MSAC Application 1815

Computed tomography (CT) of the coronary arteries to determine coronary artery calcium score

PICO Set

Abbreviations

Lp(a)	Lipoprotein a
hs-CRP	High sensitivity C-reactive protein
ATSI	Aboriginal and Torres Strait Islander
PRS	Polygenic Risk Score
CT	Computed tomography
CACS	Coronary artery calcium score
CTCA	CT coronary angiogram
GP	General Practitioner
CVD	Cardiovascular disease
ASCVD	Atherosclerotic cardiovascular disease
CAD	Coronary artery disease
CHD	Coronary heart disease
LDL-C	Low density lipoprotein C
NNT	Number needed to treat
CAC-DAD	Coronary artery calcium – density and dispersion
MESA	Multi-ethnic study of atherosclerosis
MACE	Major adverse cardiovascular events
ACC/AHA	American College of Cardiology / American Heart Association
CAUGHT-CAD	Coronary artery calcium score: use to guide management of hereditary coronary artery disease (study)
ARIC	Atherosclerosis risk in communities (study)
DHS	Dallas Heart Study
SCORE2	Systematic coronary risk evaluation 2

Population

Describe the population in which the proposed health technology is intended to be used:
Asymptomatic Australian patients 45 – 79 years of age who do not have known coronary artery disease and who are:

a. classified at intermediate (or moderate) risk of experiencing a cardiovascular event (myocardial infarction, stroke, cardiovascular death) using contemporary cardiovascular risk calculators, or

b. patients who are calculated to be at low risk by calculator but who have specific cardiovascular risk enhancers (for example, family history of premature cardiovascular disease, elevated Lp(a), persistently elevated hs-CRP, ATSI-status, PRS indicating enhanced risk) in whom imaging evidence of coronary atherosclerosis will change management decisions

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

Investigation, management & referral:

1. GP consultation +/- Heart Health Check assessment, or specialist consultation (physician/cardiologist)

2. Determine the estimated 5-year cardiovascular risk using the Australian CVD risk calculator (cvdcheck.org.au, embedded in GP electronic medical record/practice software). Obtain fasting cholesterol, glucose and glycosylated haemoglobin for AusCVD risk algorithm.

3. If patient has an intermediate absolute 5-year CVD risk (5-9%) or low absolute risk with the presence of a recognised risk enhancing factor and has not had a computed tomography coronary calcium artery score (CT-CACS) or CT coronary angiography (CTCA) performed in the past, discuss with patient the role of CT-CACS for risk re-stratification and refer for CT-CACS.

Provide a rationale for the specifics of the eligible population:
Updated (2025) international dyslipidaemia treatment guidelines recommend the identification of the presence of subclinical coronary atherosclerosis (by non-zero CAC score) for individuals at intermediate/moderate risk, or individuals who are around treatment decision thresholds (that is, low risk with potential risk-enhancers). (1)

The Aus CVD risk calculator demonstrates optimal predictive value for Australian individuals 45 – 79 years and is utilised in the Heart Health Check (with wider age ranges for First Nations people and individuals with diabetes).(2) CT-CACS independently predicts cardiovascular event risk and mortality, provides incremental risk information beyond traditional cardiovascular risk calculators and biomarkers, providing 'individualised' coronary risk scoring.(3) Both the CSANZ and Heart Foundation position statements on risk assessment recommend coronary artery calcium scoring for appropriate populations to determine risk with greater precision, in order to better guide management decisions for lipid lowering therapy

Are there any prerequisite tests?
Yes

Fasting cholesterol, glucose and glycosylated haemoglobin are used for calculating risk with the Australian CVD risk calculator.

Are the prerequisite tests MBS funded?
Yes

Provide details to fund the prerequisite tests:
Provide a response if you answered 'No' to the question above

Intervention

Name of the proposed health technology:
Computed tomography of the coronary arteries for the determination of coronary artery calcium score (CACS)

Describe the key components and clinical steps involved in delivering the proposed health technology:
Coronary artery calcium (CAC) scoring is a technique for measuring the amount of calcium in the coronary arteries using an electrocardiogram-gated non-contrast computed tomography (CT) scan of the heart. It strongly correlates with gold-standard measures of atherosclerotic coronary artery disease burden, including both intravascular ultrasound and post-mortem histology, thus providing a non-invasive direct and quantitative measure of coronary atherosclerosis - the underlying cause of myocardial infarction.

The proposed medical service is the delivery of CT imaging. This includes:

1. Acceptance of request forms with clinical information

2. Use of accredited and approved CT equipment

3. Patient preparation and taking of the image/s by a qualified radiographer

4. Processing of appropriate information and images, including with calculated coronary artery calcium score (Agatston score) using vendor-specific software, and forwarding for reporting

5. Standardised reporting of images, transfer and report delivery

Identify how the proposed technology achieves the intended patient outcomes:
Coronary artery calcium (CAC) scoring allows for the early identification of subclinical atherosclerotic cardiovascular disease (ASCVD) in asymptomatic individuals to guide the initiation or intensification of evidence-based, preventative pharmacotherapies to reduce the risk of subsequent acute cardiovascular events. The identification of ASCVD also has an inherent 'value of knowing' for the patient and caregivers, discussed further in the 'Outcomes' section of this PICO Set document. A CAC score can be used to re-classify individuals previously classified at intermediate risk into a lower risk group, thereby preventing or de-escalating unnecessary treatment.

Does the proposed health technology include a registered trademark component with characteristics that distinguishes it from other similar health components?
No

Explain whether it is essential to have this trademark component or whether there would be other components that would be suitable:
Provide a response if you answered 'Yes' to the question above

Are there any proposed limitations on the provision of the proposed health technology delivered to the patient (For example: accessibility, dosage, quantity, duration or frequency):
Yes. Consensus that the interval between repeat studies is at least 5 years

Provide details and explain:
Provide a response if you answered 'No' to the question above

If applicable, advise which health professionals will be needed to provide the proposed health technology:
Radiologists and radiographers, and providers certified by the ANZCTA Conjoint Committee for provision of cardiac CT (CTCA) services.

If applicable, advise whether delivery of the proposed health technology can be delegated to another health professional:
No

If applicable, advise if there are any limitations on which health professionals might provide a referral for the proposed health technology:
Referral by registered medical practitioners only, and potentially referral by Nurse Practitioners

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

Provide details and explain:
No additional formal training is required.
Reporting radiologists and/or cardiologists do not require additional formal accreditation for CACS (compared to CT coronary angiography).

