX (IVUS) can only be claimed in association with items 38311, 38313, 38314, 38320, 38322, 38323 if;

- The patient meets the requirements of Clause 5.10.17C referenced in explanatory note TR.8.4; and
- The patient meets one of the indications listed in item XXXXX for the lesion being treated.

**Consumer summary**

This is an application from Boston Scientific requesting Medicare Benefits Schedule (MBS) listing of intravascular ultrasound (IVUS) guided coronary stent insertion as an additional treatment to invasive coronary angiogram for patients undergoing percutaneous coronary intervention (PCI).

Coronary artery disease is a narrowing (stenosis) or blockage of arteries in the heart due to plaque build-up (atherosclerosis). A coronary stent (a small tube) can be placed in these arteries to open them up and improve blood flow. This procedure is called percutaneous coronary intervention. To work out the best type of treatment and the type of stent that should be used, and to help guide stent placement, clinicians use imaging techniques to see the arteries. These include coronary angiogram (a type of X-ray) and intravascular ultrasound (a test that uses soundwaves to see inside blood vessels).

MSAC considered IVUS-guided PCI to be a safe procedure when compared to PCI without IVUS. However, MSAC considered that IVUS would be more effective and cost-effective for people who have complex artery lesions (narrowings) – specifically, people with lesions in the left main coronary artery or lesions that are 28 mm or more in length – than an all-comers population (all patients receiving PCI). MSAC considered that IVUS-guided PCI was less effective and cost-effective for all patients receiving PCI, and there would be large financial costs if IVUS could be claimed for these patients.

### **Consumer summary**

MSAC considered that IVUS should only be used by accredited providers or those with specific training and advised that appropriate standards and accreditation would need to be developed before this service is listed on the MBS.

#### **MSAC's advice to the Commonwealth Minister for Health**

MSAC supported public funding for IVUS-guided coronary stent insertion for left main coronary artery lesions or lesions in other locations with a length of 28 mm or more. MSAC did not support funding this service for all patients receiving PCI. MSAC considered IVUS to have superior effectiveness, acceptable cost-effectiveness and financial impact for the higher risk population with complex lesions, and that this was not satisfactorily demonstrated for all patients receiving PCI. MSAC advised that IVUS training and accreditation programs should be in place before implementation.

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

MSAC noted that this application from Boston Scientific is for Medicare Benefits Schedule (MBS) listing of intravascular ultrasound- (IVUS-) guided coronary stent insertion as an adjunct to invasive coronary angiogram for patients undergoing percutaneous coronary intervention (PCI). The service would be exclusively used in the catheterisation laboratory setting for the treatment of coronary artery disease.

MSAC noted that there have been two previous applications to MSAC for IVUS. In the first application (MSAC Application 1032) submitted in 2001, IVUS was assessed as both a diagnostic and therapeutic tool for cardiac stent optimisation; MSAC deemed the clinical evidence and cost-effectiveness data insufficient to support IVUS use. In the second application (MSAC Application 1354) submitted in 2015, IVUS was assessed as a therapeutic tool for optimisation of drug eluting stent (DES) or bare metal stent (BMS) placement; MSAC did not support the application due to uncertain clinical effectiveness and cost-effectiveness estimates in the proposed patient population. MSAC noted that the current application is for the use of IVUS as a therapeutic tool.

MSAC noted that there were two population group options included in the resubmission: - an all-comers population (population 1) as an adjunct to PCI for DES insertion, and an alternative option of patients with a coronary lesion eligible for DES insertion and complex anatomical characteristics (population 2). Within the complex anatomical characteristics population, two subpopulations were defined as either a left main coronary artery lesion (i.e. left main lesions) or lesion length of 28 mm or more (i.e. long lesions).

MSAC noted there were two item descriptors proposed – one for each population group.

MSAC noted several issues with the proposed item descriptors. MSAC considered that the item descriptors should state that the service is claimable once in a single episode of care (for one or more lesions). MSAC acknowledged that the pre-MSAC response agreed to remove “invasive coronary angiogram-percutaneous angioplasty” from the item descriptor, as it may unintentionally preclude use of IVUS with standalone PCI where selective angiography has been performed in the previous 3 months.

MSAC noted that the proposed item descriptor for the all-comers population limited the use of IVUS to patients with significant stenoses. MSAC noted the threshold of stenosis, defined as 50% of the lumen or more, does not match the threshold specified in MBS explanatory note TR.8.4 for stable PCI indications (defined as 70%). The degree of vessel stenosis measured in two dimensions alone does not necessarily reflect the three-dimensional anatomy of the vessel

(proposed to be determinable by IVUS) or consequent complexity of stent insertion. Therefore, despite the stenosis threshold of 50% mentioned in the proposed descriptor, IVUS could not be used unless the patient meets the stenosis threshold specified in explanatory note TR.8.4.

MSAC also noted that the proposed item descriptor for patients with complex anatomical characteristics, did not include a stenosis threshold, and considered this should be added. MSAC noted the pre-MSAC response which the applicant agreed with ESC that the item descriptor can remove the need for PCI to be appropriately determined by a heart team, as this is already part of explanatory note TR.8.4 for PCI. Also, regarding the explanatory note, MSAC considered that the item descriptor could include subclause 2 of TR.8.2, which relates to PCI with stenting for selective coronary angiography indications, as a reminder that this service is a part of the PCI recommendations.

MSAC noted that MBS fee for IVUS (\$488.70) was based on MBS item 38241 for use of a coronary pressure wire to measure fractional flow reserve (FFR). MSAC considered that despite differences in complexity and resource use, the fee was reasonable.

MSAC noted that, since the previous submission in 2015, five randomised controlled trials (RCTs) with extended follow-up have been published that support the use of IVUS in these patient populations. MSAC noted that this evidence was supported by a published meta-analysis<sup>1</sup>, a real-world study<sup>2</sup>, and a large-scale, prospective, multicentre, nonrandomised all-comers study that demonstrates IVUS-guided PCI is associated with reduced risk of myocardial infarction (MI) and death.

MSAC noted the main source of evidence for the all-comers population was an adequately sized (approximately 1,500 patients) RCT from China (ULTIMATE trial<sup>3</sup>) that had 1- and 3-year follow-up data (with plans for 5-year follow-up). MSAC noted there was some concern raised in the commentary about the potential risk of selection bias for the ULTIMATE trial but considered the risk low because participants were randomised using a valid, although old-fashioned, method. MSAC also acknowledged the open-label nature of the trial could introduce the risk of performance bias, but considered it was difficult to eliminate this risk in an ethical way for this type of study as patients and centres cannot be blinded from knowing that they are receiving IVUS.

MSAC noted that the evidence for the subpopulation of patients with long lesions comprised two open-label RCTs and a meta-analysis. MSAC noted the results from the meta-analysis were not used in the economic analysis. MSAC acknowledged there were some concerns raised in the commentary about the risk of performance bias for the open-label trials, but considered the quality of the data to be moderate.

MSAC noted the evidence for the left main lesion subpopulation comprised two RCTs. MSAC noted both studies were underpowered due to small patient numbers. However, due to the seriousness of the condition, MSAC considered the risk for adverse outcomes to be higher for the left main lesion subpopulation than for the other populations and noted the evidence for IVUS in the left main lesion population was favourable.

---

<sup>1</sup> Elgendy IY, Gad M, Jain A, Mahmoud AN, Mintz GS (2019). Outcomes with intravascular ultrasound-guided drug eluting stent implantation for unprotected left main coronary lesions: a meta-analysis. *Am J Cardiol*, **124**(10):1652-1653.

<sup>2</sup> Mentias A, Sarrazin MV, Saad M, Panaich S, Kapadia S, Horwitz PA et al. (2020). Long-term outcomes of coronary stenting with and without use of intravascular ultrasound. *JACC Cardiovasc Interv*, **13**(16):1880-1890.

<sup>3</sup> Zhang J, Gao X, Kan J, Ge Z, Han L, Lu S et al. (2018). Intravascular ultrasound versus angiography-guided drug-eluting stent implantation: the ULTIMATE trial. *J Am Coll Cardiol*, **72**(24):3126-3137.

MSAC noted that the safety outcomes specified in the PICO confirmation were in-hospital adverse events and complications from the use of IVUS. However, MSAC noted that the applicant-developed assessment report (ADAR) did not address these outcomes, and very limited information was available from the trial publications. Where reported, MSAC noted adverse event rates were low and there was no significant difference between arms.

For comparative safety in the all-comers population, MSAC noted the ULTIMATE trial showed that overall, clinically significant stent thrombosis rates were significantly lower in patients receiving IVUS-guided PCI at 2- and 3-year follow-up, although the numbers of events in the studies for patients with long lesions and left main lesions were quite small.

MSAC noted all trials were powered for composite outcomes and were unable to show statistically significant differences in cardiac mortality or myocardial infarction (MI) at any of the time points reported. MSAC noted the rate of MI in patients with long lesions from the meta-analysis were very low, and there was no statistically significant difference between groups. MSAC noted that the limited results could not confirm a benefit for IVUS (but trial results were not powered to detect differences in MI).

MSAC noted further concerns raised in the commentary, and agreed with ESC, that the population in the ULTIMATE trial included relatively high-risk patients with complex coronary lesions and was not comparable to an all-comers population, as these patients would be referred from low-throughput centres to high-throughput centres for speciality care. MSAC noted that proportions of complex patients recorded by the Queensland Cardiac Outcomes Registry (QCOR) were similar to those seen in the ULTIMATE trial, but only public hospitals are included in QCOR, and there are a greater proportion of less complex patients in private hospitals (where the proposed service will be accessed). MSAC noted from the commentary that subgroup analyses suggest that high-risk patients and those with complex PCI receive the greatest benefit from IVUS, so the trial may overestimate the efficacy of IVUS in Australian practice. MSAC agreed that high-risk patients with complex lesions would comparatively benefit more from this service, noting findings from the ULTIMATE trial showing greater benefit for complex lesions.

For target lesion revascularisation rates, MSAC noted IVUS showed superior effectiveness for all populations (especially for long lesions), including at follow-up. For the all-comers population, MSAC also noted that IVUS showed some benefit for reducing the need for revascularisation.

In addition, MSAC noted the ADAR included a real-world study (Mentias et al. [2020]<sup>4</sup>) and IVUS meta-analysis by Elgendy et al. [2019]<sup>5</sup> to support the effect of IVUS on mortality and MI. MSAC noted the baseline characteristics of the participants in the study showed that the intervention group had sicker patients with more comorbidities and prior treatment. However, the sicker patients had a higher rate of stable disease, lower rates of MI and much higher rates of complex coronary intervention. MSAC considered that the underlying differences between the groups in the study introduced a potential for bias and was not convinced these differences were adequately corrected for. As a result, MSAC considered the supportive data to be of low quality.

MSAC noted two separate CUAs were conducted to model the cost-effectiveness and IVUS in the two patient populations specified in the ratified PICO and considered this to be appropriate.

MSAC noted the ESC advice and agreed the main driver of the economic model was the time horizon. MSAC considered that rather than assuming incremental benefits of IVUS applied to 5

---

<sup>4</sup> Mentias A, Sarrazin MV, Saad M, Panaich S, Kapadia S, Horwitz PA et al. (2020). Long-term outcomes of coronary stenting with and without use of intravascular ultrasound. *JACC Cardiovasc Interv*, **13**(16):1880-1890.

<sup>5</sup> Elgendy IY, Gad M, Jain A, Mahmoud AN, Mintz GS (2019). Outcomes with intravascular ultrasound-guided drug eluting stent implantation for unprotected left main coronary lesions: a meta-analysis. *Am J Cardiol*, **124**(10):1652-1653.

years based on trial follow up from 1 subpopulation only (long lesion subpopulation), it was more appropriate to apply only the incremental benefit of IVUS based on available trial follow-up data for each population:

- 3 years for the all-comers population (ULTIMATE trial<sup>6</sup>)
- 2 years for the left main lesion subpopulation (Tan et al.<sup>7</sup>)
- 5 years for the long lesion subpopulation (IVUS-XPL trial<sup>8</sup>).

MSAC noted the pre-MSAC response stated there is no clinical reason as to why the effectiveness would not be maintained in all groups. However, given that time horizon is the main driver of the model, MSAC considered a conservative estimate to be appropriate in the base case models. MSAC also considered the removal of post-intervention MI from the model to be appropriate, as the trials reported no statistically significant between-group differences for this outcome.

MSAC considered the incremental cost-effectiveness ratio (ICER) to be high for the all-comers population. MSAC noted that when a 3-year incremental benefit and no statistically significant difference in the rate of MI is assumed, the ICER for the all-comers population increases from \$16,317 to \$67,149 (for the lifetime time horizon). At the 10-year time horizon (added for the commentary), the ICER is estimated to be \$148,701. MSAC considered the ICER for the complex anatomical lesions population to be reasonable – assuming a 2-year incremental benefit for left main lesions, a 5-year incremental benefit for long lesions, and no statistically significant difference in the rate of MI increased the overall ICER from \$17,873 to \$32,425 (for the lifetime time horizon). At the 10-year time horizon (added for the commentary), the ICER is estimated to be \$71,405. Overall, MSAC considered that sensitivity analysis showed that the ICER for the all-comers population was higher and more sensitive (and uncertain) to variation in model parameters than the ICER for the complex anatomical characteristics.

MSAC noted the pre-ESC response claimed that because the rate of MI is of high clinical significance, the rates of MI should be included in the cost-utility analysis (CUA). MSAC acknowledged the pre-MSAC response, which the applicant provided a revised model base case where the difference in the rate of MI (from the trials) was only applied for the first 12 months on the basis that the difference in MI was sustained over trial follow-up and included supplementary evidence of an IVUS meta-analysis by Elgendy et al. [2019]<sup>9</sup> that showed a statistically significant reduction in MI at 12 months. However, MSAC noted that the applicant's revised base case did not include other assumptions challenged by the commentary (such as assuming no incremental benefit of IVUS beyond trial follow-up for each population), so considered it to be uncertain.

Regarding the financial impact, MSAC noted concern from the commentary that there was potential for the number of services to be greater than estimated, as uptake (estimated to be five new hospitals-worth per year) was based on conservative assumptions based on high capital outlay. MSAC considered the estimated uptake to be appropriate, especially if the service is confined to the population with more complex anatomical characteristics. Regarding the impact of newer technologies on the use of IVUS, such as intravascular optical coherence tomography

---

<sup>6</sup> Gao XF, Ge Z, Kong XQ, Kan J, Han L et al. (2021). 3-year outcomes of the ULTIMATE trial comparing intravascular ultrasound versus angiography-guided drug-eluting stent implantation. *JACC Cardiovasc Interv*, **14**(3):247-257.

<sup>7</sup> Tan Q, Wang Q, Liu D, Zhang S, Zhang Y, Li Y (2015). Intravascular ultrasound-guided unprotected left main coronary artery stenting in the elderly. *Saudi Med J*, **36**(5):549-553.

<sup>8</sup> Hong SJ, Mintz GS, Ahn CM, Kim JS, Kim BK, Ko YG et al. (2020). Effect of intravascular ultrasound-guided drug-eluting stent implantation: 5-year follow-up of the IVUS-XPL randomized trial. *JACC Cardiovasc Interv*, **13**(1):62-71.

<sup>9</sup> Elgendy IY, Gad M, Jain A, Mahmoud AN, Mintz GS (2019). Outcomes with intravascular ultrasound-guided drug eluting stent implantation for unprotected left main coronary lesions: a meta-analysis. *Am J Cardiol*, **124**(10):1652-1653.

(OCT), MSAC considered that, as OCT is not suitable for large lesions and is not applicable to left main lesions, IVUS will not be replaced for the population with complex lesions.

MSAC noted there were several implementation issues raised for this application. MSAC agreed that the service should be restricted to accredited providers or those with specific training, as skilled operators are needed to interpret the ultrasound. MSAC noted that letters from the Cardiac Society of Australia and New Zealand (CSANZ), requested by ESC, stated that CSANZ did not have an accreditation program for IVUS. MSAC acknowledged that the pre-MSAC response agreed with the need for training, with the applicant willing to work with CSANZ and other IVUS providers to develop appropriate training standards and accreditation. MSAC also acknowledged the issue raised around equity – because of the additional training required for the proposed services, as well as the large capital cost of the machine, it was believed that IVUS would not be available in regional and rural centres. However, MSAC considered that experts trained in IVUS would go to rural centres with catheterisation laboratories that perform PCI to provide the service.

MSAC was concerned about the likelihood of high out-of-pocket expenses for patients, noting that IVUS capital and consumables are high (between \$1,000 and \$1,500 per procedure), with MBS costs comprising approximately 25% of overall financial costs, and uncertainty regarding listing of IVUS consumables on the Protheses List (PL). MSAC did not consider this to be adequately addressed in the pre-MSAC response and advised that it may be appropriate to review the listing after 2 years to evaluate uptake and out-of-pocket costs.

MSAC did not support listing this service for the all-comers population but supported public funding for IVUS-guided coronary stent insertion for left main coronary artery lesions or lesions in other locations with a length of 28 mm or more. Overall, MSAC considered IVUS-guided PCI to be clinically safe compared to PCI without IVUS. However, MSAC considered the population with complex lesions would benefit more from the service than the all-comers population. Based on the evidence, MSAC considered IVUS to have superior effectiveness, acceptable cost-effectiveness and financial impact for the higher risk population with complex lesions (especially the long lesions subpopulation) but did not consider that the evidence for the all-comers population satisfactorily demonstrated clinical effectiveness or acceptable cost effectiveness and was associated with significant financial implications. MSAC considered the population in the ULTIMATE trial, which was the evidence presented for the all-comers population, to not be fully representative of the all-comers population in Australia, or how the service will be utilised in private practice. MSAC considered the ICER for the all-comers population to be high, and that this population had the highest potential for increased uptake. MSAC also considered the risk for leakage would be high for the all-comers population.

MSAC advised that issues needed to be satisfactorily addressed regarding physician training and credentialling (with CSANZ providing a credentialling guideline to the Department that can be referenced in the associated explanatory note) and the funding mechanism for specific consumables associated with the procedure (and possible out-of-pocket costs for patients) be completed before implementation.

