MSAC Application 1743

Optical coherence tomography guided coronary stent insertion

Application for MBS eligible service or health technology

ID:
HPP200044
Application title:
Optical coherence tomography guided coronary stent insertion
Submitting organisation:
ABBOTT MEDICAL AUSTRALIA PTY LTD.
Submitting organisation ABN:
73080212746

Application description

Succinct description of the medical condition/s:
Obstructive coronary artery disease reflects a large spectrum of clinical conditions caused by myocardial ischaemia due to narrowing of the coronary arteries. Most often the narrowing of the coronary arteries is caused by atherosclerosis, i.e. build-up of plaque. When blood to the heart muscle is completely blocked, the patient is experiencing a heart attack or myocardial infarction. Patients may present with angina pectoris, a clinical syndrome characterised by pain or discomfort in the chest, jaw, shoulder, back or arms. Percutaneous coronary intervention (PCI) and coronary stent implantation is the mainstay revascularisation intervention in patients with obstructive coronary artery disease.

Succinct description of the service or health technology:
Optical coherence tomography (OCT) is intended for guiding PCI with coronary stent insertion in patients that are eligible for coronary revascularisation. Coronary angiography is the mainstay, traditional imaging modality for visual evaluation of coronary anatomy and guidance of PCIs in patients with coronary artery disease. However, angiography is limited by its two-dimensional representation of blood vessels because it cannot depict the arterial vessel wall, evaluate vessel dimensions and plaque characteristics, or directly assess the results of stent implantation. OCT is an intracoronary imaging technology that uses infra-red light to obtain cross-sectional images capable of accurately determining vessel size and plaque morphology. OCT can identify features enabling optimal stent implantation (i.e., expansion, apposition), as well as identifying the potential for stent failure that cannot be captured using coronary angiography alone.

Application contact details

Are you the applicant, or are you a consultant or lobbyist acting on behalf of the applicant?
Applicant

Are you applying on behalf of an organisation, or as an individual?
Organisation

Is the applicant organisation the organisation you are representing in the HPP today?
Yes

Application details

Does the implementation of your service or health technology rely on a new listing on the Pharmaceutical Benefits Scheme (PBS) and/or the Prostheses List?
Yes

Which list/schedule will the other health technologies be listed on?
Prostheses List

Is the application for a new service or health technology, or an amendment to an existing listed service or health technology?
New

Please select any relevant MBS items.

MBS item number	Selected reason type

What is the type of service or health technology?
Therapeutic

PICO Sets

Application PICO sets

PICO set number	PICO set name
1	Optical coherence tomography (OCT) guided coronary stent insertion

Optical coherence tomography (OCT) guided coronary stent insertion

Supporting documentation

Document type	File name(s)
Application PICO set documents	HPP200044_OCT_PICO.docx
Reference list	REFERENCES.docx

Population

Describe the population in which the proposed health technology is intended to be used:
The use of OCT during invasive coronary angiogram percutaneous angioplasty or transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients documented with:
• Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm)
• Bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation
• Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion),
• Stent failure (including stent thrombosis, in-stent restenosis of diffuse or multi-focal pattern

Search and select the most applicable Medical condition terminology (SNOMED CT):

Intervention

Name of the proposed health technology:
Optical coherence tomography (OCT) guided coronary stent insertion as an adjunct to invasive coronary angiogram.

Comparator

Nominate the appropriate comparator(s) for the proposed medical service (i.e. how is the proposed population currently managed in the absence of the proposed medical service being available in the Australian health care system). This includes identifying health care resources that are needed to be delivered at the same time as the comparator service:
The primary comparator to OCT adjunct to coronary angiogram in the proposed population with high lesion risk as defined above, is placement of coronary stents under guidance of coronary angiography alone. IVUS was recommended for listing on the MBS for PCI guidance of either a left main coronary artery lesion (i.e. left main lesions) or lesion length of 28 mm or more (i.e. long lesions) (MSAC Application 1354.1 public summary document [PSD]). Whilst IVUS is not yet appearing on the MBS, it is nominated as a near to market, secondary comparator in the subgroup of patients with long lesions.