CT radiographers should be capable of scanning without additional training. If unsure, the CT vendor usually provides training as part of "apps" training and ongoing support.

Some effort may be required to update local guidelines regarding evidence for the use of CACS in asymptomatic population in clinical pathways to improve heart attack prevention- particularly in educational and professional forums accessed by GPs and general cardiologists. Efforts should be made to focus on equitable reach of this education- including with a particular emphasis on rural and remote general practitioners.

Indicate the proposed setting(s) in which the proposed health technology will be delivered:

(Select all relevant settings)

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

Specify further details here

Is the proposed health technology intended to be entirely rendered inside Australia?
Yes

Provide additional details on the proposed health technology to be rendered outside of Australia:
Provide a response if you answered 'No' to the question above

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 healthcare system). This includes identifying healthcare resources that are needed to be delivered at the same time as the comparator service:

Heart Health Check by GP, or equivalent consultation performed by a specialist physician

List any existing MBS item numbers that are relevant for the nominated comparators:
177 (20 minutes) or **699** (30 minutes); the equivalent is also performed in specialist physician (including cardiology) assessment, but under a standard consulting item number (**110 or 116**).

Provide a rationale for why this is a comparator:
The Heart Health Check (177), generally utilising the Aus CVD risk calculator, is the current Australian standard for assessing an asymptomatic individual's cardiovascular risk in primary practice. A CT- CACS provides synergistic data to the population level risk factors, reflecting the individual's CAD development, and provides enhanced prediction of future myocardial infarction or related CAD-event.

Pattern of substitution – Will the proposed health technology wholly replace the proposed comparator, partially replace the proposed comparator, displace the proposed comparator or be used in combination with the proposed comparator?
X. None (used with the comparator)
☐ Displaced (comparator will likely be used following the proposed technology in some patients)
☐ Partial (in some cases, the proposed technology will replace the use of the comparator, but not all)
☐ Full (subjects who receive the proposed intervention will not receive the comparator)

Outline and explain the extent to which the current comparator is expected to be substituted:
CACS will be used in combination with the Heart Health Check/cardiology assessment, in a select group of individuals at intermediate or indeterminate risk.

Outcomes

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

- **X** Health benefits
- **X** Health harms
- **X** Resources
- **X** Value of knowing

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

Outcome 1 name
Reduction in Major Adverse Cardiovascular Events (MACE) – composite endpoint of acute myocardial infarction, stroke and cardiovascular death

Outcome 1 type
Health benefit

Outcome 1 description
CAC scoring is a robust predictor of future atherosclerotic cardiovascular events, and the risk for cardiovascular events increases with increasing levels of CAC. (4-6) The presence of atherosclerotic CAD, identified by a non-zero CAC has been shown to be predictive of events across age, sex and racial/ethnic groups. (5) CAC scoring is predictive of future events independent of traditional risk factors, improving risk prediction when added to widely utilised international cardiovascular risk stratification tools. (7-9) A zero CAC score is associated with a less than 0.5% per year risk of a subsequent cardiovascular event. (10) The recent (2025) European Dyslipidaemia Guidelines consider an increased CAC (≥300) score as unequivocal evidence of documented ASCVD, placing these patients in the same 'very high risk' category as patients who have suffered a previous myocardial infarction. The recommended management includes maximally tolerated lipid-lowering therapy, targeted to an LDL-C<1.4mmol/L, to reduce the risk of a subsequent acute event.(1)

For adults at increased cardiovascular risk, but without a history of previous cardiovascular events, statin therapy is associated with a reduced risk of myocardial infarction, cardiovascular and all-cause mortality.(11) A recent large RCT randomised high-risk individuals with ASCVD, but without a history of previous myocardial infarction or stroke, to a PCSK9 inhibitor (a novel lipid-lowering therapy) or placebo. They found that, for these patients with subclinical ASCVD, PCSK9 inhibition was associated with a 24% reduction in mortality from the composite outcome of death from coronary heart disease, myocardial infarction or stroke.(12)

The health benefit utility of CT-CAC scoring for patients at intermediate/moderate risk lies with the ability to appropriately target treatment based on the presence (or absence) of atherosclerotic disease in an individual, rather than on the presence of population-based risk factors (comparator).

Outcome 2 name
Reduction in patient uncertainty

Outcome 2 type
Value of knowing

Outcome 2 description
A CAC score provides information that guides safe and effective treatment for individual patients, metrics that can be reasonably easily measured. However, there may be considerable additional value for the patient in knowing that they have subclinical ASCVD, reducing the uncertainty that comes with risk estimates derived from standard cardiovascular risk tools (the comparator).(13) The value of knowing also manifests in the patient's opportunity to take a more informed role in shared decision-making and increases their sense of control over their life, a value Lee and colleagues termed "planning value.(14) However, knowing is not universally positive. For some individuals, knowing they have subclinical ASCVD can be adaptive, driving changes in lifestyle and increased adherence to prescribed medications (15), whereas in others in can lead to maladaptive feelings of hopelessness and distress.(16)

A CAC score conveys visual information to a patient in a way that makes it easier to understand, access and appraise, when compared with an estimation of risk derived from a cardiovascular risk tool. This is of critical importance for patients with poor health literacy, a group that are often at concomitant increased risk of poor outcomes from cardiovascular disease. (17) The 'value of knowing' has increased value for Australian First Nations people, who suffer disproportionately poor health outcomes as a direct result of poor communication. (18)

Outcome 3 name
Change in rate of prescribing of lipid-lowering medications (statins, ezetimibe, PCSK9 inhibitors, bile acid sequestrants) for primary prevention in patients.