## **4. Background**

The Medical Services Advisory Committee (MSAC) has considered IVUS on two previous occasions, neither of which resulted in a recommendation for public funding.

MSAC Application [1032](#) (considered in July 2001) assessed the safety, clinical effectiveness and cost-effectiveness of IVUS as both a diagnostic and a therapeutic tool for cardiac stent

optimisation. MSAC deemed the clinical evidence and cost-effectiveness data insufficient to support IVUS as either a diagnostic or therapeutic tool.

MSAC Application [1354](#) (considered in April 2015) assessed the safety, clinical effectiveness and cost-effectiveness of IVUS as a therapeutic tool for optimisation of drug eluting stent (DES) or bare metal stent (BMS) placement. MSAC did not support public funding due to uncertain clinical effectiveness and uncertainty around the cost-effectiveness of the procedure. In particular, MSAC was concerned about the limited number of primary studies included in the analysis and the reliance on published systematic reviews and meta-analyses, which did not allow assessment of the safety and efficacy of IVUS guidance for stent insertion of either BMS or DES for the types of 'high-risk' patients nominated in the protocol. The 'high-risk' population in the protocol for Application 1354 was defined based on coronary anatomy, lesion type and complexity:

- intermediate left main coronary stenosis;
- complex coronary lesions (e.g. ostial or bifurcation lesions, calcified lesions, chronic total occlusions);
- challenging coronary anatomy (e.g. coronary artery ectasia, giant coronary arteries, hazy coronary lesions); and
- previous stents.

This resubmission (Application 1354.1) includes new randomised evidence on a broader population of 'all-comers' to PCI, as well as a narrower high-risk population defined using objective and measurable anatomical characteristics.

**Table 1 Summary of key matters of concern noted in [MSAC PSD for Application 1354](#)**

Component	Matter of concern	How the current assessment report addresses it
Patient population	MSAC noted that the algorithm in the submission allowed 'low/medium risk' patients to receive IVUS guidance. However, in the protocol, IVUS guidance was restricted to only 'high-risk' patients. Evidence was lacking on the benefit of IVUS for coronary stent insertion in 'low-risk' patient. [PSD, pp.1-2]	<b>Addressed.</b> The patient populations in the ADAR are consistent with the ratified PICO Confirmation for Application 1354.1, which defines a broader population ('all-comers to PCI with DES'), and a narrower population with complex anatomical characteristics. The evidence presented in the ADAR is aligned with these populations (although the characteristics of study participants in the all-comers population appears to be skewed towards complex CAD rather than all-comers in the Australian setting).
Clinical place in therapy	In the submission, both 'low/medium-risk' and 'high-risk' patients can receive simultaneous stent insertions at a subsequent occasion under guidance of angiography alone. This was not an option in the protocol. [PSD, p.1]	<b>Addressed.</b> The algorithm in the ratified PICO Confirmation allows for simultaneous stent insertion at the time of diagnostic angiography (with or without IVUS) or stent insertion at a separate occasion under guidance of angiography (with or without IVUS). This aligns with the current suite of MBS items for PCI.
Clinical place in therapy	Stent technology is evolving with incomplete stent deployment now being less of a problem compared with earlier generation stents. [PSD, p.2]	<b>Incompletely addressed.</b> The applicant has not clarified whether <u>all</u> included RCTs use second-generation DES. In particular, the publication for the Liu 2019 RCT (left main lesions) does not mention the type of DES used.



Component	Matter of concern	How the current assessment report addresses it
Clinical evidence base	MSAC was concerned about the limited number of primary studies included in the analysis and the reliance on systematic reviews and meta-analyses, which do not allow assessment of the safety and efficacy of IVUS guidance for stent insertion for the types of 'high-risk' patients nominated in the protocol. [PSD, p.2]	<b>Incompletely addressed.</b> The current ADAR does not rely on published meta-analyses; however, the evidence base consists of five RCTs from China and Korea (1 RCT of all-comers, 2 RCTs of patients with long lesions and 2 RCTs of patients with left main lesions). None of the RCTs are powered for the key outcomes specified in the ratified PICO. Based on judgements made during preparation of the Commentary, the 2 RCTs in patients with left main lesions are at high risk of bias and the remaining 3 RCTs have concerns regarding risk of bias.
Clinical evidence base	It remained unclear, due to lack of research evidence, whether there is benefit of IVUS in PCI stent insertion for naïve patients compared to re-stenting procedures. [PSD, p.2]	<b>Not resolved.</b> The included RCTs enrolled patients requiring PCI for new lesions (although this is not clear for the 2 RCTs relating to left main lesions). No evidence was presented to support the use of IVUS in re-stenting procedures. The applicant claims: "There is no evidence to suggest that IVUS is of greater benefit to patients receiving primary stent insertion or those receiving a re-stenting procedure. There is no clinically plausible reason as to why naïve or re-stenting patient populations would receive greater benefit than the other."
Clinical evidence base	In addition, due to the short follow-up (2-3 years) in the clinical evidence base, it is not possible to assess whether the short-term benefits of IVUS are maintained over a longer period of time. [PSD, p.2]	<b>Incompletely addressed.</b> Follow-up in the included RCTs was 3 years for all-comers to PCI, up to 5 years for patients with long lesions, and up to 2 years for patients with left main lesions.
Analysis of the clinical evidence	Due to lack of evidence, no sub-group analysis was performed for the 'high-risk' patient groups, as defined in the protocol in the submission. The applicant instead presented subgroup analysis for patients with acute coronary syndrome, diabetes and renal insufficiency; however, MSAC was concerned that this was not what the protocol mandated. [PSD, p.2]	<b>Addressed.</b> The evidence presented in the ADAR is aligned with the populations defined in the ratified PICO. Separate analyses have been conducted for the two subpopulations with complex anatomical characteristics: (1) long lesions $\geq$ 28 mm; and (2) lesions associated with the left main coronary artery. The definitions for these subpopulations is based on the consensus of an Australian KOL expert panel convened by the applicant in August 2020.
Safety	It was noted that there were no safety concerns identified, although MSAC was concerned that the safety analysis was not robust. [PSD, p.2]	<b>Incompletely addressed.</b> The ADAR does not capture the safety outcomes specified in the ratified PICO, namely adverse events and complications (including in-hospital events). The ADAR relies on stent thrombosis as the sole safety outcome. Stent thrombosis was classified as an efficacy outcome in the PICO Confirmation.

Component	Matter of concern	How the current assessment report addresses it
Clinical effectiveness	MSAC noted that there were small differences favouring IVUS. However, the data were heterogeneous and therefore the 95% CIs approached 1. MSAC was concerned that there were no significant differences in important clinical outcomes such as MIs and mortality and that pooling of major adverse cardiac events (MACE) may be inappropriate. [PSD, p.2]	<b>Incompletely resolved.</b> None of the included RCTs showed a statistically significant difference between IVUS guidance and angiography guidance in terms of cardiac mortality or MI at any of the time points reported (although the trials were not powered for these outcomes individually). Although the ADAR presented supplementary studies that all showed statistically significant reductions in the risk of mortality and MI, these studies are all at risk of bias and included BMS and/or first-generation DES, limiting the applicability of the findings to contemporary practice. Comparison of treatment effect size across the supplementary studies is hampered by differences in duration of follow-up risk and risk measures reported.
Economic evaluation	MSAC noted that a cost utility and cost-effectiveness analysis was performed with the modelled economic evaluation developed in two major steps: a trial-based evaluation (year 1) and extrapolation to a lifetime time horizon. MSAC was concerned, however, with the lack of evidence to support the lifetime time horizon of the model as the published data do not exceed 3 years and therefore, the lifetime benefits remain unknown. [PSD, p.2]	<b>Not resolved.</b> The economic evaluation uses trial-based follow-up data up to 5 years and assumes no incremental effect of IVUS beyond 5 years to a lifetime time horizon. For the all-comer population, it may be more reasonable to assume no incremental benefit beyond the trial-based follow-up of 3 years, and for left main lesions it may be more reasonable to assume no incremental benefit beyond the trial-based follow-up of 2 years. The impact of these changes has been explored in the Commentary.
Financial analysis	MSAC noted that a conservative uptake rate is assumed by the applicant, based on estimated procurement of IVUS capital equipment by hospitals. In addition, no changes in PBS costs are expected, although reductions in adverse events such as revascularisations and MIs could result in possible cost savings to the PBS in the form of reduced medications. MSAC considered this claim was uncertain as it was supported by evidence and thus claimed PBS savings were unlikely to be realised. [PSD, p.2]	<b>Incompletely addressed.</b> The financial analysis in the ADAR incorporates a conservative uptake rate, which is inadequately tested in sensitivity analysis. The financial forecasts are sensitive to uptake assumptions. Although the economic evaluation incorporates cost-offsets through reduced revascularisations and MIs in the IVUS-guided arm, the financial analysis does not model these cost-offsets to the MBS (reduced services for revascularisations) or the PBS (reduced medical treatments).

ADAR = applicant developed assessment report; BMS = bare metal stent; CI = confidence interval; CUA = cost-utility analysis; DES = drug-eluting stent; IVUS = intravascular ultrasound; KOL = key opinion leader; MI = myocardial infarction; MSAC = Medical Services Advisory Committee; PBS = Pharmaceutical Benefits Scheme; PSD = Public Summary Document; RCT = randomised controlled trial.

## 5. Prerequisites to implementation of any funding advice

The IVUS system include an imaging catheter, a mini-transducer, console and generator (termed consumables). The IVUS generator is capital equipment (purchased by hospitals) with a life span of 8 years.

Several brands of imaging catheters for ultrasound examination of coronary intravascular pathology are currently included in the ARTG (Table 2). The catheters are all Class III devices and are associated with three Global Medical Device Nomenclature (GMDN) codes:

- 40763 – Ultrasound system, imaging, cardiovascular
- 37895 – Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular

- 44141 – Transducer assembly, ultrasound, diagnostic, intracorporeal, intravascular, single-use

**Table 2 Intravascular ultrasound catheters included in the ARTG**

ARTG no.	Product Name	Sponsor	Approval date
<b>GMDN 40763</b>			
<a href="#">315943</a>	Opticross HD 60 MHz Coronary Imaging Catheter	Boston Scientific Pty Ltd	29/03/2019
<a href="#">315942</a>	Opticross 6 HD 60 MHz Coronary Imaging Catheter	Boston Scientific Pty Ltd	29/03/2019
<b>GMDN 37895</b>			
<a href="#">219096</a>	OptiCross Coronary Imaging Catheter	Boston Scientific Pty Ltd	10/01/2014
<a href="#">144141</a>	ACUNAV Ultrasound Catheter	Johnson & Johnson Medical Pty Ltd	3/09/2007
<a href="#">153484</a>	Revolution 45 MHz Rotational Intravascular Ultrasound Imaging Catheter	Philips Electronics Australia Ltd	7/07/2008
<a href="#">153485</a>	Visions PV 0.018 Intravascular Ultrasound Imaging Catheter	Philips Electronics Australia Ltd	7/07/2008
<b>GMDN 44141</b>			
<a href="#">289984</a>	ACIST Kodama Coronary Imaging Catheter	Bracco Pty Ltd	9/06/2017
<a href="#">321187</a>	REFINITY ST Rotational IVUS Catheter Model 89900	Philips Electronics Australia Ltd	1/08/2019
<a href="#">321186</a>	REFINITY Rotational IVUS Catheter Model 89800	Philips Electronics Australia Ltd	1/08/2019
<a href="#">299651</a>	Eagle Eye Platinum ST RX Digital IVUS Catheter	Philips Electronics Australia Ltd	14/02/2018
<a href="#">299650</a>	Eagle Eye Platinum RX Digital IVUS Catheter	Philips Electronics Australia Ltd	14/02/2018

ARTG = Australian Register of Therapeutic Goods; GMDN = Global Medical Device Nomenclature.

## 6. Proposal for public funding

For the purposes of this application, the intervention is the therapeutic use of IVUS when used for the placement of coronary stents. This excludes the use of IVUS for diagnostic purposes and for peripheral vascular applications.

Interventional cardiologists who perform coronary stent insertion in Australia are currently guided by the use of angiography which provides a two-dimensional image of the coronary artery. IVUS is the generic name provided to any ultrasound technology that provides tomographic, three-dimensional, 360-degree images from inside the lumen of a blood vessel. During PCI, IVUS may be used to guide coronary stent insertion as an adjunct to angiography. To use IVUS, physicians use a guide wire, and the IVUS-tipped catheter is then fed over the guide wire. Angiography is used to guide the IVUS catheter to the area of the vessel to be imaged.

IVUS plays multiple roles in coronary stenting including determining suitability for stenting, guidance of stent selection and placement, and ensuring adequate stent deployment.

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

Several hybrid IVUS intracoronary imaging modalities have also been developed, including near infrared spectroscopy-IVUS (NIRS-IVUS), virtual histology-IVUS (VH-IVUS), and IVUS combined with optical coherence tomography (IVUS-OCT). Other combined imaging technologies are on the horizon.

IVUS is not listed on the MBS and is currently not routinely used in Australia during percutaneous coronary stent insertion. According to the Victorian Cardiac Outcomes Registry ([VCOR](#) 2020 [Annual Report](#) (Lefkovits et al. 2021<sup>10</sup>), IVUS was used in 2.6% of PCI cases in Victoria in 2020 (2.8% of cases in the public sector and 2.5% of cases in the private sector). In left main coronary artery PCI (which accounted for 2.3% of all PCI procedures in Victoria in 2020), the rate of adjunctive imaging with IVUS or OCT was 37.7%.

### **Proposed MBS item descriptors**

The ADAR proposes alternative listings for IVUS, either for all-comers to PCI or for patients with complex anatomical characteristics. Separate MBS descriptors have been developed for each population. The intention is for the proposed item for IVUS to be claimed in conjunction with an existing MBS item for transluminal insertion of coronary stents (or transluminal rotational atherectomy if stenting does not proceed as planned). The phrase 'percutaneous angioplasty or transluminal insertion of stents' was added to the descriptor post-PASC in recognition of this.

The proposed descriptor refers to 'invasive coronary angiogram', which may unintentionally preclude use of IVUS with standalone PCI where selective angiography has been performed in the previous 3 months.

The proposed descriptor for the all-comers population (shown in Table 3) includes a definition for significant stenosis diagnosed using angiography, which is consistent with the clinical evidence. *As the explanatory notes relating to PCI items are regulated requirements of the service and already provide detailed patient indications (including the extent of stenosis), inclusion of a stenosis threshold in the item descriptor for IVUS may be superfluous and/or create confusion. For example, Explanatory Note [TR.8.4](#) for stable PCI indications refers to stenosis of 70% or more. Therefore, despite the stenosis threshold of 50% mentioned in the proposed descriptor, IVUS could not be used unless the patient meets the stenosis threshold specified in the explanatory notes for PCI, which may be 70% depending on indication (and not consistent with the clinical evidence presented in Section 10).*

---

<sup>10</sup> Lefkovits, J. et al. The Victorian Cardiac Outcomes Registry Annual Report 2021. (Monash University, Melbourne, Victoria, 2021).

**Table 3 New proposed MBS item for IVUS-guided PCI with stent insertion – Patients with a coronary lesion eligible for DES insertion (all-comers). ESC amendments in mark-up.**

Category 3 – Therapeutic Procedures
<p>MBS XXXXX</p> <p>The use of intravascular ultrasound (IVUS) during invasive coronary angiogram-percutaneous angioplasty or transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition in coronary vessels with significant stenoses. (<del>≥50% stenosis as defined by the diagnostic angiography</del>).</p> <p>Being a service associated with items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323.</p> <p><b>service is claimable once in a single episode of care (for one or more lesions).</b></p> <p><del>Multiple Services Rule</del> <b>Multiple operations rule</b> (Anaes.)</p> <p>Fee: \$488.70 Benefit: 75% = \$366.550 85% = \$415.40</p> <p>[Relevant explanatory notes]</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).</p>

DES = drug-eluting stent; IVUS = intravascular ultrasound; MBS = Medicare Benefits Schedule; PCI = percutaneous coronary intervention.

The proposed descriptor for the narrower population with complex anatomical characteristics (shown in Table 4) does not limit use of IVUS to coronary vessels with significant stenosis. No justification is provided in the ADAR for this omission. Explanatory Note TR.8.2, includes stenoses thresholds for patients with significant left main coronary artery disease but the MBS explanatory notes do not refer to lesion length. Any patient eligible for the proposed service under the proposed descriptor for lesion length would firstly need be indicated for PCI according to the criteria in the explanatory notes.

As noted above for the proposed all-comers descriptor, the proposed descriptor for the high-risk population refers to ‘invasive coronary angiogram’, which may unintentionally preclude use of IVUS with standalone PCI where selective angiography has been performed in the previous 3 months.

The descriptor does not refer to involvement of the bifurcation and this was not a requirement (or exclusion criteria) for study participation in the trials that evaluated IVUS for left main lesions.

The descriptor mentions ‘and/or where suitability of PCI has appropriately been determined by a Heart Team’. Heart Team decisions only apply to stable interventions, whereas PCI may be used for left main lesions in stable or acute procedures. The use of ‘or’ in the sentence opens this descriptor up to all stable indications for PCI, which is presumably not the intention.

**Table 4 New proposed MBS item for IVUS-guided PCI with stent insertion – Patients with a coronary lesion eligible for DES insertion and complex anatomical characteristics. ESC amendments in mark-up.**

Category 3 – Therapeutic Procedures
<p>MBS XXXXX</p> <p>Use of Intravascular Ultrasound (IVUS) during invasive coronary angiogram–percutaneous angioplasty or transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients documented with:</p> <p>a) Left main coronary artery lesions, <del>and/or where suitability of percutaneous coronary intervention has appropriately been determined by a Heart Team;</del> or</p> <p>b) Other lesion locations with lesion length <math>\geq 28</math>mm.</p> <p>Being a service associated with items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323).</p> <p><b>Service is claimable once in a single episode of care (for one or more lesions).</b></p> <p><del>Multiple Services Rule</del> <b>Multiple Operation Rule</b></p> <p>(Anaes.)</p> <p>Fee: \$488.70 Benefit: 75% = \$366.550 85% = \$415.40</p> <p>[Relevant explanatory notes]</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).</p>

DES = drug-eluting stent; IVUS = intravascular ultrasound; MBS = Medicare Benefits Schedule; PCI = percutaneous coronary intervention.