Outcomes

Outcome description – please include information about whether a change in patient management, or prognosis, occurs as a result of the test information:
The main outcomes include:
Target vessel Target vessel failure [TVF], defined as the composite of: cardiac death, target vessel myocardial infarction, or ischemia-driven target vessel revascularisation.
All cause / cardiac mortality
Myocardial infarction
Revascularisation
Procedural complications / adverse events

Stent thrombosis
Quality of life

Proposed MBS items

Proposed Item AAAAA
MBS item number:

Please search and select the proposed category:
3

Please search and select the proposed group:
Therapeutic Procedures

Please search and select the proposed item descriptor or draft a proposed item descriptor to define the population and health technology usage characteristics that would define eligibility for funding:
Use of optical coherence tomography (OCT) during transluminal insertion of stents, to optimise procedural strategy, appropriate stent size and assessment of stent apposition for patients documented with:
• Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm), or
• Bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation, or
• Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion), or
• Stent failure (including stent thrombosis, in-stent restenosis of diffuse or multi-focal pattern).
Being a service associated with items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323.
Service is claimable once in a single episode of care (for one or more lesions).
Multiple Operation Rule
(Anaes.)
[Relevant explanatory notes]
Fee only payable when the service is provided in association with insertion of coronary stent/s (items 38307, 38308, 38310, 38311, 38313, 38314, 38316, 38317, 38319, 38320, 38322, 38323).

Proposed MBS fee:
$496.50

Indicate the overall cost per patient of providing the proposed health technology:
REDACTED

Please specify any anticipated out of pocket costs:
$0.00

Provide details and explain:
A likely incremental cost per procedure (i.e., over the current standard practice without the availability of OCT) would be REDACTED = $248.25 (adjusted for MOR at 50%) plus $ REDACTED

(based on an assumed caseload of REDACTED per machine per year) plus $ REDACTED.
In the IVUS application, the IVUS MBS item fee was benchmarked to MBS item 38241 for use of a coronary pressure wire to measure fractional flow reserve (FFR). "MSAC considered that despite differences in complexity and resource use, the fee was reasonable" (MSAC Application 1354.1 PSD). The experts consulted in preparing this Application confirmed that the duration of the procedure, the complexity, and the resources used of OCT to be similar to that of IVUS (and hence pressure wire). As such, the proposed MBS item fee benchmarked to IVUS / pressure wire MBS item 38241 is justified.

Anticipated out of pocket expenses are unknown; it may reflect 25% of the fee for patients with private health funds that do not cover this part of the arrangement.

How is the technology/service funded at present? (For example: research funding; State-based funding; self-funded by patients; no funding or payments):
Not funded

Please provide a cost break down attachment:

Document type	**File name(s)**
Cost breakdown attachment	HPP200044_OCT_COST BREAKDOWN.docx

Claims

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

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

The results from the recently published RENOVATE trial, comparing intravascular imaging including IVUS / OCT adjunct to coronary angiography versus coronary angiography alone (Lee 2023) demonstrated statistically significantly superior outcomes with intravascular imaging with respect to target lesion failure (a composite of death from cardiac causes, target-vessel myocardial infarction, or clinically driven target-vessel revascularisation) compared to coronary angiography alone (hazard ratio [HR] [95% confidence interval (CI)]: 0.64 [0.45–0.89]). When stratified by type of intravascular imaging device, OCT performed numerically better than IVUS relative to angiography alone (HR [95%CI]: 0.47 [0.27–0.83] versus 0.66 [0.46–0.95], respectively).

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

Estimated utilisation

Estimate the prevalence and/or incidence of the proposed population:
As also noted for IVUS in the PSD of Application 1354.1, the availability of OCT would not grow the market above existing market growth of PCI with stent insertion. As described elsewhere in the application (PICO document), these procedures are currently funded under 12 MBS items (as of July 2021). While limited MBS statistics are available, the 2022 calendar year data suggested a total of 21,401 procedures. Despite limited usage data being available for these 12 items, the PCI procedure itself has been long established and funded on the MBS (although under a different item code; see further discussion below) and, to this end, its "uptake" should be mature and stable, and thus fit to inform the ADAR's Section 4 analysis.