Outcome 3 type
Resources / health harms

Outcome 3 description
Using population-based risk calculators to guide lipid-lowering therapy exposes the estimated 45% - 55% (10, 19) of intermediate/moderate risk patients with a CAC score of zero to unnecessary financial costs, inconvenience, and to the risk of adverse drug effects.(20) In Australia, this financial burden is often shared with the community, through the significant Pharmaceutical Benefits Scheme subsidisation of lipid-lowering medications, estimated at $167 million in 2022.(21) Statins are the most commonly prescribed medication in Australia, with over 30 million prescriptions per year. (22) A recent Australian cost-effectiveness analysis found that compared to current Australian guidelines (which recommend statins for patients with 5-year risk of cardiovascular events ≥10%), it would be more cost effective (from the Australian Health system perspective) to use a CACS-guided strategy to prescribe statins to patients with a 5 year CV risk ≥5% and a CAC score>100, or with a 5 year risk ≥8% and a CAC score >0. Much of the cost-benefit was driven by increased statin initiation and adherence rates associated with obtaining a CT-CACS.(23)

Outcome 4 name
Incidental findings

Outcome 4 type
Health harms

Outcome 4 description
CAC scoring is performed with a CT scan of the chest and may result in incidental findings. In a study of 966 individuals who underwent CAC scoring, 8.2% of patients had incidental findings that required further investigation and/or treatment, such as pulmonary nodules(24). The Australian Lung Cancer Screening program has an existing framework for follow up of pulmonary nodules and other relevant findings. Incidental findings may result in increased healthcare resource expenditure and psychological harm due to the unexpected nature of the findings.

Outcome 5 name
Radiation exposure

Outcome 5 type
Health harms

Outcome 5 description
CAC scoring using ECG-gated CT scanning typically exposes an individual to approximately 1mSv of radiation, compared with no exposure for the comparator. Current international guidelines recommending minimisation of exposure to between 0.5mSv and 1.5mSv.(24) The potential benefit of utilising CT-CACS to guide management should be considered against the risks of radiation exposure.(25)

Proposed MBS items

How is the technology/service funded at present? (e.g., research funding; State-based funding; self-funded by patients; no funding or payments):
Self-funded by patients

Provide at least one proposed item with their descriptor and associated costs, for each Population/Intervention:

MBS item number (where used as a template for the proposed item)	N/A
Category number	Category 5 - Diagnostic Imaging Services
Category description	A diagnostic imaging service includes the diagnostic imaging procedure, which is defined in the Act* *as 'a procedure for the production of images (for example x-rays, computerised tomography scans, ultrasound scans, magnetic resonance imaging scans and nuclear scans) for use in the rendering of diagnostic imaging services as well as the report'*
Proposed item descriptor	Non-contrast ECG-gated computed tomography of the coronary arteries on a minimum of a 64 slice (or equivalent) scanner, with the calculation of Coronary Artery Calcium Score in Agatston units to identify sub-clinical atherosclerosis in individuals who are: a. Aged 45 - 79 years of age who do NOT have known cardiovascular/coronary artery disease, AND b. are intermediate cardiovascular risk according to existing risk calculator algorithms, OR c. have risk enhancers (Lp0a0, ATSI-status, other), OR d. are at indeterminate risk and clinically require reclassification

Proposed MBS fee	$250
Indicate the overall cost per patient of providing the proposed health technology	MBS fee should cover the cost of providing the service. Anticipated gaps will depend on the Radiology provider
Please specify any anticipated out of pocket expenses	None anticipated
Provide any further details and explain	Please refer to CSANZ and the Heart Foundation statement on CAC scoring for eligible population, appropriate use and technical standards

Algorithms

PREPARATION FOR USING THE HEALTH TECHNOLOGY

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

1. GP consultation +/- Heart Health Check assessment, or specialist consultation (physician/cardiologist)

2. Determine 5-year cardiovascular risk using the AusCVD risk calculator (cvdcheck.org.au, embedded in GP electronic medical record/practice software). Obtain fasting cholesterol, glucose and glycosylated haemoglobin for AusCVD risk algorithm.

3. If patient has an intermediate absolute 5-year CVD risk (5-9%) or low absolute risk with the presence of a recognised risk enhancing factor and has not had a CT-CACS performed within 5 years, discuss with patient the role of CT-CACS for risk re-stratification and refer for CT-CACS.

Is there any expectation that the clinical management algorithm before the health technology is used will change due to the introduction of the proposed health technology?

Yes

Describe and explain any differences in the clinical management algorithm prior to the use of the proposed health technology vs. the comparator health technology:
The only change to clinical management will be the inclusion of a CT-CACS to identify the presence of subclinical ASCVD in patients at intermediate/indeterminate risk according to the AusCVD (or other) risk calculation tool. The inclusion of CT-CACS will be a shared decision between clinician and patient after discussion of potential risks and benefits.

USE OF THE HEALTH TECHNOLOGY

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

A coronary artery calcium score will be calculated using an electrocardiogram-gated non-contrast computed tomography (CT) scan of the heart, in addition to the resources utilised for the comparator (Heart Health Check assessment/ cardiology assessment)

Explain what other healthcare resources are used in conjunction with the comparator health technology:
The Heart Health Check (or assessment by consultant cardiologist) requires patient attendance to GP/consultant physician, and pathology for the measurement of fasting cholesterol, glucose and glycosylated haemoglobin for AusCVD risk algorithm/ other risk calculation algorithms.

Describe and explain any differences in the healthcare resources used in conjunction with the proposed health technology vs. the comparator health technology:
The proposed change is the addition of CAC scoring to identify the presence of subclinical ASCVD to inform the individualised and safe management of the patient.

CLINICAL MANAGEMENT AFTER THE USE OF HEALTH TECHNOLOGY

Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the proposed health technology:
1. Referring doctor reviews images and CT- CACS and discusses with patient to inform shared decision making regarding preventative strategies for coronary artery disease and heart attack:

a. CAC = 0 AU. Reclassify from intermediate to low absolute cardiovascular risk and manage as per guideline recommendations.

b. CAC 1-99 AU and < 75th percentile for age and sex. Reclassification or risk status is uncertain. Discuss benefits and harms of risk management strategies with patient, with consideration of individual patient preferences and values

c. CAC >99 AU or ≥ 75th percentile for age and sex. Reclassify risk as high absolute cardiovascular risk and manage risk per guideline recommendations.

d. CAC >300 - Reclassification as high cardiovascular risk, comparable to established atherosclerotic cardiovascular disease (ASCVD). Manage as per international guidelines with intensive lipid-lowering treatment akin to secondary prevention levels with maximum tolerated statin/ezetimibe, aim for an LDL-C goal of <1.4 mmol/l. (1)

e. CAD>1000 – very high risk, manage as per international with intensive lipid-lowering treatment as above (1), investigate for other causes of extreme coronary atherosclerosis. Ischaemic threshold stress testing may be appropriate if clinically relevant.