The descriptors nominate Category 3 – Therapeutic Procedures – as the appropriate category for an MBS item for IVUS. As the standalone item is not therapeutic per se, and IVUS is proposed as an adjunct, an alternative is to place the proposed item in Category 2 – Diagnostic Procedures and Investigations. IVUS is not proposed for diagnostic purposes in the current application; however, the Multiple Services Rule (which applies to diagnostic services) is included in the descriptor. The Multiple Operation Rule may apply if the proposed IVUS item remains in Category 3. The economic and financial analyses in the ADAR do not apply any rules in the calculation of costs for IVUS services.

### Proposed schedule fee

The proposed schedule fee is based on MBS item 38241, which the applicant claims most closely resembles IVUS in terms of complexity and time. MBS item 38241 is for use of a coronary pressure wire during selective coronary angiography to measure fractional flow reserve (FFR), non-hyperaemic pressure ratios or coronary flow reserve (CFR) in one or more intermediate coronary artery or graft lesions (stenosis of 50-70%), to determine whether revascularisation should be performed.

PASC noted that the proposed MBS fee for IVUS was twice as high as that for intraoperative transoesophageal echocardiography (TOE), which was considered by PASC to be a comparable modality with an MBS fee of \$185.40. The applicant claims that TOE is substantially different to IVUS as it requires the presence of additional experts (TOE technician and anaesthetist) and additional drugs. FFR is similar to IVUS in terms of procedural access site, indication (symptomatic coronary artery disease), with no additional healthcare resources as it is performed by the same interventional cardiologist who may perform the PCI procedure.

## 7. Population

The patient populations specified in the PICO Confirmation were recommended by an expert KOL (Key Opinion Leader) panel convened by the applicant in August 2020 to provide guidance on the resubmission. Based on the availability of new, high level clinical evidence, the KOL panel recommended two alternative patient criteria options for IVUS use in combination with DES (noting BMS is no longer used in clinical practice):

1. All-comers to PCI with DES.
2. Patients undergoing PCI who have had a coronary lesion eligible for DES implantation with either:
  - a. lesions associated with the left main coronary artery; and/or where suitability of PCI has appropriately been determined by a Heart Team approach for significant stenoses ( $\geq 50\%$  as defined by the coronary angiogram) of the left main coronary artery, including in cases of unprotected left main lesions (i.e., left main lesions); or
  - b. other lesion locations where lesion length  $\geq 28$  mm (i.e., long lesions).

Both populations must also meet one of the regulated indications specified in the explanatory notes for the PCI items.

In contrast to the previous application, the 'high-risk' population in the current ADAR is well-defined on the basis of objective and measurable anatomical characteristics. In relation to the current MBS items for PCI a lesion length of  $\geq 28$  mm is not universally recognised as the cut-off for a 'long lesion'.

## 8. Comparator

The comparator is placement of coronary stents under guidance of angiography alone.

As of July 2021, 12 MBS items are available for transluminal insertion of coronary stents, split according to whether PCI is performed within three months of selective coronary angiography (Items 38316, 38317, 38319, 38320, 38322, 38323), or selective coronary angiography has not been completed in the previous three months (Items 38307, 38308, 38310, 38311, 38313, 38314). Each category is then split based on whether patients meet the clinical indications for acute coronary syndrome (ACS) or not (i.e., stable PCI indications) and how many vascular territories are treated (see Table 5).

**Table 5 MBS items relating to PCI with coronary stent insertion**

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

CT = computed tomography; MBS = Medicare Benefits Schedule; PCI = percutaneous coronary intervention.

The associated MBS explanatory notes provide details of the indications for selective coronary angiography ([TR.8.2](#)) and stable PCI indications ([TR.8.4](#)), documentation requirements ([TR.8.5](#)), Heart Team conferences ([TR.8.6](#) & [TR.8.7](#)), staging rules and disease definitions ([TN.8.217](#), [TN.8.218](#), [TN.8.219](#), [TN.8.225](#) & [TN.8.226](#)).

Where percutaneous transluminal coronary rotational atherectomy is considered prior to stenting, MBS item 38309 is appropriate (indications are explained in [TN.8.222](#)).

MBS items for PCI with coronary stent insertion and transluminal rotational atherectomy (and relevant explanatory notes) are presented in [Appendix A.](#)

The ADAR notes that in some cases, such as patients with renal impairment, IVUS may be used as a replacement for angiography in order to avoid the use of contrast dyes however, clinical data are not provided to support use of IVUS as a replacement for angiography in patients with renal impairment or other conditions. Significant renal dysfunction was an exclusion criterion in three of the five RCTs presented in the ADAR. The Assessment Report for the previous IVUS MSAC application ([1354](#)) included an analysis of patients with impaired renal function, but no clinical data were provided to support the analysis.

## 9. Summary of public consultation input

Targeted consultation feedback was received from one (1) consultant interventional cardiologist. Overall feedback was strongly supportive of public funding for the inclusion of IVUS on the Medicare Benefits Schedule for use as a therapeutic device to guide and optimize coronary drug-eluting stent (DES) insertion during percutaneous coronary intervention (PCI) to treat coronary artery disease (CAD).

Key benefits of the proposed therapeutic device were identified as

- IVUS provides a better understanding of atherosclerotic disease than angiography alone
- IVUS assists in deciding which patients require stents and those who do not
- IVUS has the ability to overcome limitations of coronary angiography such as assessing the severity of coronary stenosis thus supporting optimal treatment strategy, stent selection, stent placement, stent apposition to the vessel, and adequate deployment to restore blood flow at the target site.



- IVUS ensures that procedures to coronary vessels are performed at the highest quality standard

Potential disadvantages of the proposed therapeutic device were identified as:

- There were no identified potential disadvantages of IVUS

Other technical comments made in the consultation feedback were:

- The ULTIMATE trial highlighted how the use of IVUS guidance in all-comers population led to significantly less stent thrombosis (ST) events over the long-term follow up
- At two years, IVUS was associated with a lower risk of ST compared to angiography alone
- At three-year follow up there was a statistically significant reduction in the relative risk of ST for patients receiving IVUS guidance compared to angiography alone
- Over nine randomized control trials showed the benefit of IVUS to patients' outcomes
- Funding of IVUS will assist physicians and improve patient outcomes

As sought by ESC, targeted consultation input was received from the Cardiac Society of Australia and New Zealand (CSANZ) regarding appropriate IVUS training and accreditation standards in Australia. The CSANZ advised that there are currently there are no specific detailed IVUS training requirements set out in US or Europe, noted the 1995 American College of Cardiology (ACC) Core Cardiovascular Training Statement (COCATS) and more recently the 2020 European Association of Percutaneous Coronary Intervention core curriculum published online 2020 (EuroIntervention 2021;17:23-31). In this document, IVUS training should be accomplished to Level IV standard, namely, performance as first operator without supervision.

In addition, the CSANZ also noted that there are no major international guidelines with the adequate rigour of a mandated training to attain competency and maintenance of such in Australia and New Zealand.

## 10. Characteristics of the evidence base

The applicant's literature search identified five RCTs (all from China or Korea) comparing IVUS-guided PCI with angiography-guided PCI, of which one enrolled all-comers to PCI (ULTIMATE), two enrolled patients with long lesions (IVUS-XPL, RESET) and two enrolled patients with left main lesions (Liu 2019<sup>11</sup>; Tan 2015<sup>12</sup>). The key features of the RCTs are summarised in Table 6. Follow-up is ongoing in at least two of the trials (ULTIMATE and IVUS-XPL).

Although the literature search was restricted to RCTs, The ADAR introduced a published meta-analysis, a large scale non-randomised study and a large real-world study. Such studies are potentially useful to examine safety outcomes and rare events; however, no information was provided on how these studies were identified or selected for inclusion. The applicability of this additional evidence is also of concern as none of these studies were restricted to PCI with second-generation DES.

The Assessment Report for the previous application (1354) included 14 observational studies and three RCTs relating to the use of IVUS guidance during DES deployment. One of these RCTs

---

<sup>11</sup> Liu, X. M. et al. Intravascular ultrasound-guided drug-eluting stent implantation for patients with unprotected left main coronary artery lesions: A single-center randomized trial. *Anatol J Cardiol* 21, 83-90, doi:10.14744/AnatolJCardiol.2018.21447 (2019).

<sup>12</sup> Tan, Q. et al. Intravascular ultrasound-guided unprotected left main coronary artery stenting in the elderly. *Saudi Med J* 36, 549-553, doi:10.15537/smj.2015.5.11251 (2015).

(RESET) is included in the current ADAR. The other two RCTs included participants with complex patient characteristics and/or a range of complex coronary lesions (not exclusively long lesions or left main lesions).

The five trials included in the current ADAR were not powered individually for the critical outcomes specified in the ratified PICO: cardiac mortality, myocardial infarction (MI), target lesion revascularisation (TLR) and stent thrombosis. The primary outcome in the all-comers trial (ULTIMATE) was target vessel failure (TVF), which was defined as a composite of cardiac death, target-vessel MI, and clinically driven target vessel revascularisation (TVR). The primary outcome in all trials of patients with complex anatomical characteristics was the composite of major cardiac adverse events (MACE), which was defined differently in each trial reporting this outcome (see footnote to Table 6).

**Table 6 Key features of the included evidence**

Trial ID	N	Design/ follow-up / Country	Risk of bias**	Patient population	Outcome(s)	Use in modelled evaluation
<b>All-comers</b>						
ULTIMATE <a href="#">[NCT02215915]</a>	1,448	RCT, MC, OL 30 d, 1 yr, 2 yrs, 3 yrs (ongoing to 5 yrs) China	<i>Some concerns</i>	Patients with <i>de novo</i> coronary lesion eligible for DES implantation (everolimus-, zotarolimus- or sirolimus-eluting)	<u>Critical:</u> Cardiac death Target-vessel MI Clinically driven TLR Stent thrombosis (definite/probable) <u>Other:</u> All-cause death Target vessel failure (TVF)* Clinically driven TVR#	TLR Target- vessel MI
<b>Long lesions</b>						
IVUS-XPL 1 yr: <a href="#">[NCT01308281]</a> To 10 yrs: <a href="#">[NCT03866486]</a>	1,400	R, MC, OL 1 yr, 5 yrs (ongoing to 10 yrs) Korea	<i>Some concerns</i>	Patients with long coronary lesions (stent length ≥28 mm) DES: everolimus- eluting	<u>Critical:</u> Cardiac death Target-lesion MI Ischaemia-driven TLR Stent thrombosis (definite/probable) <u>Other:</u> MACE^	TLR Target- lesion MI
RESET <a href="#">[NCT01145079]</a>	543	R, MC, OL substudy 1 yr Korea	<i>Some concerns</i>	Patients with <i>de novo</i> long coronary lesions (stent length ≥28 mm) DES: everolimus- or zotarolimus-eluting	<u>Critical:</u> Cardiovascular death MI Stent thrombosis (definite/probable/possible) <u>Other:</u> All-cause death MACE^ TVR	MI
<b>Left main lesions</b>						
Liu 2019	348	R, SC, OL 1 yr China	<i>High risk</i>	Patients with unprotected left main lesions DES at discretion of operator (type not reported)	<u>Critical:</u> Cardiac death MI TLR Stent thrombosis (definite/probable) <u>Other:</u> MACE^ TVR	TLR MI

Trial ID	N	Design/ follow-up / Country	Risk of bias**	Patient population	Outcome(s)	Use in modelled evaluation
Tan 2015	123	R, SC, OL 2 yrs China	<i>High risk</i>	Elderly patients (≥70 yrs) with unprotected left main lesions DES: sirolimus- eluting	<u>Critical:</u> Cardiovascular death Non-fatal MI TLR Stent thrombosis (definite/probable) <u>Other:</u> MACE <sup>^</sup>	TLR

MACE = major cardiac adverse event; MC = multicentre; MI = myocardial infarction; N = number randomised; OL = open label; R = randomised; SC = single centre; TLR = target lesion revascularisation; TVR = target vessel revascularisation; TVF = target vessel failure.

\*\* Assessed using Cochrane risk of bias tool suitable for RCTs. The risk of bias for all trials were upgraded in the Commentary.

\* Composite of cardiac death, target-vessel MI, and clinically driven TVR.

# Defined as angina or ischaemia referable to the target vessel requiring repeat PCI or coronary artery bypass graft (CABG).

<sup>^</sup> MACE was defined differently in each trial. In IVUS-XPL, composite of cardiac death, target lesion related MI or ischemia driven TLR. In RESET, composite of cardiovascular death, MI, stent thrombosis or TVR. In Liu 2019, composite of cardiac death, MI or TVR. In Tan 2015, composite of death, non-fatal MI or TLR.

There are several notable issues with the included trials: variable definitions in the clinical outcomes assessed, lack of clarity around how IVUS was being used (after DES implantation and in some cases also during or before implantation), variation in study eligibility criteria relating to recent MI, potential for reporting bias (Liu 2019 and Tan 2015), the inability to blind the surgeon to the intervention (potentially introducing performance bias), and crossover between groups.

Across the trials that reported crossover (ULTIMATE, IVUS-XPL and RESET), the reasons provided for patients crossing over from angiography guidance to IVUS guidance were ambiguous anatomy and operator preference in complex lesions. In cases where patients randomised to IVUS guidance received angiography guidance instead, the reasons cited were patient refusal, technical failure to deliver IVUS catheter, and physician decision due to unfavourable coronary anatomy (i.e., severe tortuosity). The highest crossover rate was in RESET where 15% of patients assigned to angiography guidance received IVUS guidance, and 4.8% vice versa.

The trial populations would largely meet the current MBS criteria for PCI and the proposed MBS criteria for IVUS. The Victorian Cardiac Outcomes Registry (VCOR) captures data from 'all-comers' to PCI in Victoria and is a reliable source for comparison with study participants in the all-comer trial (ULTIMATE).

According to the trial authors, the ULTIMATE study population reflects the typical characteristics of high-volume PCI centres in China. The majority of patients (78.5%) presented with ACS, indicating a relatively high-risk population, and two-thirds of participants had complex PCI<sup>13</sup>. Mean lesion length was almost identical to the IVUS-XPL trial that exclusively enrolled patients with long lesions. By comparison, the rate of ACS in Victorian patients undergoing PCI in 2020 was 51% (27% in private patients) and the rate of stable angina was 30.4% (46.3% in private patients). Rates of unprotected left main lesions and chronic total occlusions reported by VCOR are also notably lower than those reported in ULTIMATE. This has implications for patient outcomes because subgroup analyses from the ULTIMATE trial suggest that patients with complex PCI or at higher risk receive the greatest benefit from IVUS guidance.

The ADAR did not provide a comparison of baseline characteristics between participants in the long lesion trials (IVUS-XPL and RESET) or the left main lesion trials (Liu 2019 and Tan 2015)

<sup>13</sup> Defined as a composite of multivessel disease, bifurcation with 2 stents implanted, ≥ moderate calcification, chronic total occlusion, >3 stents implanted, and total stent length > 90 mm

with Australian patients who would also meet these anatomical criteria. According to data from VCOR, 4% of Victorian PCI procedures in 2020 were long lesions and 2.3% were left main lesions.

One final concern regarding the body of evidence is that despite investigators' having extensive experience with IVUS guidance, just under half the patients in the IVUS arm of the ULTIMATE and IVUS-XPL trials were regarded as having undergone IVUS-defined 'suboptimal' PCI<sup>14</sup>. Both trials reported that patients in the IVUS arm who received IVUS-defined suboptimal PCI had a significantly higher risk of adverse events (e.g., cardiac mortality, MI, TVR) than patients with 'optimal PCI' according to protocol-defined criteria. The rate of TVF in ULTIMATE patients who underwent a 'suboptimal' procedure was similar to those in the angiography guidance arm. This has implications for real-world effectiveness; operators with less experience may not achieve optimal stent deployment with IVUS despite best efforts and therefore the magnitude of any beneficial effect of IVUS may be reduced in practice.

## 11. Comparative safety

The safety outcomes specified in the PICO Confirmation were in-hospital adverse events and complications from the use of IVUS. The ADAR did not address these outcomes and very limited information was available from the trial publications. Where reported, event rates were low and there was no significant difference between arms.

### Stent thrombosis

Stent thrombosis was the only safety outcome reported in the ADAR (it was classified as an efficacy outcome in the ratified PICO Confirmation).

Numerically lower rates of stent thrombosis were reported in the IVUS-guided arm of the ULTIMATE trial, which reached borderline ( $p=0.05$ ) statistical significance in terms of relative risk (RR) at 3 years (risk difference [RD] was statistically significant). Stent thrombosis rates were low in both arms of long lesion and left main lesion trials, and differences between arms were not significant.

---

<sup>14</sup> In ULTIMATE, IVUS-defined 'optimal' procedures were identified if three criteria were simultaneously met: 1) minimum luminal area in the stented segment more than 5.0 mm<sup>2</sup> or 90% of the minimal luminal area at the distal reference segments; 2) plaque burden 5 mm proximal or distal to the stent edge <50%; and 3) no edge dissection involving the media with length more than 3 mm. In the IVUS-XPL trial an 'optimal' IVUS-guided stenting procedure was defined as the attainment of a minimal luminal cross-sectional area greater than the luminal cross-sectional area at the distal reference segments (i.e., expansion index >1.0).