These MBS statistics are also well corroborated by the number of PCI procedures performed at private hospitals in Victoria as per to the Victorian Cardiac Outcomes Registry (VCOR) (Lefkovits 2022). In 2021, 5,518 procedures were provided at Victorian private centres and roughly 25% of the Australian population live in the state of Victoria, thus translating to ≈22,000 procedures nationally. According to the VCOR (Lefkovits 2022), 93.5% of PCI cases in 2021 involved deployment of at least one stent and virtually all stents were DES (99.9%). As discussed and justified elsewhere in this application, a set of additional eligibility criteria based on clinical characteristics of the treated lesion are proposed to accompany the MBS listing of OCT, as informed by the pivotal RCT as well as KOL inputs:
• Long or multiple lesions, defined as intended total stent length (continuous or separated) in any single target vessel ≥28 mm)
• Bifurcation and where the planned side branch is ≥ 2.5 mm in diameter by angiographic visual estimation
• Angiographic severe calcification (defined as angiographically visible calcification on both sides of the vessel wall in the absence of cardiac motion)
• Stent failure (including stent thrombosis, in-stent restenosis of diffuse or multi-focal pattern)
As described in the UTILISATON ESTIMATE attachment, a number of studies were identified to inform the potential eligible population for OCT based on these criteria. When simply summed together, >50% of all PCI procedures with an intended deployment of DES (93.4% of all PCIs) would meet the proposed eligibility criteria; this is likely to overestimate the actual eligibility rate given that it is possible for one patient to meet multiple criteria. The presence of calcification in these patients, for example, is described as "a marker of advanced atherosclerosis and is correlated with multivessel coronary disease and the presence of complex lesions, including long lesions, chronic total occlusions and bifurcations" (Didi 2019). On the other hand, the most conservative scenario based on the available evidence would be 30% meeting the proposed eligibility criteria, i.e., the 'long or multiple lesion' criterion entirely absorbing other eligibility criteria.

On balance, the available evidence would suggest a sizable proportion of all PCIs (app. 21,401 procedures in 2022) may be eligible for adjunctive use of OCT. That is, 93.4% of these procedures would involve the deployment of DES (= 19,989) and based on a pragmatic eligibility rate of 40%, the number of eligible patients would be 7,995 procedures. The ADAR will seek epidemiological inputs with further granularity to inform the Section 4 analysis.

Provide the percentage uptake of the proposed health technology by the proposed population:

Year 1 estimated uptake(%):
REDACTED
Year 2 estimated uptake(%):
REDACTED
Year 3 estimated uptake(%):
REDACTED
Year 3 estimated uptake(%):
REDACTED

Estimate the number of patients who will utilise the proposed technology for the first full year:
REDACTED

Optionally, provide details:

Will the technology be needed more than once per patient?
No, once only

Provide references to support these calculations.

Document type	File name(s)
Estimated utilisation references	HPP200044_OCT_UTILISATION ESTIMATE.docx

Consultation

List all appropriate professional bodies / organisations representing the group(s) of health professionals who provide the health technology/service:

Professional body name:
Cardiac Society of Australia and New Zealand (CSANZ)

List all appropriate professional bodies / organisations representing the group(s) of health professionals that may be impacted by the health technology/service:

Professional body name:
CSANZ

List the patient and consumer advocacy organisations or individuals relevant to the proposed health technology:

Number of organisations listed: 1
Professional body name:
Hearts4heart

List the relevant sponsor(s) and / or manufacturer(s) who produce similar products relevant to the proposed service or health technology:

Regulatory information

Would the proposed health technology involve the use of a medical device, in-vitro diagnostic test, radioactive tracer or any other type of therapeutic good?
Yes

Has it been listed or registered or included in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA)?
Yes

Is the therapeutic good classified by the TGA as either a Class III or Active Implantable Medical Device (AIMD) against the TGA regulatory scheme for devices?
Class III

Please enter all relevant ARTG IDs:

ARTG ID	ARTG name
314829	Coronary optical coherence tomography system
317614	Coronary optical coherence tomography system catheter
370978	Coronary optical coherence tomography system (OPTIS™ Integrated Next Imaging System)

Is the intended purpose in this application the same as the intended purpose of the ARTG listing(s)?
Yes

Codependent details

Will a submission be made to the Prostheses List Advisory Committee (PLAC)?
Yes

Please provide a rationale for the codependency:
A submission will be made to the PLAC following MSAC deliberation to seek listing of the imaging catheter.

Are there any other sponsor(s) and / or manufacturer(s) that have similar prosthesis or device component in the Australian market place which this application is relevant to?
No

Are there any single and/or multi-use consumables delivered as part of the service or health technology?
Yes

Provide details:
The imaging catheter is considered a single use consumable. However, the use of the imaging catheter is principal to delivering the service.