2. Encourage, support and advise a healthy lifestyle for all.

3. Prescribe blood pressure lowering and lipid-modifying pharmacotherapy for individuals re-classified as high or very high cardiovascular risk. Current international guidelines recommend intensive secondary prevention goals for LDL-C and other modifiable risk factors. (1)

4. Consider blood pressure lowering and lipid-modifying pharmacotherapy for individuals classified as intermediate risk.

5. Reassess absolute CVD risk every 2 years if not currently receiving pharmacotherapy to reduce CVD risk.

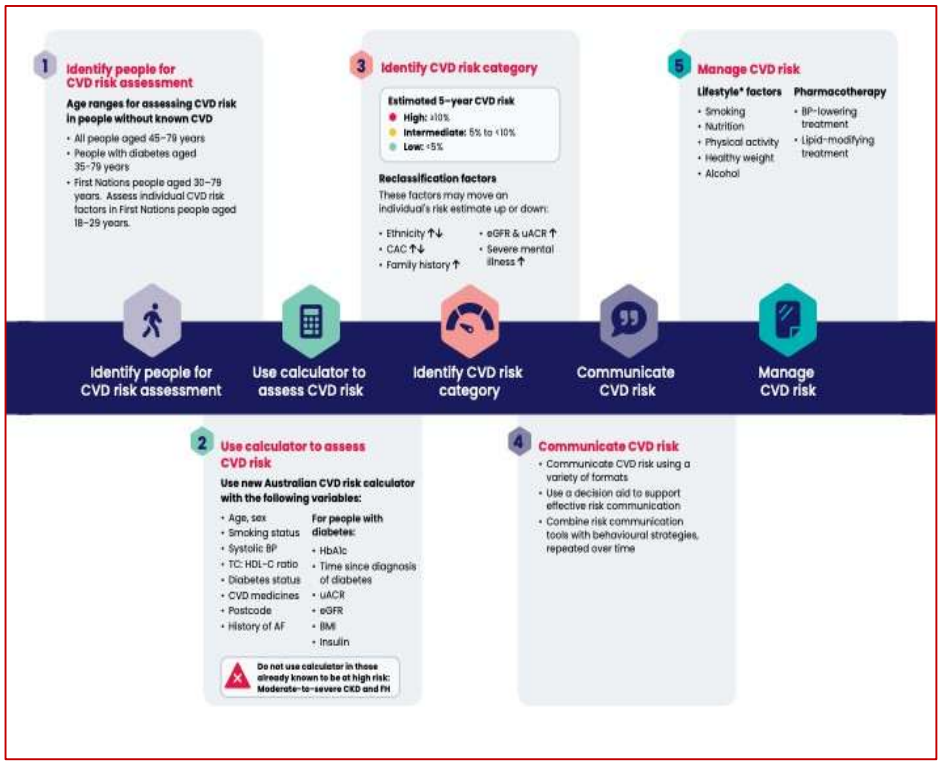
Define and summarise the clinical management algorithm, including any required tests or healthcare resources, *after* the use of the <u>comparator health technology</u>:
As per the recommendations of the 2023 Australian Guideline for assessing and managing cardiovascular disease risk. (2) See clinical flowchart in following section

Describe and explain any differences in the healthcare resources used *after* the <u>proposed health technology</u> vs. the <u>comparator health technology</u>:
None expected

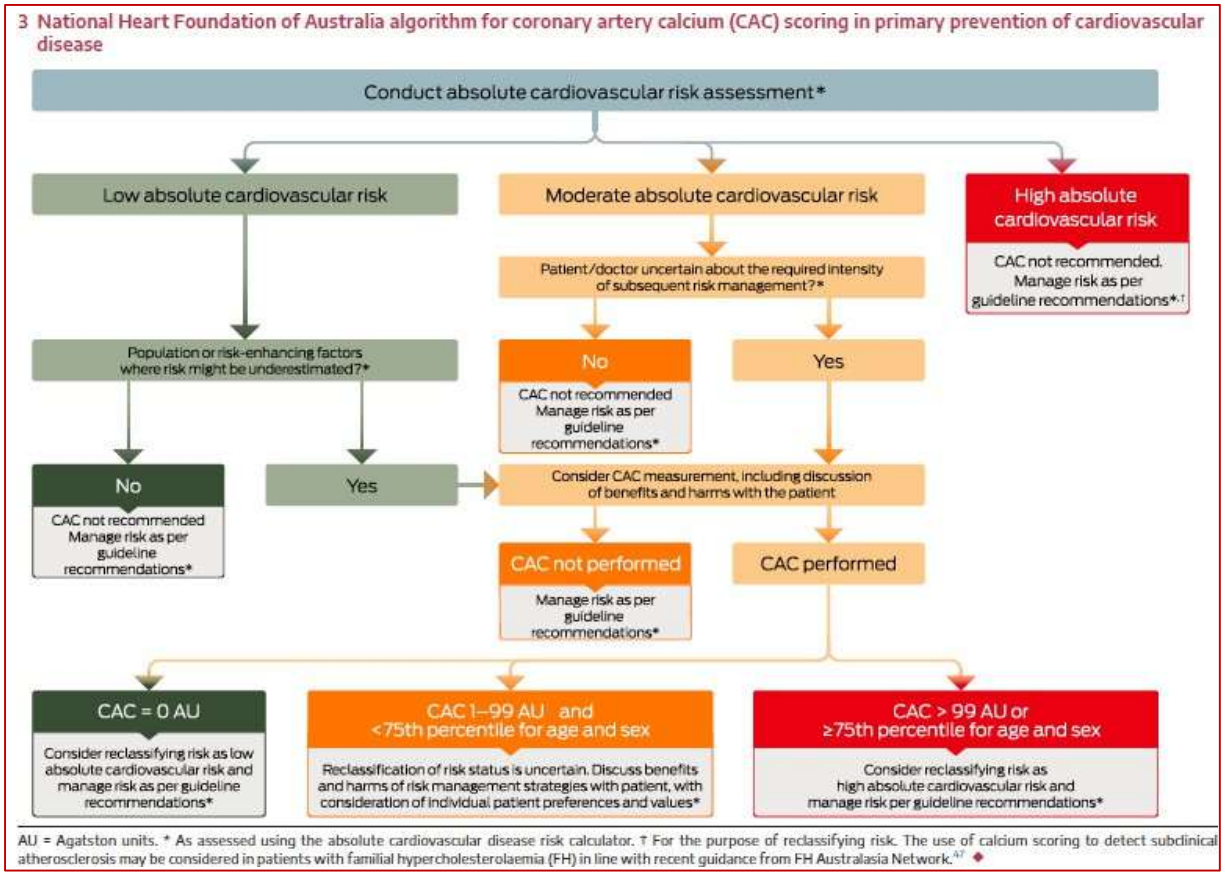
Insert diagrams demonstrating the clinical management algorithm with and without the proposed health technology:

(Please ensure that the diagrams provided do not contain information under copyright)

1. Comparator clinical management algorithm (without proposed CACS) - Australian Guideline for assessing and managing cardiovascular disease risk (https://www.cvdcheck.org.au/)



2. **Clinical management algorithm (with proposed CACS**) – from Liew et al, Cardiac Society of Australia and New Zealand Position Statement: Coronary Artery Calcium Scoring. Heart Lung Circ. 2017 Dec;26(12):1239-1251.