**Table 7 Definite/probable stent thrombosis**

Trial ID	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography-guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>						
ULTIMATE	⊕⊕⊕⊖ Moderate	1 yr	1/724 (0.1)	5/724 (0.7)	0.20 (0.02, 1.71) p = 0.14	-0.01 (-0.01, 0.00) p = 0.10
		2 yrs	1/724 (0.1)	7/724 (1.0)	0.14 (0.02, 1.16) p = 0.07	<b>-0.01 (-0.02, -0.00)</b> <b>p = 0.03</b>
		3 yrs	1/724 (0.1)	8/724 (1.0)	0.1 (0.02, 1.00) p = 0.05	<b>-0.01 (-0.02, -0.00)</b> <b>p = 0.02</b>
<b>Long lesions*</b>						
IVUS-XPL	⊕⊕⊖⊖ Low	1 yr	2/700 (0.29)	2/700 (0.29)	1.00 (0.14, 7.08) p = 1.00	0.00 (-0.01, -0.01) p = 1.00
		5 yrs	2/700 (0.29)	2/700 (0.29)	1.00 (0.14, 7.08) p = 1.00	0.00 (-0.01, -0.01) p = 1.00
RESET#	⊕⊕⊖⊖ Low	1 yr	1/269 (0.37)	1/274 (0.36)	1.02 (0.06, 16.20) p = 0.99	0.00 (-0.01, 0.01) p = 0.99
<b>Left main lesions^</b>						
Liu 2019	⊕⊖⊖⊖ Very low	1 yr	2/174 (1.1)	4/174 (2.3)	0.50 (0.09, 2.69) p = 0.42	-0.01 (-0.04, 0.02) p = 0.41
Tan 2015	⊕⊖⊖⊖ Very low	2 yrs	1/61 (1.6)	2/62 (3.2)	0.51 (0.05, 5.46) p = 0.58	-0.02 (-0.07, 0.04) p = 0.31

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

\*\* Quality has been downgraded in all cases by assessment group.

\* Meta-analysis was not appropriate because different definitions were used.

# Although not clear from the RESET trial publication<sup>15</sup>, stent thrombosis appears to include definite/probable/possible.

^ Meta-analysis was not appropriate because of different populations (Tan 2015 enrolled elderly patients) and durations of follow-up.

## Safety conclusions

Data relating to in-hospital adverse events and complications from the use of the intervention are lacking. Where reported, event rates were low and there was no significant difference between arms. Notwithstanding the limitations in the evidence base, data for definite/probable stent thrombosis support a clinical conclusion of at least non-inferior safety for all-comers to PCI with DES and for patients with complex anatomical characteristics.

## 12. Comparative effectiveness

### Cardiac mortality

Across all trials, rates of cardiac death were numerically lower in patients who received IVUS-guided PCI, but studies were underpowered for this outcome and differences between arms did not reach statistical significance.

<sup>15</sup> Kim, J.-S. *et al.* Randomized Comparison of Clinical Outcomes Between Intravascular Ultrasound and Angiography-Guided Drug-Eluting Stent Implantation for Long Coronary Artery Stenoses. *JACC Cardiovasc Interv* 6, 369-376, doi: <https://doi.org/10.1016/j.jcin.2012.11.009> (2013).

**Table 8 Cardiac mortality**

Trial ID <i>Outcome definition</i>	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography- guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>						
ULTIMATE <i>Cardiac mortality</i>	⊕⊕⊕⊙ Moderate	1 yr	5/724 (0.7)	10/724 (1.4)	0.50 (0.17, 1.46) p = 0.20	-0.01 (-0.02, 0.00) p = 0.19
		2 yrs	9/724 (1.2)	16/724 (2.2)	0.56 (0.25, 1.26) p = 0.16	-0.01 (-0.02, 0.00) p = 0.16
		3 yrs	13/724 (1.8)	19/724 (2.6)	0.68 (0.34, 1.37) p = 0.29	-0.01 (-0.02, 0.01) p = 0.28
<b>Long lesions</b>						
IVUS-XPL <i>Cardiac mortality</i>	⊕⊕⊙⊙ Low	1 yr	3/700 (0.4)	5/700 (0.7)	0.6 (0.14, 2.50) p = 0.49	0.00 (-0.01, 0.01) p = 0.48
		5 yrs	6/700 (0.9)	14/700 (2.0)	0.43 (0.17, 1.11) p = 0.08	-0.01 (-0.02, 0.00) p = 0.07
RESET <i>Cardiovascular mortality</i>	⊕⊕⊙⊙ Low	1 yr	0/269	1/274 (0.4)	0.34 (0.01, 8.30) p = 0.51	-0.00 (-0.01, 0.01) p = 0.36)
Meta-analysis	Chi <sup>2</sup> = 0.10 (p = 0.75); I <sup>2</sup> = 0%	1 yr	3/969 (0.3)	6/974 (0.6)	0.54 (0.15, 1.98) p = 0.35	-0.00 (-0.01, 0.00) p = 0.34
<b>Left main lesions<sup>^</sup></b>						
Liu 2019 <i>Cardiac mortality</i>	⊕⊙⊙⊙ Very low	1 yr	3/174 (1.7)	10/174 (5.7)	0.30 (0.08, 1.07) p = 0.06	-0.04 (-0.08, -0.00) p = 0.05
Tan 2015 <i>Cardiovascular mortality</i>	⊕⊙⊙⊙ Very low	2 yrs	2/61 (3.3)	3/62 (4.8)	0.68 (0.12, 3.91) p = 0.68	-0.02 (-0.09, 0.05) p = 0.45

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

\*\* Quality has been downgraded in all cases by assessment group.

<sup>^</sup> Meta-analysis was not appropriate because of different populations (Tan 2015 enrolled elderly patients) and durations of follow-up.

## Myocardial infarction

Different definitions of MI were used across the trials, as shown in Table 9. Of note, Tan 2015 only reported non-fatal MIs.

Although rates of MI were numerically lower in the IVUS-guided arms of each trial, differences between arms did not reach statistical significance.

**Table 9 Myocardial infarction**

Trial ID <i>Outcome definition</i>	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography- guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>						
ULTIMATE <i>Clinically driven target vessel MI</i>	⊕⊕⊕⊙ Moderate	1 yr	7/724 (1)	11/724 (1.5)	0.64 (0.25, 1.63) p = 0.35	-0.01 (-0.02, 0.01) p = 0.34
		2 yrs	7/724 (1)	14/724 (1.9)	0.5 (0.2, 1.23) p = 0.13	-0.01 (-0.02, 0.00) p = 0.12
		3 yrs	7/724 (1)	15/724 (2.1)	0.47 (0.19, 1.14) p = 0.09	-0.01 (-0.02, 0.00) p = 0.09
<b>Long lesions</b>						
IVUS-XPL <i>Target lesion related MI</i>	⊕⊕⊙⊙ Low	1 yr	0/700 (0)	1/700 (0.1)	0.33 (0.01, 8.17) p = 0.50	-0.00 (-0.01, 0.00) p = 0.48
		5 yrs	4/700 (0.6)	6/700 (0.9)	0.67 (0.19, 2.35) p = 0.53	-0.00 (-0.01, 0.01) p = 0.53
RESET <i>MI</i>	⊕⊕⊙⊙ Low	1 yr	0/269 (0)	2/274 (0.7)	0.20 (0.01, 4.22) p = 0.30	-0.01 (-0.02, 0.01) p = 0.35
Meta-analysis	Chi <sup>2</sup> = 0.05, (p = 0.83); I <sup>2</sup> = 0%	1 yr	0/969 (0%)	3/974 (0.3)	0.25 (0.03, 2.26) p = 0.22	-0.00 (-0.01, 0.00) p = 0.18
<b>Left main lesions<sup>^</sup></b>						
Liu 2019 <i>MI</i>	⊕⊙⊙⊙ Very low	1 yr	19/174 (10.9)	23/174 (13.2)	0.83 (0.47, 1.46) p = 0.51	-0.02 (-0.09, 0.05) p = 0.51
Tan 2015 <i>Non-fatal MI</i>	⊕⊙⊙⊙ Very low	2 yrs	1/61 (1.6)	2/62 (3.2)	0.51 (0.05, 5.46) p = 0.58	-0.02 (-0.07, 0.04) p = 0.57

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

\*\* Quality has been downgraded in all cases by assessment group.

<sup>^</sup> Meta-analysis was not appropriate because of different populations (Tan 2015 enrolled elderly patients) and durations of follow-up. Data extraction errors were noted for Liu 2019 during preparation of the Commentary and have been corrected.

### Target lesion revascularisation

IVUS guidance resulted in significantly lower rates of TLR compared with angiography guidance in the ULTIMATE trial (all-comers to PCI) at 3 years, and the IVUS-XPL trial (patients with long lesions) at 1 year and 5 years.

Rates of TLR were numerically lower in patients with left main lesions who received IVUS-guided PCI, but differences between arms did not reach statistical significance.

TLR was not an outcome reported in the RESET trial.

Target vessel revascularisation (TVR) was reported in three trials (ULTIMATE, RESET and Liu 2019) but was not a specified outcome in the ratified PICO. Across all three trials, rates of TVR were numerically lower in patients who received IVUS-guided PCI, but differences between arms did not reach statistical significance.

**Table 10 Target lesion revascularisation**

Trial ID <i>Outcome definition</i>	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography- guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>						
ULTIMATE <i>Clinically driven TLR</i>	⊕⊕⊕⊙ Moderate	1 yr	9/724 (1.2)	19/724 (2.6)	0.47 (0.22, 1.04) p = 0.06	-0.01 (-0.03, 0.00) p = 0.06
		2 yrs	26/724 (3.6)	40/724 (5.5)	0.65 (0.40, 1.05) p = 0.08	-0.02 (-0.04, 0.00) p = 0.09
		3 yrs	27/724 (3.7)	45/724 (6.2)	<b>0.60 (0.38, 0.96)</b> p = 0.03	<b>-0.02 (-0.05, -0.00)</b> p = 0.03
<b>Long lesions</b>						
IVUS-XPL# <i>Ischaemia driven TLR</i>	⊕⊕⊙⊙ Low	1 yr	17/700 (2.4)	33/700 (4.7)	<b>0.52 (0.29, 0.92)</b> p = 0.02	<b>-0.02 (-0.04, -0.00)</b> p = 0.02
		5 yrs	31/700 (4.4)	55/700 (7.9)	<b>0.56 (0.37, 0.86)</b> p = 0.009	<b>-0.03 (-0.06, -0.01)</b> p = 0.007
<b>Left main lesions<sup>^</sup></b>						
Liu 2019 <i>TLR</i>	⊕⊙⊙⊙ Very low	1 yr	2/174 (1.1)	5/174 (2.9)	0.40 (0.08, 2.03) p = 0.27	-0.02 (-0.05, 0.01) p = 0.25
Tan 2015 <i>TLR</i>	⊕⊙⊙⊙ Very low	2 yrs	5/61 (8.2)	12/62 (19.4)	0.42 (0.16, 1.13) p = 0.09	-0.11 (-0.23, 0.01) p = 0.07

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

\*\* Quality has been downgraded in all cases by assessment group.

# Risk analysis errors were noted for IVUS-XPL during preparation of the Commentary and have been corrected.

<sup>^</sup> Meta-analysis was not appropriate because of different populations (Tan 2015 enrolled elderly patients) and durations of follow-up.

## Other outcomes

### All-cause mortality

In the two trials reporting all-cause mortality, rates were not significantly different between arms.

**Table 11 All-cause mortality**

Trial ID	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography- guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>						
ULTIMATE#	⊕⊕⊕⊙ Moderate	1 yr	10/724 (1.4)	17/724 (2.3)	0.59 (0.27, 1.28) p = 0.18	-0.01 (-0.02, 0.00) p = 0.17
		2 yrs	24/724 (3.3)	27/724 (3.7)	0.89 (0.52, 1.53) p = 0.68	-0.00 (-0.02, 0.01) p = 0.67
		3 yrs	31/724 (4.3)	31/724 (4.3)	1.00 (0.61, 1.63) p = 1.00	0.00 (-0.02, 0.02) p = 1.00
<b>Long lesions</b>						
RESET	⊕⊕⊙⊙ Low	1 yr	3/269 (1.1)	2/274 (0.7)	1.53 (0.26, 9.07) p = 0.64	0.00 (-0.00, 0.01) p = 0.34

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

\*\* Quality has been downgraded in all cases by assessment group.


# Data extraction errors were noted for ULTIMATE during preparation of the Commentary and have been corrected.



## Target vessel failure

ULTIMATE was the only RCT to report the composite outcome of TVF, which was the primary efficacy outcome for this trial. The incidence of TVF was significantly lower in the IVUS-guided arm compared with the angiography-guided arm at all three timepoints, which the authors of the publication claim is driven mainly by the increased occurrence of TVR in the angiographic guidance group (6.8% vs. 4.8% at 3 years;  $p = 0.05$ ). The result for the ITT analysis at 5 years was similar to the per-protocol analysis and the on-treatment analysis (which took group crossovers into account).

**Table 12 Target vessel failure**

Trial ID	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography-guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>						
ULTIMATE	 Moderate	1 yr	21/724 (2.9)	39/724 (5.4)	<b>0.54 (0.32, 0.91)</b> <b>p = 0.02</b>	<b>-0.02 (-0.05, -0.00)</b> <b>p = 0.02</b>
		2 yrs	43/724 (5.9)	65/724 (9.0)	<b>0.66 (0.46, 0.96)</b> <b>p = 0.03</b>	<b>-0.03 (-0.06, -0.00)</b> <b>p = 0.03</b>
		3 yrs	47/724 (6.5)	76/724 (10.5)	<b>0.62 (0.44, 0.88)</b> <b>p = 0.01</b>	<b>-0.04 (-0.07, -0.01)</b> <b>p = 0.006</b>

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

\*\* Quality has been downgraded in all cases by assessment group.

Given that ULTIMATE included an all-comer population, analysis by lesion complexity may be of interest to MSAC. *Post hoc* analysis suggested that IVUS guidance provided greater benefit in complex PCI, defined as a composite of multivessel disease, bifurcation with two stents implanted, at least moderate calcification, chronic total occlusion, more than three stents implanted, and total stent length greater than 90 mm. Approximately two-thirds of ULTIMATE study participants had complex PCI according to this definition.

**Table 13 Post hoc analysis of 3-year target vessel failure in patients with complex PCI**

Trial ID	Complex PCI#	IVUS-guided PCI n/N (%)	Angiography-guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>All-comers</b>					
ULTIMATE	No	12/245 (4.9%)	16/242 (6.6%)	0.74 (0.36, 1.53) p = 0.42	-0.02 (-0.06, 0.02) p = 0.42
	Yes	35/479 (7.3%)	60/482 (12.4%)	<b>0.59 (0.39, 0.87)</b> <b>p = 0.009</b>	<b>-0.05 (-0.09, -0.01)</b> <b>p = 0.007</b>

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Statistically significant differences are shown in bold.

# Complex PCI was defined as a composite of multivessel disease, bifurcation with 2 stents implanted,  $\geq$  moderate calcification, chronic total occlusion,  $> 3$  stents implanted, and total stent length  $> 90$  mm.

## MACE

MACE was the primary efficacy outcome for all trials in patients with long lesions and left main lesions and was defined differently in each trial (see footnotes to Table 14).

IVUS guidance resulted in significantly lower rates of MACE compared with angiography guidance in the IVUS-XPL trial (long lesions) at 1 year and 5 years, and in the Liu 2019 trial (left main lesions) at 1 year. Rates of MACE were numerically lower in patients who received IVUS-guided PCI in RESET and Tan 2015, but differences between arms did not reach statistical significance in terms of RR.

**Table 14 Major cardiac adverse events**

Trial ID <i>Outcome definition</i>	Quality**	Timepoint	IVUS-guided PCI n/N (%)	Angiography- guided PCI n/N (%)	RR (95% CI) p-value	RD (95% CI) p-value
<b>Long lesions<sup>^</sup></b>						
IVUS-XPL <sup>#</sup>	⊕⊕⊖⊖ Low	1 yr	19/700 (2.7)	39/700 (5.6)	<b>0.49 (0.28, 0.83)</b> p = 0.009	<b>-0.03 (-0.05, -0.01)</b> p = 0.007
		5 yrs	36/700 (5.1)	70/700 (10)	<b>0.51 (0.35, 0.76)</b> p = 0.0008	<b>-0.05 (-0.08, -0.02)</b> p = 0.0006
RESET <sup>##</sup>	⊕⊕⊖⊖ Low	1 yr	12/269 (4.5)	20/274 (7.3)	0.61 (0.3, 1.23) p = 0.17	-0.03 (-0.07, 0.01) p = 0.16
<b>Left main lesions<sup>^</sup></b>						
Liu 2019 <sup>*</sup>	⊕⊖⊖⊖ Very low	1 yr	22/174 (12.6)	37/174 (21.3)	<b>0.59 (0.37, 0.96)</b> p = 0.04	<b>-0.09 (-0.16, -0.01)</b> p = 0.03
Tan 2015 <sup>**</sup>	⊕⊖⊖⊖ Very low	2 yrs	8/61 (13.1)	17/62 (27.4)	0.48 (0.22, 1.03) p = 0.06	<b>-0.14 (-0.28, -0.00)</b> p = 0.04

CI = confidence interval; HR = hazard ratio; IVUS = intravascular ultrasound; N = number randomised; PCI = percutaneous coronary intervention; RR = risk ratio; RD = risk difference.

Note: Data are shown for the ITT population. Statistically significant differences are shown in bold.

<sup>^</sup> Meta-analysis was not appropriate because of different outcome definitions.

<sup>#</sup> Composite of cardiac death, target lesion related MI or ischemia driven TLR.

<sup>##</sup> Composite of cardiovascular death, MI, stent thrombosis or TVR. Errors in p-values in the ADAR have been corrected.

<sup>\*</sup> Composite of cardiac death, MI or TVR.

<sup>\*\*</sup> Composite of death, non-fatal MI or TLR. Errors in p-values in the ADAR have been corrected.

## Effectiveness conclusions

The evidence for all-comers to PCI with second-generation DES is from one multicentre RCT from China with some concerns regarding risk of bias. Follow-up in the ULTIMATE trial is ongoing to 5 years. TLR data at 3 years supports a clinical conclusion of superior effectiveness of IVUS-guided PCI compared with angiography-guided PCI. This conclusion is further supported by the primary composite outcome, TLR, on which the study was powered. The other critical effectiveness outcomes – cardiac mortality and MI – showed numerically lower event rates in the IVUS arm compared with angiography alone, although the differences between arms did not reach statistical significance. The study population in ULTIMATE included relatively high-risk patients with complex coronary lesions and is not comparable to PCI all-comers in Australia.

The evidence for patients with long lesions is from two multicentre RCTs from Korea that enrolled patients with stent length of at least 28 mm. Both trials are at risk of bias and had patients' crossover to the alternative group, often at the discretion of the unblinded operator. TLR data at 1 and 5 years supports a clinical conclusion of superior effectiveness of IVUS-guided PCI compared with angiography-guided PCI, although only one of the trials reported this outcome.

This same trial, IVUS-XPL, reported superior effectiveness of IVUS in terms of the primary composite outcome (MACE), and numerically lower rates of cardiac mortality and MI in the IVUS-guided arm, which did not reach statistical significance. The second trial, RESET, reported numerically lower rates of MACE in the IVUS-guided arm, but event rates for cardiac mortality and MI were too low to draw any conclusions regarding relative effectiveness. Data specifically relating to Australian patients with long lesions were not presented in the ADAR for comparison with study participants in the IVUS-XPL and RESET trials. Follow-up in IVUS-XPL is ongoing to 10 years.

The evidence for patients with left main lesions is from two relatively small, single centre RCTs from China at very serious risk of bias. Although statistically significant between-group differences were reported for MACE, favouring IVUS-guided PCI, there were no significant differences between IVUS-guided PCI and angiography-guided PCI in the individual components of the composite outcome. These data support a clinical conclusion of non-inferior effectiveness, although longer term follow-up from higher quality evidence is needed to confirm this.

### Clinical claims

For **all-comers to PCI with DES**, the interpretation of the clinical claim in Section B.8 of the ADAR is that adjunct IVUS guidance during DES implantation is superior in terms of effectiveness and superior in terms of safety, compared with angiography alone. Note, this is inconsistent with the clinical claim for this population in Section A.8 of the ADAR, which is that IVUS guidance is superior in terms of effectiveness and non-inferior in terms of safety.

- The clinical evidence available for all-comers to PCI with DES supports a clinical claim of superior effectiveness (based on TLR at 3 years) and non-inferior safety (based on stent thrombosis).

For patients with **long coronary lesions**, the interpretation of the clinical claim in Section B.8 is that adjunct IVUS guidance during DES implantation is superior in terms of effectiveness and non-inferior in terms of safety, compared with angiography alone.

- The clinical evidence available for patients with long lesions supports the clinical claim of superior effectiveness (based on TLR at 1 and 5 years) and non-inferior safety (based on stent thrombosis), although these claims are subject to some uncertainty (particularly as the effectiveness claim hinges on data from only one of the two trials available).

For patients with **left main lesions**, the clinical claim in Section B.8 is that adjunct IVUS guidance during DES implantation is non-inferior in terms of effectiveness and non-inferior in terms of safety, compared with angiography alone.

- The clinical evidence available for this population supports the non-inferiority claims, although confidence is low because the trials are at serious risk of bias.

On the basis of the clinical claims, the presentation of separate cost-utility analyses for all-comers to PCI with DES (Population 1) and patients with complex anatomical characteristics (Population 2) is appropriate.

## 13. Economic evaluation

Two separate cost-utility analyses were conducted to model the cost-effectiveness of IVUS in the two patient populations specified in the ratified PICO. The ICER for patients with complex anatomical characteristics was calculated as a weighted average of the ICER for patients with left main lesions (37%) and long lesions (63%), based on data from VCOR.

A summary of the economic evaluation is provided in Table 15. The economic evaluation follows the same methods as the previous submission with the following key updates:

- BMS has been removed to align with new RCT evidence and contemporary practice;
- revascularisation events are restricted to TLR data from the RCTs in Section 8, due to lack of clarity around definitions of TVR and whether TVR and TLR are mutually exclusive;
- transitions between health states are derived from event rates from the IVUS and angiography arms of the RCTs in Section 8;
- no incremental benefit of IVUS is assumed after 5 years to align with the maximum follow-up for any RCT in Section 8;
- patients cannot transition between the post-MI and post-TLR health states;
- all-cause and event-specific mortality has been updated to reflect progressions in standard practice (no difference in mortality between treatment arms).

**Table 15 Summary of the economic evaluation**

Component	Description
Perspective	Australian health care system perspective
Population	1) All-comers to PCI with DES 2) Patients with complex anatomical characteristics (long lesions and left main lesions) requiring DES
Comparator	Angiography-guided PCI for DES implantation
Type of analysis	Cost-utility analysis
Outcomes	QALYs and costs
Time horizon	<u>Model base case:</u> Lifetime (33 years from a start age of 67 years) <u>Trial-based follow-up:</u> 3 years for all-comers, ≤ 5 years for long lesions, ≤ 2 years left main lesions
Computational method	Markov model
Generation of the base case	Stepped evaluation, with Steps 0 and 1 being quasi-trial-based analyses at a time horizon of 5 years <u>Step 0:</u> incremental cost per life-year; <u>Step 1:</u> incremental cost per QALY; <u>Step 2:</u> incremental cost per QALY to a lifetime time horizon
Health states	<u>No event:</u> All patients begin the model in this state. Patients from both arms remain in this health state until they experience an event. <u>Post MI:</u> A proportion of the cohort transitions to this state based on data from trials in Section B. Patients in this state are treated with either revascularisation (PCI or CABG) or medically. <u>Post TLR:</u> A proportion of the cohort transitions to this state based on data from trials in Section B. Patients in this state are treated with either PCI or CABG. <u>Dead:</u> A portion of the cohort can die from either all-cause mortality, TLR-related mortality or MI-related mortality.
Cycle length	1 year
Transition probabilities	<u>MI with IVUS or angiography:</u> sourced from trials in Section B <u>TLR with IVUS or angiography:</u> sourced from trials in Section B <u>Death after initial PCI:</u> ABS 2019 life tables, weighted by sex <u>Death after TLR:</u> sourced from VCOR Annual Report 2019 <u>Death after MI:</u> sourced from a published Australian CUA <sup>16</sup> , with US-based values and no specific justification for their selection by the authors <u>MI treated with a revascularisation:</u> sourced from VCOR Annual Report 2019 <u>MI treated medically:</u> sourced from VCOR Annual Report 2019 <u>MI revascularisation with PCI:</u> sourced from NHF/CSANZ clinical guidelines 2016 <u>MI revascularisation with CABG:</u> sourced from NHF/CSANZ clinical guidelines 2016
Utility weights	Sourced from a published Australian CUA <sup>14</sup> <u>No event:</u> 0.830; <u>Post-MI:</u> 0.704; <u>Post-TLR:</u> 0.830; <u>TLR:</u> -0.06

<sup>16</sup> Zhou, J. *et al.* Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation: A Health Economic Analysis. *Circ Cardiovasc Qual Outcomes* **14**, e006789, doi:10.1161/circoutcomes.120.006789 (2021)

Component	Description
Discount rate	5% for both costs and outcomes
Software	TreeAge Pro Healthcare 2020

CABG = coronary artery bypass graft; CUA = cost-utility analysis; DES = drug-eluting stent; MI = myocardial infarction; NHF/CSANZ = National Heart Foundation & Cardiac Society of Australia and New Zealand; PCI = percutaneous coronary intervention; QALY = quality-adjusted life year; TLR = target lesion revascularisation; VCOR = Victorian Cardiac Outcomes Registry.

The stepped economic analysis for the base-case results of the economic evaluation is shown in Table 16 for all-comers to PCI with DES, and Table 17 for patients with complex anatomical characteristics.

In the alternative base case scenario presented in the commentary and for all sensitivity analyses presented, two changes have been made. Firstly, it has been assumed that there is no incremental benefit for an all-comers population beyond the 3-year available data from ULTIMATE. Beyond 3 years, the probability for angiography alone has been applied. The long lesion population has 5-year follow-up from a single study (IVUS-XPL) and so the incremental benefit to 5 years has been retained in the model. For the left main lesion population, the assumption of the long lesion probability for TLR has been retained, as this assumption is explained, if not fully justified. This is varied in a sensitivity analysis.

Secondly, there was no statistically significant difference in MI between IVUS versus angiography alone for any subpopulation and so the probability of MI for angiography alone has been applied throughout in the alternate base case scenario. Beyond the first year, the probability of MI for the angiography alone long lesion and left main lesion populations are the same.

**Table 16 Results of the stepped economic analysis for all-comers to PCI with DES**

	Cost	Incremental cost	Effectiveness	Incremental effectiveness	ICER
<b>Step 0 cost per life-year (5-year time horizon based on latest follow-up time point in Section B)</b>					
IVUS	\$12,543 [ <b>\$12,887</b> ]	\$1,059 [ <b>\$1,403</b> ]	4.30	0.01 [ <b>0.00</b> ]	
Angiography	\$11,484		4.30		\$152,480 [ <b>\$307,059</b> ]
<b>Step 1 cost per QALY (5-year time horizon based on latest follow-up time point in Section B)</b>					
IVUS	\$12,543 [ <b>\$12,887</b> ]	\$1,059 [ <b>\$1,403</b> ]	3.57	0.01	
Angiography	\$11,484		3.55 [ <b>3.56</b> ]		\$83,332 [ <b>\$274,355</b> ]
<b>Step 2 cost per QALY (lifetime time horizon)</b>					
IVUS	\$13,434 [ <b>\$13,851</b> ]	\$1,009 [ <b>\$1,425</b> ]	9.57 [ <b>9.53</b> ]	0.06 [ <b>0.02</b> ]	
Angiography only	\$12,426		9.50		\$16,317 [ <b>\$67,149</b> ]

DES = drug-eluting stent; ICER = incremental cost-effectiveness ratio; IVUS = intravascular ultrasound; PCI = percutaneous coronary intervention; QALY = quality-adjusted life year.

Note: Data shown in blue text are derived from the alternative base case proposed in the Commentary.

**Table 17 Results of the stepped economic analysis for patients with complex anatomical characteristics**

	Cost	Incremental cost	Effectiveness	Incremental effectiveness	ICER
<b>Step 0 cost per life-year (5-year time horizon based on latest follow-up time point in Section B)</b>					
<b>Long lesions</b>					
IVUS	\$12,477 [ <b>\$12,538</b> ]	\$1,183 [ <b>\$1,285</b> ]	4.31	0.01	\$164,888 [ <b>\$206,163</b> ]
Angiography	\$11,294 [ <b>\$11,253</b> ]		4.30		
<b>Left main lesions</b>					
IVUS	\$15,053 [ <b>\$15,385</b> ]	\$250 [ <b>\$749</b> ]	4.28 [ <b>4.27</b> ]	0.02 [ <b>0.01</b> ]	\$12,734 [ <b>\$52,111</b> ]
Angiography	\$14,802 [ <b>\$14,636</b> ]		4.26		
Complex anatomical characteristics					\$109,339 [ <b>\$149,922</b> ]
<b>Step 1 cost per QALY (5-year time horizon based on latest follow-up time point in Section B)</b>					
<b>Long lesions</b>					
IVUS	\$12,477 [ <b>\$12,538</b> ]	\$1,183 [ <b>\$1,285</b> ]	3.57	0.01	\$115,557 [ <b>\$181,998</b> ]
Angiography	\$11,294 [ <b>\$11,253</b> ]		3.56		
<b>Left main lesions</b>					
IVUS	\$15,053 [ <b>\$15,385</b> ]	\$250 [ <b>\$749</b> ]	3.49 [ <b>3.48</b> ]	0.03 [ <b>0.02</b> ]	\$7,694 [ <b>\$45,866</b> ]
Angiography	\$14,802 [ <b>\$14,636</b> ]		3.45 [ <b>3.46</b> ]		
Complex anatomical characteristics					\$76,179 [ <b>\$132,299</b> ]
<b>Step 2 (lifetime time horizon)</b>					
<b>Long lesions</b>					
IVUS	\$13,489 [ <b>\$13,509</b> ]	\$1,186 [ <b>\$1,318</b> ]	9.57 [ <b>9.56</b> ]	0.04 [ <b>0.03</b> ]	\$27,284 [ <b>\$44,220</b> ]
Angiography only	\$12,303 [ <b>\$12,191</b> ]		9.52 [ <b>9.53</b> ]		
<b>Left main lesions</b>					
IVUS	\$16,693 [ <b>\$17,082</b> ]	\$201 [ <b>\$827</b> ]	9.24 [ <b>9.20</b> ]	0.13 [ <b>0.07</b> ]	\$1,506 [ <b>\$11,912</b> ]
Angiography only	\$16,492 [ <b>\$16,256</b> ]		9.11 [ <b>9.13</b> ]		
Complex anatomical characteristics					\$17,873 [ <b>\$32,425</b> ]

ICER = incremental cost-effectiveness ratio; IVUS = intravascular ultrasound; QALY = quality-adjusted life year.

Note: Data shown in blue text are derived from the alternative base case proposed in the Commentary.

The results of key univariate sensitivity analyses are summarised below. The magnitude of effect is similar to the original ADAR analysis for all parameters, except for the change in TLR mortality to 1.5%, where the increase in ICER is 57% compared to an original increase of 19%.

**Table 18 Sensitivity analyses**

Analyses	Incremental cost	Incremental QALY	ICER	% change
<b>All-comers to PCI with DES</b>				
Base case	\$1,009 [\$1,425]	0.06 [0.02]	\$16,317 [\$67,149]	-
Incremental benefit in terms of MI retained for first 3 years	\$1,159	0.05	\$23,803	46% [-65%]
Time horizon 5 years (also presented in stepped economic evaluation above)	\$1,059 [\$1,403]	0.01 [0.01]	\$83,332 [\$274,355]	411% [309%]
Time horizon 10 years (added for commentary)	\$1,032 [\$1,412]	0.03 [0.01]	\$38,456 [\$148,701]	136% [121%]
Time horizon 20 years	\$1,009 [\$1,422]	0.05 [0.02]	\$20,134 [\$83,480]	23% [24%]
Benefit of IVUS held after 5 (3) years for lifetime horizon	\$313 [\$865]	0.11 [0.06]	\$2,737 [\$14,517]	-83% [-78%]
Benefit of IVUS held after 5 (3) years for 20-year horizon	\$396 [\$910]	0.08 [0.04]	\$5,061 [\$23,416]	-69% [-65%]
Mortality of TLR equal to all-population in hospital mortality of PCI	\$1,009 [\$1,425]	0.05 [0.01]	\$19,470 [\$105,212]	19% [57%]
<b>Complex anatomical characteristics</b>				
Base case			\$17,873 [\$32,217]	-
Incremental benefit in terms of MI retained for first 3 years	\$876	0.07	\$21,369	20% [-34%]
Time horizon 5 years (also presented in stepped economic evaluation above)	\$842 [\$1,089]	0.02 [0.01]	\$76,179 [\$132,299]	326% [308%]
Time horizon 10 years (added for commentary)	\$830 [\$1,110]	0.04 [0.02]	\$39,358 [\$71,405]	120% [120%]
Time horizon 20 years	\$824 [\$1,133]	0.06 [0.04]	\$21,887 [\$40,231]	22% [24%]
Benefit of IVUS held after 5 years for lifetime horizon	\$536 [\$454]	0.10 [0.00]	\$8,350 [\$17,406]	-53% [-46%]
Benefit of IVUS held after 5 years for 20-year horizon	\$564 [\$463]	0.07 [0.00]	\$12,072 [\$24,900]	-32% [-23%]
Mortality of TLR equal to all-population in hospital mortality of PCI	\$827 [\$1,139]	0.06 [0.03]	\$23,604 [\$50,638]	32% [56%]
Left main data not extrapolated beyond maximal trial follow-up of 2 years	-	-	\$33,189	2%

DES = drug-eluting stent; ICER = incremental cost effectiveness ratio; IVUS = intravascular ultrasound; PCI = percutaneous coronary intervention; QALY = quality-adjusted life year; TLR = target lesion revascularisation.

Note: Data shown in blue text are derived from the alternative base case proposed in the Commentary.

## 14. Financial/budgetary impacts

An epidemiological approach was adopted to inform the utilisation estimates and financial implication to the Government upon MBS listing of IVUS as an adjunct to angiography in patients undergoing PCI with DES insertion in Australia. Sources used to estimate the extent of use included Medicare statistics (2016 to 2019) for MBS item 38306 (which was replaced in July 2021 with 12 new items for PCI with stent insertion) and the VCOR Annual Report 2020.

The structure of the budget impact model remained largely unchanged from the previous application (1354). The listing of IVUS as an adjunct to angiography-guided PCI is not expected to grow the market above existing market growth of PCI with stent insertion.

The applicant claims that the speed of IVUS uptake will be influenced by the level of training, experience and the learning curve associated with reading IVUS images by PCI operators across the healthcare sector. Given the smaller population size, the applicant expects that the growth in uptake rate will be slightly lower for the complex anatomical characteristics populations. However, the use of adjunct IVUS is expected to be higher in these high-risk patients compared with all-comers (IVUS is used more frequently as an adjunct to angiography in patients with complex anatomical lesions). However, the uptake assumptions (shown in Table 19) are not adequately justified and there is potential for the number of services to be greater than those estimated in Table 19.

Given the nature of IVUS as an adjunctive procedure to be used alongside angiography, no changes to other MBS services are expected. In contrast to the economic evaluation, the financial analysis does not include any potential cost savings associated with reduced major cardiac events in patients who receive IVUS-guided stent implantation.

The financial implications to the MBS resulting from the proposed listing of IVUS for guidance of coronary stent insertion are summarised in Table 19. For reference, VCOR reported a total of 327 adjunctive IVUS procedures conducted in Victoria in 2020, of which 127 procedures were in the private setting.