Guideline recommended management of risk after integration of CACS as per NHF algorithm above (*from cvdcheck.org.au)*

Table 1: Overview of CVD risk management according to risk category

Risk category	Estimated 5-year CVD risk[a]	Management	Reassessment interval
High	≥10%	Encourage, support and advise a healthy lifestyle.[b] Prescribe blood pressure-lowering and lipid-modifying pharmacotherapy.[c]	**Formal reassessment of CVD risk is not generally required.** High-risk status requires clinical management and follow up supported by ongoing communication.
Intermediate	5% to <10%	Encourage, support and advise a healthy lifestyle.[b] Consider blood pressure-lowering and lipid-modifying pharmacotherapy, depending on clinical context.	**Reassess risk every 2 years if not currently receiving pharmacotherapy to reduce CVD risk.** Assess sooner if close to the threshold for high risk, if CVD risk factors worsen, or new CVD risk factors are identified. For First Nations people, reassess every year as part of an annual health check (or opportunistically) or at least every 2 years.
Low	<5%	Encourage, support and advise a healthy lifestyle.[b] Pharmacotherapy is not routinely recommended.	**Reassess risk every 5 years.** Assess sooner if close to the threshold for intermediate risk, if CVD risk factors worsen, or new CVD risk factors are identified. For First Nations people, reassess every year as part of an annual health check (or opportunistically) or at least every 2 years.

a. *Estimated probability of a cardiovascular event within the next 5 years, determined using the Aus CVD Risk Calculator.*

b. *This guideline refers to certain modifiable risk factors as 'lifestyle' factors. However, it is recognised that these behaviours are not necessarily an individual's choice, but reflect the complex interplay of social, cultural, and environmental factors, which may be further influenced by clinical conditions. Use of the term 'lifestyle' does not attribute blame to a person.*

c. *Unless contraindicated or clinically inappropriate, and in discussion with the person on the benefits and harms of treatment. Encourage shared decision-making.*

Claims

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

(Please select your response)

☐ Superior
X. Non-inferior
☐ Inferior

Please state what the overall claim is, and provide a rationale:
Coronary artery calcium (CAC) scoring allows for the identification of subclinical atherosclerotic cardiovascular disease (ASCVD) in asymptomatic individuals to guide the initiation or intensification of evidence-based, preventative pharmacotherapies to reduce the risk of subsequent acute cardiovascular events. The identification of ASCVD also has an inherent 'value of knowing' for the patient and caregivers, discussed in the 'Outcomes' section of this document. A CAC score can be used to re-classify individuals previously classified at intermediate risk into a lower risk group, thereby preventing or de-escalating unnecessary treatment.

Why would the requestor seek to use the proposed investigative technology rather than the comparator(s)?
The addition of a CACS to a Heart Health Check provides important additional information (the presence/absence of subclinical ASCVD) which will allow the requestor (and patient) to make a more informed decision about the benefits and risks of lipid-lowering therapy, compared to a population-based risk category (e.g. AusCVD).

Identify how the proposed technology achieves the intended patient outcomes:
A CT-CACS will provide information (identification of subclinical ASCVD) to inform the appropriate, evidence-based initiation, intensification or cessation of lipid-lowering therapy for patients at intermediate risk, reducing an individual's risk of a subsequent myocardial infarction or stroke. For patients at intermediate risk, the absence of subclinical ASCVD on CT-CACS can inform the decision to reduce or cease lipid-lowering medication, reducing the potential for unnecessary harm and financial burden.

For some people, compared with the comparator(s), does the test information result in: *)*

A change in clinical management? Yes

A change in health outcome? Yes

Other benefits? Yes

Please provide a rationale, and information on other benefits if relevant:
A CACS can identify subclinical atherosclerosis in an asymptomatic patient, potentially changing their risk classification (either increasing or decreasing), resulting in initiation, intensification or cessation of evidence-based medications (notably lipid-lowering therapies and antiplatelets). These medications have been shown to halt the progression of coronary atherosclerosis, significantly reducing the risk of subsequent acute cardiovascular

events. (11,12,20) A CACS can provide non-clinical value to a patient, in the form of the 'value of knowing' of they have subclinical ASCVD, reducing the uncertainty inherent in population-based cardiovascular risk calculators.

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

(Please select your response)

X. More costly
☐ Same cost
☐ Less costly

Provide a brief rationale for the claim:
The additional immediate costs will be the cost for acquiring a CT-CACS, estimated at $250 per individual. From the perspective of the Australian health care system, the current management approach (the comparator), which uses population-based risk calculators to guide lipid-lowering therapy, exposes the estimated 45% - 55% (10, 19) of intermediate/moderate risk patients with a CAC score of zero to unnecessary financial costs, inconvenience, and to the risk of adverse drug effects.(20) In Australia, this financial burden is often shared with the community, through the significant Pharmaceutical Benefits Scheme subsidisation of lipid-lowering medications, estimated at $167 million in 2022.(21) Statins are the most commonly prescribed medication in Australia, with over 30 million prescriptions per year. (22) A recent Australian cost-effectiveness analysis found that compared to current Australian guidelines (which recommend statins for patients with 5-year risk of cardiovascular events ≥10%), it would be more cost effective (from the Australian Health system perspective) to use a CACS-guided strategy to prescribe statins to patients with a 5 year CV risk ≥5% and a CAC score>100, or with a 5 year risk ≥8% and a CAC score >0. Much of the cost-benefit was driven by increased statin initiation and adherence rates associated with obtaining a CT-CACS.(23)

If your application is in relation to a specific radiopharmaceutical(s) or a set of radiopharmaceuticals, identify whether your clinical claim is dependent on the evidence base of the radiopharmaceutical(s) for which MBS funding is being requested. If your clinical claim is dependent on the evidence base of another radiopharmaceutical product(s), a claim of clinical noninferiority between the radiopharmaceutical products is also required.