**Table 19 Net financial implications to the MBS of IVUS as an adjunct to angiography for coronary stent insertion**

	2022	2023	2024	2025	2026
<b>All-comers to PCI with DES</b>					
Total number of PCI with DES procedures	33,117	34,233	35,387	36,579	37,812
Assumed uptake rate of IVUS	5%	10%	15%	20%	25%
Estimated number of IVUS-guided stent procedures	1,656	3,423	5,308	7,316	9,453
Total MBS cost for IVUS-guided stent insertion	\$606,905	\$1,254,719	\$1,945,510	\$2,681,438	\$3,464,761
<b>Patients with complex anatomical characteristics</b>					
Number of coronary stent insertion services for patients with long lesions $\geq$ 28 mm	1,325	1,369	1,415	1,463	1,512
Number of coronary stent insertion services for patients with left main lesions	762	787	814	841	870
Total number of coronary stent insertion services for patients with complex anatomical characteristics	2,086	2,157	2,229	2,304	2,382
Assumed uptake rate of IVUS	40%	43%	46%	49%	52%
Estimated number of IVUS-guided stent procedures for patients with complex anatomical characteristics	835	927	1,026	1,129	1,239
Total MBS cost for IVUS-guided stent insertion	\$305,880	\$339,903	\$375,872	\$413,880	\$454,022

DES = drug-eluting stent; IVUS = intravascular ultrasound; MBS = Medicare Benefits Schedule; PCI = percutaneous coronary intervention.

Note: Total cost to MBS has been calculated using 75% benefit but does not take into account the Multiple Operations Rule.

MBS costs comprise a minor (less than 25%) component of the overall financial costs. The majority of the costs of IVUS are borne by hospitals and health funds, including capital equipment and consumable costs, which are funded indirectly by the Federal Government through the funding of state level health budgets. The most significant cost is associated with the IVUS consumables (an imaging catheter, mini-transducer and console), which is estimated by the applicant to be between \$1,000 and \$1,500 per procedure. No breakdown of this cost was provided in the ADAR. The imaging catheters are disposable whereas the mini-transducer and console are presumably reusable. The capital equipment cost per procedure will occur on a per



hospital basis, given that each hospital will be required to purchase its own generator. The IVUS generator costs \$redacted and has an 8-year life span.

According to the ADAR, 77 hospitals (30 in the private setting) are currently using IVUS in Australia. Given the significant financial outlay required to purchase an IVUS generator, the applicant estimates that no more than five new hospitals each year will purchase a new IVUS generator if IVUS is listed on the MBS. This may be an underestimate as the cost of procurement may not be high compared to the benefit of MBS funding.

If an additional 25 private hospitals across Australia purchase an IVUS generator over the five-year period from 2022 to 2026, there will be a total of 55 generators in the private sector. Using the uptake rates assumed by the applicant, each generator would be used, on average, for 172 procedures in 2026 in all-comers or, alternatively, for 23 procedures in patients with complex anatomical characteristics.

The estimated total cost of IVUS to private hospitals for use in all-comers is approximately \$2,100,800 in 2022, increasing to \$11,457,400 in 2026. The estimated cost incurred by hospital budgets for IVUS use in patients with complex anatomical characteristics is approximately \$1,115,200 in 2022, increasing to \$1,600,200 in 2026.

The applicant expects there will be cost savings to the PBS in the form of reduced medications due to a reduced incidence of major cardiac events in patients receiving IVUS-guided PCI. It is unclear whether savings to the PBS will be realised in practice as the trials in Section B showed no statistically significant difference in MI between IVUS-guided and angiography-guided PCI. Based on the costs presented in Section D of the ADAR, any potential reduction in PBS costs is expected to be small.

Patient out-of-pocket costs were not considered in the ADAR.

## 15. Other relevant information

An independent scan of clinical trial registries identified two large ongoing RCTs in the United States, Canada and Europe that may be of interest to MSAC: IVUS-CHIP ([NCT04854070](#)) and IMPROVE ([NCT04221815](#)). These RCTs (which are both expected to be completed by 2025) compare IVUS-guided PCI with angiography-guided PCI in patients with high risk or complex coronary lesions (broader than long lesions and left main lesions). Follow-up is at least 2 years. Of note, there are also several large-scale trials of OCT underway, either as an alternative to IVUS or comparing OCT with IVUS.

## 16. Key issues from ESC to MSAC

ESC key issue	ESC advice to MSAC
Restriction of clinical providers	The service should be restricted to accredited providers or those with specific training. The appropriate training standard needs to be confirmed and included in the item descriptor explanatory notes.
Item descriptor	<p>The item descriptors should state that the service is claimable once in a single episode of care (for one or more lesions).</p> <p>For both items, MSAC could consider removal of invasive coronary angiogram, which may unintentionally preclude use of IVUS with standalone PCI where selective angiography has been performed in the previous 3 months</p> <p>The threshold of stenosis, defined as 50% of the lumen or more, does not meet the threshold specified in MBS explanatory note TR.8.4 for stable PCI indications (70%). A stenosis threshold should be identified in the item descriptor for patients with complex anatomical characteristics.</p> <p>In the item descriptor for patients with complex anatomical characteristics, the requirement to have suitability for PCI determined by a heart team should be removed.</p>
Clinical trial data- all populations	All trials were powered for composite outcomes and were unable to show statistically significant differences in cardiac mortality or myocardial infarction (MI) at any of the time points reported. Nonetheless ESC noted the effect of IVUS on MI was sustained over trial follow-up.
The evidence supporting the predominant use of IVUS (left main lesions)	The evidence provided for patients with left main lesions comprised two RCTs with low participant numbers, and only 2-year trial follow-up. Overall, the quality of evidence was considered very low.
Time horizon	<p>The time horizon was the main driver of the model; it has been changed to assume no incremental benefit of IVUS after 5 years, aligning with RCT evidence from one subpopulation (long lesions). Based on follow-up trial data from the evidence, the base case economic evaluation should assume no incremental benefit of IVUS after:</p> <ul style="list-style-type: none"> <li>• 3 years for all-comers</li> <li>• 2 years for patients with a left main lesion</li> <li>• 5 years for patients with long lesions.</li> </ul>
Transition probabilities for MI	Transition probabilities for MI after IVUS or angiography alone were taken from trials that reported no statistically significant between-group differences for this outcome. A more conservative approach – assuming no statistically significant difference in the rate of MI – is more appropriate in the base case model.
Rate of uptake and cost offsets	There is potential for the number of services to be greater than estimated, as uptake was based on conservative assumptions based on high capital outlay.
Out-of-pocket costs	The proposed services are unlikely to be bulk-billed and may incur significant out-of-pocket costs for patients. It is also unlikely that IVUS consumables will be included on the Protheses List (does not fit the criteria for Protheses Listing), so patients may also have to bear the cost of consumables for this service. Confirmation needs to be sought on how potential out-of-pocket costs will be managed.
Equity in access	Due to the additional training required for the proposed services, it is likely that IVUS will not be available in regional and rural centres.

## ESC discussion

ESC noted that this application was for Medicare Benefits Schedule (MBS) listing of intravascular ultrasound (IVUS) guided coronary stent insertion as an adjunct to invasive coronary angiogram for patients undergoing percutaneous coronary intervention (PCI). The service would be exclusively used in the catheterisation laboratory setting for the treatment of coronary artery disease.

ESC noted that there are 12 MBS items available for transluminal insertion of coronary stents, split according to whether PCI is performed within three months of selective coronary angiography (items 38316, 38317, 38319, 38320, 38322, 38323), or selective coronary angiography has not been completed in the previous three months (items 38307, 38308, 38310, 38311, 38313, 38314). Each category is then split based on whether patients meet the clinical indications for acute coronary syndrome or not, and how many vascular territories are treated.

ESC noted that there have been two previous applications to MSAC for IVUS. Application 1032 (2001) assessed IVUS as both a diagnostic and therapeutic tool for cardiac stent optimisation. ESC noted that this application was not supported by MSAC, as it deemed the clinical evidence and cost-effectiveness data to be insufficient. Application 1354 (2015) assessed IVUS as a therapeutic tool for optimisation of drug eluting stent (DES) or bare metal stent (BMS) placement. ESC noted that this application was not supported by MSAC due to wide and uncertain clinical effectiveness and cost-effectiveness estimates in the proposed patient populations. ESC noted that the current application is for the use of IVUS as a therapeutic tool.

ESC noted that there were two population group options included in the application: all-comers to PCI for DES insertion (i.e. all-comers; population 1); and an alternative option was patients with a coronary lesion with complex anatomical characteristics who would be eligible for DES insertion (population 2) with two subpopulations defined as either lesion length of 28 mm or more (i.e. long lesions) or left main coronary artery lesion (i.e. left main lesions).

ESC noted that there were two item descriptors proposed – one for each population group.

ESC noted that the proposed item descriptor for the all-comers population limited the use of IVUS to patients with significant stenoses, described as stenosis of 50% or more as defined by the diagnostic angiography. ESC considered that while a stenosis threshold of 50% may be appropriate for the left main lesion subpopulation, for other arteries this threshold is usually 70% (as described in MBS explanatory note TR.8.4 for stable PCI indications). However, the degree of vessel stenosis measured in two dimensions, alone, does not necessarily reflect the three-dimensional anatomy of the vessel (proposed to be determinable by IVUS) or consequent complexity of stent insertion. Therefore, despite the stenosis threshold of 50% mentioned in the proposed descriptor, IVUS could not be used unless the patient meets the stenosis threshold specified in explanatory note TR.8.4, which may be 70% depending on indication. ESC also noted that the proposed item descriptor for the all-comers population indicated a multiple services rule. ESC considered that this may be appropriate if IVUS was used as a diagnostic tool (category 2), but as it was proposed a therapeutic tool (category 3), the multiple operation rule would be more suitable.

ESC noted that the proposed item descriptor for patients with complex anatomical characteristics stated that suitability for PCI had to be appropriately determined by a heart team. ESC considered this to be an inappropriate inclusion, as the decision to perform PCI is made while the patient is on the operating table. ESC also noted that the proposed descriptor for the complex anatomical characteristics population did not include a stenosis threshold and considered that this should be added.

ESC considered that both item descriptors should state that the service is claimable once in a single episode of care (for one or more lesions). ESC also considered that the service should be restricted to accredited providers or those with specific training and noted the applicant's pre-ESC response stating that they could provide specific training programs, in combination with regular case teaching by senior in-hospital IVUS-experienced physicians, to ensure an adequate preparation of operators before the use of IVUS. ESC considered that input could be sought from the Cardiac Society of Australia and New Zealand (CSANZ) on certifying training programs, and how to conduct the training program in hospitals.

ESC noted that the Commentary raised concerns that the proposed MBS fee may need more justification, which is based on an existing item for coronary pressure wire used during selective coronary angiography. ESC agreed with the pre-ESC response that the use of a coronary pressure wire during selective coronary angiography to measure fractional flow reserve represents the most comparable interventions to the use of IVUS during invasive coronary angiogram and percutaneous angioplasty or transluminal insertion of stents, both in terms of complexity and time.

ESC also noted that the proposed services are unlikely to be bulk-billed and may incur significant out-of-pocket costs for patients (approximately 20% of the estimated MBS fee). ESC noted that the patient may bear the estimated cost of consumables (between \$1,000 and \$1,500), particularly of the single-use catheter, as the catheter does not satisfy the criteria for listing on the Protheses List (PL). In addition, the Department is unaware that there is an intent to make imaging catheters or consumables eligible for listing on the PL.

ESC noted that there was no consultation feedback received for this application. ESC discussed issues for consumers such as the risk of out-of-pocket costs due to the uncertainty with who will pay for the IVUS consumables. Thus, ESC considered the applicant should seek to clarify who will pay for the IVUS consumables.

ESC also noted the potential issues around equity of access, due to the additional training required for the proposed services, it is likely that IVUS will not be available in regional and rural centres. Also, ESC confirmed that the proposed services can only be provided in-hospital, which may perpetuate issues with access.

ESC noted that the safety and effectiveness outcomes outlined in the PICO were the same for both populations. ESC noted that the effectiveness outcomes were target vessel failure (TVF) or major adverse cardiac events (MACE), including cardiac death, target-vessel myocardial infarction (MI), and clinically driven target vessel revascularisation (TLR). ESC considered that the safety outcome stent thrombosis (ST) was reasonable.

ESC noted that the clinical claim for both population groups was that IVUS had superior effectiveness and non-inferior safety compared to guidance with angiography without IVUS.

ESC noted that since the previous submission in 2015, there have been five RCTs (with extended follow-up) published that support the use of IVUS in the proposed patient populations– all demonstrated that IVUS-guided PCI is associated with reduced risk of MI and death, but differences between arms did not reach statistical significance. Nonetheless ESC noted the new evidence showed that the effect of IVUS on MI was sustained over trial follow-up. ESC noted that these results was supported by a published meta-analysis, a real-world study, and a large-scale, prospective, multicentre, nonrandomised all-comers study.

ESC noted that for the all-comers population, the main source of data was the ULTIMATE trial<sup>17</sup>, which was a multicentre RCT comprising around 1,500 patients but limited to one country (China). ESC noted that there were some concerns raised in the commentary about the potential risk of selection bias of the ULTIMATE trial. ESC acknowledged this concern, but also considered this risk could be low because participants were randomised using a valid, although old-fashioned, method. ESC considered that it is difficult to eliminate risk of performance bias in an ethical way, as patients and centres cannot be blinded from knowing that they are receiving IVUS.

ESC noted further concerns raised in the commentary that the population in the ULTIMATE trial included relatively high-risk patients with complex coronary lesions and was not comparable to PCI all-comers in Australia. The commentary stated that subgroup analyses suggest that high-risk patients and those with complex PCI receive the greatest benefit from IVUS, so the trial may overestimate the efficacy of IVUS in Australian practice. ESC acknowledged this concern, and also considered that the results from the trial had well-defined clinical outcomes that reflect high-volume centres, and then the findings may be applicable to what would be found in high-volume centres in Australia. ESC also considered the high incidence of adverse outcomes reported from the ULTIMATE trial would be expected in high-volume centres. ESC considered this population may not be representative of all comers as they would be referred from low throughput centres to high throughput centres for speciality care.

ESC noted that the ULTIMATE trial had 1- and 3-year follow-up data, which ESC noted the commentary considered the quality of evidence to be moderate. ESC noted that these data showed the use of IVUS improved outcomes for TVF over all timepoints, TLR (at 3 years) and ST (at 2-3 years) when compared to angiography alone.

ESC noted that for the long lesion subpopulation, the evidence comprised two RCTs and a meta-analysis. ESC noted that the meta-analysis was not included in the economic analysis. ESC noted that the two RCTs were both open label studies and limited to one country (South Korea), but one study (the IVUS-XPL trial<sup>18</sup>) was multicentred. ESC noted the quality of the evidence was low for all outcomes. ESC noted that the 1- and 5-year follow-up results showed an approximate 50% reduction in MACE, but no difference in the incidence of ST; however, ESC noted that the number of study participants with ST was low.

ESC noted that for the left main lesion subpopulation, the evidence comprised two RCTs. ESC noted that in Australia, IVUS is predominantly used in this indication. ESC noted that the 1- and 2-year follow-up data showed that the addition of IVUS in PCI improved incidences of MACE, TLR and ST; however, the number of participants for both studies was small, the quality of evidence was considered very low, and the improvements were not significant (except results for MACE at 1 year in Liu 2019).

ESC noted that, according to the 2021 Guideline for Coronary Artery Revascularization by the American College of Cardiology and American Heart Association<sup>19</sup>, IVUS is recommended as a class 2a (moderate) procedure, where the benefits are likely exceeding the risks. The guidelines recommend that:

---

<sup>17</sup> Zhang J, Gao X, Kan J, Ge Z, Han L, Lu S et al. (2018). Intravascular ultrasound versus angiography-guided drug-eluting stent implantation: the ULTIMATE trial. *J Am Coll Cardiol*, **72**(24):3126-3137.

<sup>18</sup> Hong SJ, Kim BK, Shin DH, Nam CM, Kim JS, Ko YG et al. (2015). Effect of intravascular ultrasound-guided vs angiography-guided everolimus-eluting stent implantation: the IVUS-XPL randomized clinical trial. *JAMA*, **314**(20):2155-2163.

<sup>19</sup> American College of Cardiology and American Heart Association Joint Committee on Clinical Practice Guidelines (2022). 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization. *JACC*, **79**(2):e21-e129.

- in patients undergoing coronary stent implantation, IVUS can be useful for procedural guidance, particularly in cases of left main or complex coronary artery stenting, to reduce ischemic events (based on moderate-quality evidence from 1 or more randomised control trials [RCTs])
- in patients with stent failure, IVUS (or optical coherence tomography) is reasonable to determine the mechanism of stent failure (based on limited data from randomised or nonrandomised observational or registry studies, or physiological or mechanistic studies in humans).

ESC noted that the population with complex anatomical characteristics, and in particular left main lesions subpopulation is supported by these clinical guidelines.

ESC noted that the economic evaluation included a cost-utility analysis to model the cost-effectiveness of IVUS in each population group, which ESC considered to be appropriate. ESC noted that there had been several changes made to the economic evaluation since the 2015 application and, overall, it had become more conservative – ESC considered this to be appropriate. Changes included:

- the comparator being modified to remove BMS, aligning it with clinical practice and evidence
- the time horizon in the base case model being changed to assume no incremental benefit of IVUS after 5 years, aligning with RCT evidence from one subpopulation. ESC considered that:
  - for the all-comers population, it may be appropriate to assume no incremental benefit beyond 3 years, based on follow-up data from the ULTIMATE trial<sup>20</sup>
  - for the left main lesions subpopulation, it may be appropriate to assume no incremental benefit beyond 2 years, based on follow-up data from Tan et al. (2015)<sup>21</sup>
  - for the long lesions subpopulation, no incremental benefit beyond 5 years is reasonable, based on follow-up data from the IVUS-XPL trial<sup>22</sup>
  - the pre-ESC response stated that there is no clinical reason as to why the effectiveness would not be maintained in all groups; however, given that the time horizon is the main driver of the model, ESC considered a conservative estimate to be more appropriate in the base case models.
- revascularisation events being restricted to TLR data from RCTs, due to a lack of clarity around definitions of different revascularisation events
- the transitions between health states being derived from event rates from the IVUS and angiography arms of RCTs
- the transition between health states from post-MI to post-TLR being removed to align with RCT evidence
- all-cause and event-specific mortality being updated to reflect progressions in standard practice (no mortality between treatment arms).

ESC noted that, similar to the 2015 application, a Markov model was used.

---

<sup>20</sup> Gao XF, Ge Z, Kong XQ, Kan J, Han L et al. (2021). 3-year outcomes of the ULTIMATE trial comparing intravascular ultrasound versus angiography-guided drug-eluting stent implantation. *JACC Cardiovasc Interv*, **14**(3):247-257.