N/A

Summary of Evidence

Provide one or more recent (published) high quality clinical studies that support use of the proposed health service/technology. At 'Application Form lodgement',

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
1.	Prospective observational cohort	Bergström G, et al. **Prevalence of Subclinical Coronary Artery Atherosclerosis in the General Population.** Circulation. 2021 Sep 21;144(12):916-929	In this large, Swedish, community-based sample of over 25,000 asymptomatic adults with no known coronary heart disease, 42.1% had evidence of atherosclerosis on CTCA imaging.The presence of atherosclerosis increased with increasing CAC score - all individuals with a CAC score >400 had CTCA evidence of atherosclerosis.	doi: 10.1161/CIRCULATIONAHA.121.055340.	21 September 2021
2.	Clinical guideline	Mach F, et al; ESC/EAS Scientific Document Group. 2025 Focused Update of the 2019 ESC/EAS **Guidelines for the management of dyslipidaemias**. Eur Heart J. 2025 Nov 7;46(42):4359-4378.	2025 update of 2019 ESC/EAS Dyslipidaemia guideline, necessitated by new evidence of clinical risk associated with subclinical atherosclerosis documented on CT coronary imaging in persons without clinical ASCVD, recommends that CACS≥300 constitutes 'documented ASCVD' and patients should be managed aggressively as per secondary prevention guidelines	doi: 10.1093/eurheartj/ehaf190. PMID: 40878289	7 November 2025

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
3.	Randomised, controlled trial	Nerlekar N et al. **Effects of Combining Coronary Calcium Score with Treatment on Plaque Progression in Familial Coronary Artery Disease: A Randomized Clinical Trial.** *JAMA.* 2025;333(16):1403–1412.	Multisite Australian RCT. Randomised 365 individuals to GP-delivered usual care versus CACS informed care. Participants were statin-naive, asymptomatic adults (40-70 years old) with a family history of premature coronary artery disease (CAD), LDL-C <4.9, CACS 1-399, and at intermediate CV risk. The primary outcome was CTCA measured total plaque volume at 3 years. Patients in CAC-informed group had reduced plaque progression, reduced LDL-C compared to usual-care group.	doi:10.1001/jama.2025.0584	22 April 2025
4	Prospective, observational registry study	Budoff MJ et al. **When Does a Calcium Score Equate to Secondary Prevention? Insights from the Multinational CONFIRM Registry**. JACC Cardiovasc Imaging. 2023 Sep;16(9):1181-1189.	Analysis of 4949 asymptomatic individuals found patients with CACS >300 were at equivalent risk of major adverse cardiovascular events as those with established ASCVD. This provides robust evidence for high-dose statins in persons with CAC scores >300, and intensification of therapy in those who have subclinical ASCVD.	doi: 10.1016/j.jcmg.2023.03.008	24 May 2023

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
5	Guideline summary	Golub IS, et al. **Major Global Coronary Artery Calcium Guidelines**. JACC Cardiovasc Imaging. 2023 Jan;16(1):98-117.	Summary of global primary prevention and dyslipidaemia guidelines on CACS to guide management of asymptomatic individuals. Concludes minor differences in treatment thresholds, but broad accord regarding clinical utility CACS. Did not include 2025 ESC Dyslipidaemia guideline recommendation CACS≥300 is 'unequivocal documented ASCVD' managed with maximally tolerated statin/LLT, target LDL-C <1.4mmol/L	doi: 10.1016/j.jcmg.2022.06.018	14 September 2022
6	Prospective observational cohort	Javaid A et al. **Distribution of coronary artery calcium by age, sex, and race among patients 30-45 years old**. J Am Coll Cardiol. 2022;79(19):1873-1886.	In a cohort of 19725 asymptomatic young adults (30-45 years) with no known CAD, 21% had a non-zero CACS. Prevalence of non-zero CACS in white males (26%), black males (16%), white females (10%), black females (7%)	doi:10.1016/j.jacc. 2022.02.051	17 May 2022
7	Prospective observational cohort	Greenland P et al. **Coronary artery calcium score combined with Framingham score for risk prediction in asymptomatic individuals**. JAMA. 2004 Jan 14;291(2):210-5	Compared with CACS = 0, CACS > 300 predictive (HR = 3.9) of the combination of non-fatal myocardial infarction and CV mortality. Across categories of Framingham Risk Score, CACS predictive of risk for patients with an FRS greater than 10% (P<.001) but not with an FRS less than 10%.	doi: 10.1001/jama.291.2.210.	14 January 2004

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
8	Prospective, community-based observational cohort (MESA)	Detrano R, et al. **Coronary calcium as a predictor of coronary events in four racial or ethnic groups.** N Engl J Med. 2008 Mar 27;358(13):1336-45	In this multi-ethnic cohort 6722 asymptomatic adults (45 – 84 years) the adjusted risk of a coronary event was increased by factor of 7.73 among participants with CACS 101-300 and a factor of 9.67 among participants with CACS >300, compared with individuals with a CACS=0	doi: 10.1056/NEJMoa072100.	27 March 2008
9	Prospective observational cohort study	Budoff MJ, Shaw LJ, et al. **Long-term prognosis associated with coronary calcification: observations from a registry of 25,253 patients.** J Am Coll Cardiol. 2007 May 8;49(18):1860-70	Prospective cohort 10,746 asymptomatic individuals, no known CAD (22-96 years). Age-adjusted rates (per 1,000 person-years) of non-fatal MI or CV mortality for four CAC categories: CAC=0 and incremental sex-specific thirds of detectable CAC; rates were, respectively, 0.4, 1.5, 4.8, and 8.7 for men and 0.7, 2.3, 3.1, and 6.3 for women.	doi: 10.1016/j.jacc.2006.10.079	20 April 2007
10	Prospective observational cohort	LaMonte MJ, et al. **Coronary artery calcium score and coronary heart disease events in a large cohort of asymptomatic men and women**. Am J Epidemiol. 2005 Sep 1;162(5):421-9	Prospective cohort of 10,746 asymptomatic individuals, no known CAD (22-96 years). Age-adjusted rates (per 1,000 person-years) of non-fatal MI or cardiovascular mortality for four CAC categories: no detectable CAC and incremental sex-specific thirds of detectable CAC; rates were, respectively, 0.4, 1.5, 4.8, and 8.7 for men and 0.7, 2.3, 3.1, and 6.3 for women. CAC levels also were positively associated with rates of total CHD events for all.	doi: 10.1093/aje/kwi228	2 August 2005