<sup>21</sup> Tan Q, Wang Q, Liu D, Zhang S, Zhang Y, Li Y (2015). Intravascular ultrasound-guided unprotected left main coronary artery stenting in the elderly. *Saudi Med J*, **36**(5):549-553.

<sup>22</sup> Hong SJ, Mintz GS, Ahn CM, Kim JS, Kim BK, Ko YG et al. (2020). Effect of intravascular ultrasound-guided drug-eluting stent implantation: 5-year follow-up of the IVUS-XPL randomized trial. *JACC Cardiovasc Interv*, **13**(1):62-71.

ESC noted that transition probabilities for MI after IVUS or angiography alone were taken from trials that reported no statistically significant between-group differences for this outcome. ESC noted the pre-ESC response stating that because the rate of MI is of high clinical significance it should be captured in the model. ESC considered the real-world study (Mentias et al. [2020]<sup>23</sup>) which was one of the studies used to support the effect of IVUS on mortality (and also cited in the pre-ESC response). ESC noted the baseline characteristics of the participants in the study, which used American Medicare data, suggested that the intervention group had sicker patients with more co-morbidities and prior treatment. However, ESC noted that the sicker patients had a higher rate of stable disease, lower rates of MI, and much higher rates of complex coronary intervention. The results showed statistically significant lower MI with IVUS, even before propensity score matching. ESC considered that the underlying differences between the groups in the study introduced a potential for bias. Overall, ESC considered that using a more conservative approach – assuming no statistically significant difference in the rate of MI – was more appropriate in the base case model.

ESC noted that the commentary adjusted the economic analysis to align with the trial-based evidence of follow-up for each population, creating the revised base case:

- For the all-comers population, ESC noted that assuming a 3-year incremental benefit and no statistically significant difference in the rate of MI increased the ICER estimates from \$16,317 to \$67,149 (for the lifetime time horizon).
- For the complex anatomical characteristics population, assuming a 2-year incremental benefit for left main lesions, a 5-year incremental benefit for long lesions, and no statistically significant difference in the rate of MI increased the overall ICER from \$17,873 to \$32,425 (for the lifetime horizon).

ESC considered the commentary's revised base case estimates were the appropriate base case for MSAC consideration. ESC noted the ICER for the all-comers population was highly sensitive to this model change but remained below \$50,000 per QALY for the complex anatomical characteristics population.

ESC noted that the time horizon was the main driver of the model. ESC also noted that including the incremental benefit of MI in the sensitivity analysis decreased the ICER for both populations, demonstrating why the applicant felt it was important to include it in the model.

ESC noted commentary concerns about a lack of interrogation of the source of utilities. ESC agreed this would have been ideal; however, in this case omitting this was reasonable, given the revised utility weight estimates were more conservative than the previous submission, and not a main driver of the model.

ESC noted that the estimated financial and budgetary impacts remained largely unchanged from the previous application. ESC noted that the estimated MBS costs (up to a total of approximately \$4 million in 2026) comprise around 25% of the overall financial costs. ESC considered the cost of IVUS capital and consumables (a disposable imaging catheter, a mini transducer and a console), estimated to be between \$1,000 and \$1,500 per procedure, to be high, noting that the applicant-developed assessment report (ADAR) did not provide a breakdown for this cost.

ESC noted that the financial implications were based on 77 hospitals (including 30 private hospitals) that currently use IVUS, and assumed that, because of the cost of the generator (\$redacted with an 8-year life span), the uptake will be no more than five new hospitals per year. ESC noted concerns raised in the commentary about the estimated uptake of the service; ESC

---

<sup>23</sup> Mentias A, Sarrazin MV, Saad M, Panaich S, Kapadia S, Horwitz PA et al. (2020). Long-term outcomes of coronary stenting with and without use of intravascular ultrasound. *JACC Cardiovasc Interv*, **13**(16):1880-1890.

considered there was potential for the number of services to be greater than estimated, as uptake was based on conservative assumptions based on high capital outlay. In addition, ESC noted that the financial analysis did not include cost offsets to the MBS (reduced services for revascularisations) or the Pharmaceutical Benefits Scheme (reduced medical treatments) compared with the economic evaluation incorporating cost offsets through reduced revascularisation and MI in the IVUS-guided arm.

## **17. Applicant comments on MSAC's Public Summary Document**

The Applicant is pleased with the decision by the MSAC to recommend listing of IVUS in patients with complex anatomical characteristics.

## **18. Further information on MSAC**

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



# Appendix A – MBS items for percutaneous coronary stent insertion

## MBS items for PCI with coronary stenting (12 items)

Category 3 – THERAPEUTIC PROCEDURES
<p><b>MBS 38307</b></p> <p>Note: (acute coronary syndrome - 1 coronary territory with selective coronary angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.2 and TR.8.5</p> <p>Percutaneous coronary intervention:</p> <p>(a) for a patient:</p> <ul style="list-style-type: none"> <li>(i) eligible for the service under clause 5.10.17A; and</li> <li>(ii) for whom selective coronary angiography has not been completed in the previous 3 months; and</li> </ul> <p>(b) including selective coronary angiography and all associated imaging, catheter and contrast; and</p> <p>(c) including either or both:</p> <ul style="list-style-type: none"> <li>(i) percutaneous angioplasty;</li> <li>(ii) transluminal insertion of one or more stents; and</li> </ul> <p>(d) performed on one coronary vascular territory; and</p> <p>(e) excluding aftercare;</p> <p>other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.)f</p> <p>Fee: \$1,844.60 Benefit: 75% = \$1,383.45 85% = \$1,759.90</p> <p>(See para TN.8.217, TN.8.225, TR.8.2, TR.8.5 of explanatory notes to this Category)</p>
Category 3 – THERAPEUTIC PROCEDURES
<p><b>MBS 38308</b></p> <p>Note: (acute coronary syndrome - 2 coronary territories with selective coronary angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.2 and TR.8.5</p> <p>Percutaneous coronary intervention:</p> <p>(a) for a patient:</p> <ul style="list-style-type: none"> <li>(i) eligible for the service under clause 5.10.17A; and</li> <li>(ii) for whom selective coronary angiography has not been completed in the previous 3 months; and</li> </ul> <p>(b) including selective coronary angiography and all associated imaging, catheter and contrast; and</p> <p>(c) including either or both:</p> <ul style="list-style-type: none"> <li>(i) percutaneous angioplasty; and</li> <li>(ii) transluminal insertion of one or more stents; and</li> </ul> <p>(d) performed on 2 coronary vascular territories; and</p> <p>(e) excluding aftercare;</p> <p>other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies</p> <p>Multiple Operation Rule (Anaes.) (Assist.)</p> <p>Fee: \$2,122.25 Benefit: 75% = \$1,591.70 85% = \$2,037.55</p> <p>(See para TN.8.217, TN.8.225, TR.8.2, TR.8.5 of explanatory notes to this Category)</p>
Category 3 – THERAPEUTIC PROCEDURES
<p><b>MBS 38310</b></p> <p>Note: (acute coronary syndrome - 3 coronary territories with selective coronary angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.2 and TR.8.5</p> <p>Percutaneous coronary intervention:</p> <p>(a) for a patient:</p> <ul style="list-style-type: none"> <li>(i) eligible for the service under clause 5.10.17A; and</li> <li>(ii) for whom selective coronary angiography has not been completed in the previous 3 months; and</li> </ul> <p>(b) including selective coronary angiography and all associated imaging, catheter and contrast; and</p> <p>(c) including either or both:</p> <ul style="list-style-type: none"> <li>(i) percutaneous angioplasty; and</li> <li>(ii) transluminal insertion of one or more stents; and</li> </ul>

(d) performed on 3 coronary vascular territories; and  
 (e) excluding aftercare;  
 other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies  
 Multiple Operation Rule  
 (Anaes.) (Assist.)  
 Fee: \$2,399.90 Benefit: 75% = \$1,799.95 85% = \$2,315.20  
 (See para TN.8.217, TN.8.225, TR.8.2, TR.8.5 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38311**

Note: (stable multi-vessel disease - 1 coronary territory with selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.4 and TR.8.5

Percutaneous coronary intervention:

- (a) for a patient:
  - (i) eligible under clause 5.10.17C for the service and a service to which item 38314 applies; and
  - (ii) for whom selective coronary angiography has not been completed in the previous 3 months; and
- (b) including selective coronary angiography and all associated imaging, catheter and contrast; and
- (c) including either or both:
  - (i) percutaneous angioplasty; and
  - (ii) transluminal insertion of one or more stents; and

(d) performed on one coronary vascular territory; and  
 (e) excluding aftercare;  
 other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies

Multiple Operation Rule  
 (Anaes.) (Assist.)

Fee: \$1,844.60 Benefit: 75% = \$1,383.45 85% = \$1,759.90  
 (See para TN.8.218, TN.8.226, TR.8.4, TR.8.5, TR.8.6 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38313**

Note: (stable multi-vessel disease - 2 coronary territories with selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.4 and TR.8.5

Percutaneous coronary intervention:

- (a) for a patient:
  - (i) eligible under clause 5.10.17C for the service and a service to which item 38314 applies; and
  - (ii) for whom selective coronary angiography has not been completed in the previous 3 months; and
- (b) including selective coronary angiography and all associated imaging, catheter and contrast; and
- (c) including either or both:
  - (i) percutaneous angioplasty; and
  - (ii) transluminal insertion of one or more stents; and

(d) performed on 2 coronary vascular territories; and  
 (e) excluding aftercare;  
 other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies

Multiple Operation Rule  
 (Anaes.) (Assist.)

Fee: \$2,122.25 Benefit: 75% = \$1,591.70 85% = \$2,037.55  
 (See para TN.8.218, TN.8.226, TR.8.4, TR.8.5, TR.8.6 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38314**

Note: (stable multi-vessel disease - 3 coronary territory with selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.4 and TR.8.5

Percutaneous coronary intervention:

- (a) for a patient:
  - (i) eligible for the service under clause 5.10.17C; and
  - (ii) for whom selective coronary angiography has not been completed in the previous 3 months; and
- (b) including selective coronary angiography and all associated imaging, catheter and contrast; and
- (c) including either or both:
  - (i) percutaneous angioplasty; and

(ii) transluminal insertion of one or more stents; and  
 (d) performed on 3 coronary vascular territories; and  
 (e) excluding aftercare;  
 other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38316, 38317, 38319, 38320, 38322 or 38323 applies  
 Multiple Operation Rule  
 (Anaes.) (Assist.)  
 Fee: \$2,399.90 Benefit: 75% = \$1,799.95 85% = \$2,315.20  
 (See para TN.8.218, TN.8.219, TN.8.226, TR.8.4, TR.8.5, TR.8.7 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38316**  
 Note: (acute coronary syndrome - 1 coronary territory without selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.2 and TR.8.5  
 Percutaneous coronary intervention:  
 (a) for a patient:  
     (i) eligible for the service under clause 5.10.17A; and  
     (ii) for whom selective coronary angiography has been completed in the previous 3 months; and  
 (b) including any associated coronary angiography; and  
 (c) including either or both:  
     (i) percutaneous angioplasty; and  
     (ii) transluminal insertion of one or more stents; and  
 (d) performed on one coronary vascular territory; and  
 (e) excluding aftercare;  
 other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38317, 38319, 38320, 38322 or 38323 applies  
 Multiple Operation Rule  
 (Anaes.) (Assist.)  
 Fee: \$1,648.95 Benefit: 75% = \$1,236.75 85% = \$1,564.25  
 (See para TN.8.217, TN.8.225, TR.8.2, TR.8.5 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38317**  
 Note: (acute coronary syndrome - 2 coronary territories without selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.2 and TR.8.5  
 Percutaneous coronary intervention:  
 (a) for a patient:  
     (i) eligible for the service under clause 5.10.17A; and  
     (ii) for whom selective coronary angiography has been completed in the previous 3 months; and  
 (b) including any associated coronary angiography; and  
 (c) including either or both:  
     (i) percutaneous angioplasty; and  
     (ii) transluminal insertion of one or more stents; and  
 (d) performed on 2 coronary vascular territories; and  
 (e) excluding aftercare;  
 other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 3808, 38310, 38311, 38313, 38314, 38316, 38319, 38320, 38322 or 38323 applies  
 Multiple Operation Rule  
 (Anaes.) (Assist.)  
 Fee: \$2,088.80 Benefit: 75% = \$1,566.60 85% = \$2,004.10  
 (See para TN.8.217, TN.8.225, TR.8.2, TR.8.5 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38319**  
 Note: (acute coronary syndrome - 3 coronary territories without selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.2 and TR.8.5  
 Percutaneous coronary intervention:  
 (a) for a patient:  
     (i) eligible for the service under clause 5.10.17A; and  
     (ii) for whom selective coronary angiography has been completed in the previous 3 months; and  
 (b) including any associated coronary angiography; and  
 (c) including either or both:

(i) percutaneous angioplasty; and  
(ii) transluminal insertion of one or more stents; and  
(d) performed on 3 coronary vascular territories; and  
(e) excluding aftercare;  
other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38320, 38322 or 38323 applies  
Multiple Operation Rule  
(Anaes.) (Assist.)  
Fee: \$2,366.45 Benefit: 75% = \$1,774.85 85% = \$2,281.75  
(See para TN.8.217, TN.8.225, TR.8.2, TR.8.5 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38320**  
Note: (stable multi-vessel disease - 1 coronary territory without selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.4 and TR.8.5  
Percutaneous coronary intervention:  
(a) for a patient:  
(i) eligible under clause 5.10.17C for the service and a service to which item 38323 applies; and  
(ii) for whom selective coronary angiography has been completed in the previous 3 months; and  
(b) including any associated coronary angiography; and  
(c) including either or both:  
(i) percutaneous angioplasty; and  
(ii) transluminal insertion of one or more stents; and  
(d) performed on one coronary vascular territory; and  
(e) excluding aftercare;  
other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38322 or 38323 applies  
Multiple Operation Rule  
(Anaes.) (Assist.)  
Fee: \$1,648.95 Benefit: 75% = \$1,236.75 85% = \$1,564.25  
(See para TN.8.218, TN.8.226, TR.8.4, TR.8.5, TR.8.6 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38322**  
Note: (stable multi-vessel disease - 2 coronary territories with selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.4 and TR.8.5  
Percutaneous coronary intervention:  
(a) for a patient:  
(i) eligible under clause 5.10.17C for the service and a service to which item 38323 applies; and  
(ii) for whom selective coronary angiography has been completed in the previous 3 months; and  
(b) including any associated coronary angiography; and  
(c) including either or both:  
(i) percutaneous angioplasty; and  
(ii) transluminal insertion of one or more stents; and  
(d) performed on 2 coronary vascular territories; and  
(e) excluding aftercare;  
other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320 or 38323 applies  
Multiple Operation Rule  
(Anaes.) (Assist.)  
Fee: \$2,088.80 Benefit: 75% = \$1,566.60 85% = \$2,004.10  
(See para TN.8.218, TN.8.226, TR.8.4, TR.8.5, TR.8.6 of explanatory notes to this Category)

**Category 3 – THERAPEUTIC PROCEDURES**

**MBS 38323**  
Note: (stable multi-vessel disease - 3 coronary territories with selective angiography) the service only applies if the patient meets the requirements of the descriptor and the requirements of Note: TR.8.4 and TR.8.5  
Percutaneous coronary intervention:  
(a) for a patient:  
(i) eligible for the service under clause 5.10.17C; and  
(ii) for whom selective coronary angiography has been completed in the previous 3 months; and  
(b) including any associated coronary angiography; and

(c) including either or both:

- (i) percutaneous angioplasty; and
- (ii) transluminal insertion of one or more stents; and

(d) performed on 3 coronary vascular territories; and

(e) excluding aftercare;

other than a service associated with a service to which item 38200, 38203, 38206, 38244, 38247, 38248, 38249, 38251, 38252, 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320 or 38322 applies

Multiple Operation Rule  
(Anaes.) (Assist.)  
Fee: \$2,366.45 Benefit: 75% = \$1,774.85 85% = \$2,281.75  
(See para TN.8.218, TN.8.219, TN.8.226, TR.8.4, TR.8.5, TR.8.7 of explanatory notes to this Category)

## MBS item for transluminal rotational atherectomy

Category 3 – THERAPEUTIC PROCEDURES
<p><b>MBS 38309</b> Percutaneous transluminal rotational atherectomy of one or more coronary arteries, including all associated imaging, if:</p> <p>(a) the target stenosis within at least one coronary artery is heavily calcified and balloon angioplasty with or without stenting is not feasible without rotational atherectomy; and</p> <p>(b) the service is performed in conjunction with a service to which item 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322 or 38323 applies</p> <p>Applicable only once on each occasion the service is performed</p> <p>Multiple Operation Rule (Anaes.) (Assist.) <b>Fee:</b> \$1,250.70 <b>Benefit:</b> 75% = \$938.05 85% = \$1,166.00 (See para TN.8.222 of explanatory notes to this Category)</p>

## Explanatory notes with indications for transluminal stent insertion or rotational atherectomy

Category 3 – THERAPEUTIC PROCEDURES
<p><b>TR.8.2</b></p> <p style="text-align: center;"><b>Selective Coronary Angiography Indications</b></p> <p>Clause 5.10.17A Items 38244, 38247, 38307, 38308, 38310, 38316, 38317 and 38319—patient eligibility and timing</p> <p>(1) A patient is eligible for a service to which item 38244, 38247, 38307, 38308, 38310, 38316, 38317 or 38319 applies if:</p> <ul style="list-style-type: none"> <li>(a) subclause (2) applies to the patient; and</li> <li>(b) a service to which the item applies has not been provided to the patient in the previous 3 months, unless: <ul style="list-style-type: none"> <li>(i) the patient experiences a new acute coronary syndrome or angina, as described in paragraph (2)(a), (b) or (c), in that period; or</li> <li>(ii) for a service to which item 38316, 38317 or 38319 applies—the service was provided to the patient in that period as a subsequent stage following an initial primary percutaneous coronary intervention procedure.</li> </ul> </li> </ul> <p>(2) This subclause applies to a patient who has:</p> <ul style="list-style-type: none"> <li>(a) an acute coronary syndrome evidenced by any of the following: <ul style="list-style-type: none"> <li>(i) ST segment elevation;</li> <li>(ii) new left bundle branch block;</li> <li>(iii) troponin elevation above the local upper reference limit;</li> <li>(iv) new resting wall motion abnormality or perfusion defect;</li> <li>(v) cardiogenic shock;</li> <li>(vi) resuscitated cardiac arrest;</li> <li>(vii) ventricular fibrillation;</li> <li>(viii) sustained ventricular tachycardia; or</li> </ul> </li> <li>(b) unstable angina or angina equivalent with a crescendo pattern, rest pain or other high-risk clinical features, such as hypotension, dizziness, pallor, diaphoresis or syncope occurring at a low threshold; or</li> <li>(c) either of the following, detected on computed tomography coronary angiography: <ul style="list-style-type: none"> <li>(i) significant left main coronary artery disease with greater than 50% stenosis or a cross-sectional area of less than 6 mm<sup>2</sup>;</li> </ul> </li> </ul>

(ii) severe proximal left anterior descending coronary artery disease (with stenosis of more than 70% or a cross-sectional area of less than 4 mm<sup>2</sup> before the first major diagonal branch).