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
11	Prospective observational cohort	Shaw LJ, et al. **Long-Term Prognosis After Coronary Artery Calcification Testing in Asymptomatic Patients: A Cohort Study.** Ann Intern Med. 2015 Jul 7;163(1):14-21.	Prospective cohort of 9715 asymptomatic adults, no known CAD referred for cardiology screening. Mean follow-up of 14 years, mortality was 3%, 6%, 9%, 14%, 21%, and 28%, respectively, for CAC subgroups with scores of 0, 1 to 10, 11 to 100, 101 to 399, 400 to 999, and 1000 or greater. The relative hazard for all-cause death was 1.68, 2.91, 4.52, 5.53, and 6.26, respectively.	doi: 10.7326/M14-0612	7 July 2015
12	Prospective observational cohort study (MESA)	McClelland RL,et al. **10-Year Coronary Heart Disease Risk Prediction Using Coronary Artery Calcium and Traditional Risk Factors: Derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) With Validation in the HNR (Heinz Nixdorf Recall) Study and the DHS (Dallas Heart Study)**. J Am Coll Cardiol. 2015 Oct 13;66(15):1643-53	Cohort of 6814 asymptomatic adults (45 – 84 years) with no CHD at baseline used to model first cardiovascular risk score (MESA risk score) incorporating CAC. Inclusion of CAC in the MESA risk score offered significant improvements in risk prediction (C-statistic 0.80vs.0.75; $p < 0.0001$). External validation in both the HNR and DHS studies provided evidence of very good discrimination and calibration.	doi: 10.1016/j.jacc.2015.08.035	13 October 2015

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
13.	Prospective observational cohort	Fernández-Friera L, et al. **Association between subclinical atherosclerosis burden and unrecognized myocardial infarction detected by cardiac magnetic resonance in middle-aged low-risk adults**. Eur Heart J Cardiovasc Imaging. 2024 Jun 28;25(7):968-975	In cohort of 712 low-risk asymptomatic individuals, CACS ≥78 independently associated with increased risk ischaemic scarring (OR 8.31) after adjustment for SCORE2 baseline risk. Ischaemic scarring proxy for prior unrecognised (subclinical) MI. Reinforces value of CACS for identifying sub-clinical ASCVD in low-risk individuals.	doi: 10.1093/ehjci/jeae044.	28 June 2024
14	Prospective observational cohort study	Dzaye O, et al. **Coronary artery calcium scores indicating secondary prevention level risk: Findings from the CAC consortium and FOURIER trial.** Atherosclerosis. 2022 Apr;347:70-76	Cohort 444 asymptomatic adults ≥50y with hsCRP≥2. 47% had CAC=0, rate CHD events 0·8/1000 person-years. 74% coronary events in participants with CAC >100. In total population (2083 patients) including pts with hsCRP<2, CAC>0 associated with HR 4·29 for CHD, and 2·57 for CVD. hsCRP was not associated with CHD or CVD after multivariable adjustment.	doi: 10.1016/S0140-6736(11)60784-8	12 February 2022

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
15	Prospective observational cohort study	Budoff MJ, et al. **Ten-year association of coronary artery calcium with atherosclerotic cardiovascular disease (ASCVD) events: the multi-ethnic** study of atherosclerosis (MESA). Eur Heart J. 2018 Jul 1;39(25):2401-2408.	10y follow-up 6814 adults no clinical CVD at baseline. Participants CAC> 100 had >7.5% risk of ASCVD event regardless demographic subset. 10y ASCVD event rates increased across CACS categories regardless of age, sex, race/ethnicity. For each doubling CACS there was 14% increment in ASCVD risk, not significantly modified by age, sex, race/ethnicity, baseline lipid-lowering use.	doi: 10.1093/eurheartj/ehy217.	1 July 2018
16	Clinical practice guideline	Royal Australian College of General Practitioners (RACGP). **Coronary artery calcium scoring in asymptomatic people**. 01 Nov 2022.	Royal Australian College of General Practitioners 2022 recommendations for the use of CAC scoring for the 'reduction of risk' in asymptomatic people.	https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/first-do-no-harm/gp-resources/coronary-artery-calcium-scoring	01 November 2022
17	Position statement	Liew G, Chow C, van Pelt N, Younger J, Jelinek M, Chan J, Hamilton-Craig C. **Cardiac Society of Australia and New Zealand Position Statement: Coronary Artery Calcium Scoring**. Heart Lung Circ. 2017 Dec;26(12):1239-1251.	2017 Position statement from the Cardiac Society of Australia and New Zealand (CSANZ) on the utilisation of CAC for risk stratification in primary prevention.	doi: 10.1016/j.hlc.2017.05.130.	December 2017

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
18	Review	Playford D, Hamilton-Craig C, Dwivedi G, Figtree G. **Examining the Potential for Coronary Artery Calcium (CAC) Scoring for Individuals at Low Cardiovascular Risk**. Heart Lung Circ. 2021 Dec;30(12):1819-1828.	Australian review proposing model for CV risk assessment incorporating CACS for asymptomatic non-high-risk adults to inform management. Patients with CAC=0 "low-risk" and statins may be withheld unless strong independent indication exists. Patients CAC 1-100 should be treated on individual basis, considering cost of treatment. CAC>100 should receive treatment, including lipid lowering therapy.	doi: 10.1016/j.hlc.2021.04.026.	December 2021
19	Prospective observational cohort study	Hageman SHJ, et al. **Improving 10-year cardiovascular risk prediction in apparently healthy people: flexible addition of risk modifiers on top of SCORE2**. Eur J Prev Cardiol. 2023 Oct 26;30(15):1705-1714.	Model of the addition of risk modifying characteristics to SCORE2, used combined cohort of MESA, ARIC, UK Biobank and Heinz Nixdorf Recall Study, of > 400 000 baseline healthy individuals. Found adding CACS, NT-proBNP, hs-Troponin-T to SCORE2 improved the accuracy predicted CVD risk, with CACS demonstrating the best discrimination	doi: 10.1093/eurjpc/zwad187.	26 October 2023
20	Prospective observational cohort study (MESA)	Peng AW, et al. **Very High Coronary Artery Calcium (≥1000) and Association with Cardiovascular Disease Events, Non-Cardiovascular Disease Outcomes, and Mortality: Results From MESA**. Circulation. 2021 Apr 20;143(16):1571-1583.	Individuals with CAC≥1000 at higher risk for CVD events/mortality compared lower CAC, with adverse CV event rates similar to those in secondary prevention population. After adjustment, CAC ≥1000 demonstrated a 4.71, 7.57, 4.86, 1.94-fold increased risk for all CVD events, all CHD events, hard CHD events, and all-cause mortality, respectively, compared CAC=0	doi: 10.1161/CIRCULATIONAHA.120.050545.	20 April 2021