Related Items: **38244 38247 38307 38308 38310 38316 38317 38319 57364**

**TR.8.4**

**Stable - Percutaneous Coronary Intervention Indications**

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

- (1) A patient is eligible for a service to which item 38311, 38313, 38314, 38320, 38322 or 38323 applies if:
- (a) subclause (2) applies to the patient; or
  - (b) the patient is recommended for the service as a result of a heart team conference that meets the requirements of subclause (4).
- (2) This subclause applies to a patient if:
- (a) the patient has any of the following:
    - (i) limiting angina or angina equivalent despite an adequate trial of optimal medical therapy;
    - (ii) myocardial ischaemia demonstrated on functional imaging;
    - (iii) high risk features such as ST segment elevation, sustained ST depression, hypotension or a Duke treadmill score of minus 11 or less, demonstrated by stress electrocardiogram testing; and
  - (b) the patient has either of the following in a vascular territory treated:
    - (i) a stenosis of 70% or more;
    - (ii) a fractional flow reserve of 0.80 or less, or non-hyperaemic pressure ratios distal to the lesions of 0.89 or less; and
  - (c) for items 38314 and 38323—either:
    - (i) the patient does not have diabetes mellitus and the multi-vessel coronary artery disease of the patient meets the criterion in subclause (3); or
    - (ii) despite a recommendation that surgery is preferable, the patient has expressed a preference for catheter-based intervention.
- (3) For the purposes of subparagraph (2)(c)(i), the criterion for the multi-vessel coronary artery disease is that the disease does not involve any of the following:
- (a) stenosis of more than 50% in the left main coronary artery;
  - (b) bifurcation lesions involving side branches with a diameter of more than 2.75 mm;
  - (c) chronic vessel occlusions for more than 3 months;
  - (d) severely angulated or calcified lesions;
  - (e) a SYNTAX score of more than 23.
- (4) For the purposes of paragraph (1)(b), the requirements for a heart team conference are as follows:
- (a) the conference must be conducted by a team of specialists or consultant physicians practising in the speciality of cardiology or cardiothoracic surgery, including each of the following:
    - (i) an interventional cardiologist;
    - (ii) a specialist or consultant physician;
    - (iii) for items 38314 and 38323—a cardiothoracic surgeon;
    - (iv) for items 38311, 38313, 38320 and 38322—a cardiothoracic surgeon or a non-interventional cardiologist; and
  - (b) the team must:
    - (i) assess the patient's risk and technical suitability to receive the service; and
    - (ii) make a recommendation about whether or not the patient is suitable for percutaneous coronary intervention; and
  - (c) a record of the conference must be created, and must include the following:
    - (i) the particulars of the assessment of the patient during the conference;
    - (ii) the recommendations made as a result of the conference;
    - (iii) the names of the members of the team making the recommendations.

Related Items: **38311 38313 38314 38320 38322 38323**

**TN.8.222**

**Indications for Percutaneous transluminal coronary rotational atherectomy**

Percutaneous transluminal coronary rotational atherectomy is suitable for revascularisation of stenoses in heavily calcified coronary arteries in the absence of significant lesion angulation or vessel tortuosity in patients for whom coronary artery bypass graft surgery is not indicated.

Item 38309 describes an episode of care and can only be claimed once in a single episode.

Related Items: **38309**

## Explanatory notes with staging rules and disease definitions

Category 3 – THERAPEUTIC PROCEDURES	
<b>TN.8.217</b>	<b>Staging rules for PCI for acute</b>
<b>Staging</b>	<ul style="list-style-type: none"><li>• If a staged procedure is appropriately performed over multiple days, items 38316, 38317 or 38319 must be used for subsequent stages.</li><li>• For subsequent stages of an acute percutaneous coronary intervention completed up to 3 months after the initial procedure, it is expected that the patient would receive the subsequent stage/s of the intervention based on the qualifying indication for the initial procedure</li></ul>
<b>Vascular Territories</b>	<ul style="list-style-type: none"><li>• The item number claimed should reflect the number of coronary vascular territories (Left Anterior Descending, Circumflex or Right Coronary Artery distribution) that are treated during the procedure, not the total number of treated territories the patient has received to date.</li><li>• For isolated Left Main (no involvement of the bifurcation), a single territory should be claimed but if the treated segment involves the bifurcation then 2 territories should be claimed.</li><li>• The Intermediate Artery when treated in isolation is single territory, when treated with the Left Anterior Descending or Circumflex or both, should be claimed as two territories.</li><li>• A single lesion in a bypass graft should be claimed as single territory regardless of how many vascular territories are supplied by that graft. If the graft has multiple lesions and those lesions are in separate skip portions to a different territory, then an additional territory may be claimed.</li></ul>
Related Items: 38307 38308 38310 38316 38317 38319	
<b>TN.8.218</b>	<b>Percutaneous Coronary Intervention (PCI) for stable patients</b>
<b>Stable Angina or Angina Equivalent</b>	<ul style="list-style-type: none"><li>• Stable angina or angina equivalent includes chest pain, chest discomfort and/or shortness of breath due to myocardial ischaemia.</li><li>• Limiting angina includes patients with symptoms that are Canadian Cardiovascular Society (CCS) class II, III or IV.</li></ul>
<b>Staging</b>	<ul style="list-style-type: none"><li>• If a staged procedure is appropriately performed over multiple days, items 38320, 38322 or 38323 should be used for subsequent stages.</li><li>• For subsequent stages of a stable percutaneous coronary intervention completed up to 3 months after the initial procedure, it is expected that the patient would receive the subsequent stage/s of the intervention based on the qualifying indication for the initial procedure</li></ul>
<b>Coronary Vascular Territories</b>	<ul style="list-style-type: none"><li>• The item number claimed should reflect the number of coronary vascular territories (Left Anterior Descending, Circumflex or Right Coronary Artery distribution) that are treated during the procedure, not the total number of treated territories the patient has received to date.</li><li>• The number of coronary vascular territory refers to any of the 3 major arteries (Left Anterior Descending, Circumflex or Right Coronary Artery) or their branches. The item number claimed should reflect the number of coronary vascular territories that are treated during the procedure, not the total number of diseased territories.</li><li>• For isolated Left Main (no involvement of the bifurcation), a single territory should be claimed but if the treated segment involves the bifurcation then 2 territories should be claimed.</li><li>• The immediate artery when treated in isolation is considered a single territory, however when treated with the Left Anterior Descending or Circumflex or both, it can be claimed as two territories.</li><li>• A single lesion in a bypass graft should be claimed as a single territory regardless of how many vascular territories are supplied by that graft. If the graft has multiple lesions and those lesions are in separate skip portions to a different territory, then an additional territory may be claimed.</li></ul>
Related Items: 38311 38313 38314 38320 38322 38323	
<b>TN.8.219</b>	<b>Complex coronary artery disease definition</b>
<b>Complex Coronary Artery Disease</b>	<p>Complex coronary artery disease is defined as</p> <ol style="list-style-type: none"><li>a. a stenosis &gt;50% in the left main coronary artery; or</li><li>b. &gt;90% in the proximal left anterior coronary artery; or</li><li>c. bifurcation lesions involving side branches with a diameter &gt;2.75mm; or</li><li>d. chronic vessel occlusions (&gt;3 months); or</li><li>e. severely angulated or severely calcified lesions; or</li><li>f. SYNTAX score &gt;23.</li></ol>
Such disease should only undergo PCI with a documented recommendation from a Heart Team Conference.	
Related Items: 38314 38323	

## **TN.8.225**

### **Percutaneous Coronary Intervention (PCI) Acute/Unstable**

#### **Staging of acute/unstable PCI**

- Staging of acute PCI is permissible when clinically appropriate.
- An example of appropriate Acute Coronary Syndrome (ACS) staging could include intervention on an occluded proximal lesion in the context of an ST elevation myocardial infarction (STEMI) and a decision is made not to intervene on a distal lesion as it is difficult to determine whether it is a real lesion (possibly a thrombus) or the patient's haemodynamic status remains compromised (clinically unsafe to continue).

#### **Requirements of subsequent stages of a staged acute/unstable PCI**

- The qualifying indication for the initial procedure is to be used as the qualifier for the relevant subsequent stages.
- Subsequent stages are required to be completed within 3 months of the initial procedure otherwise the patient will need to requalify under the appropriate indication (if applicable).
- It would generally be expected that subsequent stages would be completed as soon as is practicable proceeding the initial intervention.
- For subsequent stages of an acute/unstable PCI it is implied that diagnostic angiography has been completed in the previous 3 months and therefore it is only permissible to claim items 38316, 38317 or 38319 for subsequent stages.

#### **Multiple Providers of one episode of care (acute/unstable or stable) PCI – Separate interventional sites or Same interventional site**

One of the primary intentions of the changes to selective coronary angiography and PCI items, is to encourage the provision of the entire intervention in a single episode of care. Therefore, the provider should consider that there will be a reasonable need to intervene (revascularise), noting that in some cases intervention is not required (e.g. pressure testing – FFR result does not support the need for stenting).

However, it is recognised that some providers of interventional cardiology services only provide selective coronary angiography (diagnostic) and require a secondary provider to undertake angioplasty, stenting and/or atherectomy.

#### **Non-interventional – selective angiography providers (clinical assessment suggests intervention required)**

##### *Acute/Unstable patients*

- Acute/Unstable patients should undergo both selective coronary angiography and PCI by an accredited PCI provider in a single episode of care, unless staging is clinically required.
- Rare exceptions might include rural or remote sites that offer diagnostic angiography as a triage service prior to limited availability PCI.
- It would be expected that the non-interventional cardiologist (non-PCI accredited) has a limited role in the management of acute/unstable patients.

#### **Separate hospital/procedural sites (Acute/Unstable or Stable)**

- The first provider undertakes the diagnostic angiography and either makes an independent decision or following discussion with the interventional cardiologist refers to the secondary provider at another site for the purposes of revascularisation (e.g. referral from a rural or regional hospital to a metropolitan hospital); therefore
- In this scenario there is a clear delineation between the angiography and revascularisation services due to the different geographical locations (separate episodes of care). Example claiming is as follows:

##### *Acute (ACS) - claiming example*

- Provider 1 – site 1 (diagnostic angiography) claims item 38244 (ACS – selective angiography). Provider 2 – site 2 (PCI) claims item 38316 (ACS – PCI single territory)

#### **Abandoned T8 Surgical Procedures and Acute or Stable Percutaneous Coronary Intervention (PCI) – Excluding appropriate staging**

The new acute PCI items have time restrictions applied whether claimed by the same or different providers. It is important for the patient that if a provider cannot complete (abandoned) the PCI and rescue PCI needs to be conducted by another provider, item 30001 is claimed. This will allow claiming by the provider who subsequently completes the rescue PCI, taking into consideration the time restrictions for each of the selective angiography items.

The new stable PCI items do not have time restrictions. However, it is important for the patient that if a provider cannot complete (abandoned) the PCI and rescue PCI needs to be conducted by another provider, item 30001 is claimed. This will allow claiming by the provider who subsequently completes the rescue PCI, taking into consideration the time restrictions for each of the selective angiography items.

Related Items: 38307 38308 38310 38316 38317 38319

## **TN.8.226**

### **Staging Rules for Stable PCI**

#### **Staging of non-acute (stable) PCI**

- Staging of stable PCI is permissible when clinically appropriate. An example of appropriate stable staging could include intervention on the primary target lesion and a decision is made not to intervene on secondary lesions (in triple vessel disease) due to the patient's deteriorating haemodynamic status (clinically unsafe to continue).

#### **Requirements of subsequent stages of a staged stable PCI**

- The qualifying indication for the initial procedure is to be used as the qualifier for the relevant subsequent stages. Subsequent stages are expected to be completed within a reasonable time period following the initial intervention.
- For subsequent stages of a stable PCI it is implied that diagnostic angiography has been completed in the previous 3 months and therefore it is only permissible to claim items 38320, 38322 or 38323 (standalone PCI items) for subsequent stages.
- Note: For patients who meet the criteria in subclause (2)(b) of note TR.8.4 in 3 vascular territories (triple vessel disease), whether treated in an initial procedure (items 38314 or 38323) or in subsequent stages (items 38311, 38313, 38320 or 38322) it is expected that the patient must meet the criteria for (2)(b) of note TR.8.4 for each territory for each subsequent stage. This requirement ensures that the patient who has triple vessel disease must meet the criteria for (2)(b) for each territory when staged or completed in an initial procedure.

The Department will be closely monitoring claiming patterns for staged procedures, particularly where volumes for staged procedures at the same site are not consistent with the broader provider claiming base.

#### **Multiple Providers of one episode of care (stable) PCI – Separate interventional sites or Same interventional site.**



One of the primary intentions of the changes to selective coronary angiography and PCI items, is to encourage the provision of the entire intervention in a single episode of care. Therefore, the provider should consider that there will be a reasonable need to intervene (revascularise), noting that in some cases intervention is not required (e.g. pressure testing – FFR result does not support the need for stenting).

It is recognised that some providers of interventional cardiology services only provide selective coronary angiography (diagnostic) and require a secondary provider to undertake angioplasty, stenting and/or atherectomy.

**Non-interventional – selective angiography providers (clinical assessment suggests intervention required)**

*Stable patients*

It is accepted clinical practice that the following patient pathways for stable PCI service provision (other than a complete service by an accredited PCI cardiologist) may occur when considering the role of the non-interventional cardiologist (non-PCI accredited) as follows:

**Ad-hoc PCI:**

- Provider 1 completes the selective angiography and hands over to provider 2 to perform the PCI while the patient is still on the cardiac catheterisation table with the arterial access still in place.
- Similar to the acute items, this scenario would likely be rare for e.g. dissection of a coronary artery caused by the angiography catheter that may convert the patient from stable to unstable.
- It is current accepted practice that the selective coronary angiography component of the service can be performed by a non-interventional cardiologist and the PCI component (when required) completed by a PCI accredited provider.
- Ideally ad-hoc stable PCI should be completed by a PCI accredited provider and therefore consideration should be given to current practice site arrangements going forward.

**Delayed PCI:**

- Provider 1 completes ICA and refers the patient to provider 2, who performs the PCI later on the same day.
- In the stable patient this scenario presents the opportunity to pause and consider whether optimal medical therapy, PCI or coronary artery bypass may be the preferred option in consultation with a PCI accredited cardiologist and/or cardiothoracic surgeon; and
- It also allows for a further opportunity to obtain informed consent from the patient for the proposed intervention.
- In most cases this would involve maintaining the arterial access with an indwelling arterial sheath to avoid repuncture.

**Elective PCI:**

- Provider 1 completes ICA and refers the patient to provider 2, who performs the PCI on the next day, or any subsequent day.
- Similar to delayed PCI, however the PCI accredited cardiologist may not be available on the same day as when the selective coronary angiography was completed; or
- A short trial of optimal medical therapy is recommended; or
- Further non-invasive functional testing is recommended.

The Department will be closely monitoring claiming patterns, particularly at the same site where selective angiography is completed by a non-accredited cardiologist and the PCI component completed by a PCI accredited provider.

**The following provides guidance for when the provider can only undertake the selective angiography component of a complete PCI service (PCI non-accredited provider):**

*Separate hospital/procedural sites (Stable)*

The first provider undertakes the diagnostic angiography and either makes an independent decision or following discussion with the interventional cardiologist refers to the secondary provider at another site for the purposes of revascularisation (e.g. referral from a rural or regional hospital to a metropolitan hospital). In this scenario there is a clear delineation between the angiography and revascularisation services due to the different geographical locations (separate episodes of care). Example claiming is as follows:

- Stable - example  
Provider 1 – site 1 (diagnostic angiography) claims item 38248 stable – selective angiography). Provider 2 – site 2 (PCI) claims item 38320 (stable – PCI single territory)

*Same hospital/procedural site (Stable)*

- The first provider undertakes the diagnostic angiography and either makes an independent decision or following discussion with the interventional cardiologist requesting that the secondary provider undertakes the revascularisation component.
- Please note that the underlying intention of a complete PCI service is that the entire service, including diagnostic angiography is completed by a single provider where possible.

**Abandoned T8 Surgical Procedures and Acute or Stable Percutaneous Coronary Intervention (PCI) – Excluding appropriate staging**

The new acute PCI items have time restrictions applied whether claimed by the same or different providers. It is important for the patient that if a provider cannot complete (abandoned) the PCI and rescue PCI needs to be conducted by another provider, item 30001 is claimed. This will allow claiming by the provider who subsequently completes the rescue PCI, taking into consideration the time restrictions for each of the selective angiography items.

The new stable PCI items do not have time restrictions. However, it is important for the patient that if a provider cannot complete (abandoned) the PCI and rescue PCI needs to be conducted by another provider, item 30001 is claimed. This will allow claiming by the provider who subsequently completes the rescue PCI, taking into consideration the time restrictions for each of the selective angiography items.

Related Items: 38311 38313 38314 38320 38322 38323