	Type of study design*	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)**	Website link to journal article or research (if available)	Date of publication***
21	Multisite prospective observational cohort study	Mehta A, et al. **Predictive Value of Coronary Artery Calcium Score Categories for Coronary Events Versus Strokes: Impact of Sex and Race: MESA and DHS**. Circ Cardiovasc Imaging. 2020 Aug;13(8):e010153.	Compared with CAC=0, CAC>100 independently associated with 2.3-3.4-fold risk of ASCVD and 3.3 - 5.6-fold risk of CHD events in the entire cohort across all sex/race groups. The addition of CAC score categories to a traditional risk factor model of pooled cohort equations risk factors, family history of myocardial infarction, and statin use at baseline resulted in a significant improvement in ASCVD and CHD risk discrimination but not stroke risk.	doi: 10.1161/CIRCIMAGING.119.010153	18 August 2018
22	Cost-effectiveness analysis	Venkataraman P, et al. **The cost-effectiveness of coronary calcium score-guided statin therapy initiation for Australians with family histories of premature coronary artery disease.** Med J Aust. 2023 Mar 20;218(5):216-222	Australian CAUGHT-CAD RCT data (asymptomatic adults with family history of premature CAD) modelling comparative cost-effectiveness of different criteria for initiating statin therapy in Australian context. Estimated that systematic CAC screening of people with baseline 5-year CVD risk of ≥ 5% cost-effective if CACS≥100 is threshold for statin therapy, and for CVD risk ≥8% when CACS>0	doi: 10.5694/mja2.51860	20 March 2023

	Type of study design	Title of journal article or research project (including any trial identifier or study lead if relevant)	Short description of research (max 50 words)	Website link to journal article or research (if available)	Date of publication
23	Cost-effectiveness analysis	Venkataraman P, et al; CAUGHT-CAD investigators. **Cost-Effectiveness of Coronary Artery Calcium Scoring in People With a Family History of Coronary Disease**. JACC Cardiovasc Imaging. 2021;14(6):1206-1217	USA Cost-effectiveness of CAC-guided strategy in low- and intermediate-risk cohort with family history of premature CHD. Statin-initiation strategy incorporating CAC compared with standard, non-CAC care. A CAC screening protocol was found to be cost effective in those with family history of premature CAD and baseline PCE risk ≥5% compared to standard risk factor assessment.	doi: 10.1016/j.jcmg.2020.11.008.	13 January 2021
24	Prospective cohort study (BioHEART biobank)	Fathieh S, Tang O, Gray MP, Zanchin C, Vernon ST, Genetzakis E, Tran C, Sullivan DR, Nicholls SJ, Celermajer DS, Psaltis PJ, Grieve SM, Figtree GA. **Evaluating the Role of Lipoprotein(a) in Enhancing Risk Stratification for the Presence and Extent of Subclinical Coronary Artery Disease Burden - A BioHEART-CT Study**. Eur J Prev Cardiol. 2025 Jun 3:zwaf323. Epub ahead of print.	This study confirmed Lp(a) as independent risk factor for CAD in a stable cohort undergoing CTCA. Lp(a) a non-invasive early screening tool for CAD: integrating Lp(a) with traditional risk models significantly improves prediction of CTCA-determined clinically actionable CAD, particularly in low and intermediate-risk groups, supporting use in routine screening and triaging for early CT imaging.	doi: 10.1093/eurjpc/zwaf323	3 June 2025

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

	Type of study design	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)	Website link to research (if available)	Date
1.	Systematic review of published CACS data, with modelling across diverse populations- establishing prevalence of CACS>100 across diverse sub-populations (age, gender, ethnicity, geography, traditional risk categories)	Prevalence of atherosclerotic CAD (CACS>100), meeting guidelines for intensive LDL treatment, in diverse populations	Review of published and available CACS data in asymptomatic populations to examine prevalence of atherosclerotic CAD meeting guidelines for intensive LDL treatment, across diverse populations in both Australia and around globe.	In progress- PhD studies of Ms Suzanne Avis, under co-supervision of A/Prof Michelle Cunich, Professor Gemma Figtree, and Professor Stuart Grieve.	2025-ongoing
2.	Health economics- systematic review of published CACS studies and re-evaluation integrating recent European Lipid Guidelines for intensive "secondary" prevention level LDL and risk factor management.	Re-evaluation of the health and economic benefit of coronary artery calcium score utility in asymptomatic populations- with consideration of guideline shift towards intensive "secondary" LDL and risk factor management	This work will re-evaluate the health and economic value of CACS in different subpopulations taking into considerations recommendation for maximum statin/ezetimibe (and LDL goal <1.4 mmol/L) versus standard primary prevention goals which have been used previously (with LDL <3.5 mmol/L targets). These levels are associated with substantial differences in effect at the plaque level and at MACE level.	In progress- PhD studies of Ms Suzanne Avis, under co-supervision of Professor Gemma Figtree, A/Prof Michelle Cunich, and Professor Stuart Grieve.	2025-ongoing

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
3.	Observational- survey study Equitable access- Survey study examining CACS service provision across Australia according to rural/remote/urban, SES, sex, ethnicity.	A study of CACS service provision according to rural vs urban, socioeconomic, sex and ethnicity in Australia	In partnership with Australian Diagnostic Imaging Association, the CACS MSAC Working Group will evaluate current CACS service provision (reflecting access) according to variety of demographic factors.	In progress- PhD studies of Ms Suzanne Avis, under co-supervision of Professor Gemma Figtree, A/Prof Michelle Cunich, and Professor Stuart Grieve.	2025-ongoing
4.	Observational – retrospective evaluation of novel CACS dispersion and density score for prognostic value versus standard Agatston Score	Novel CAC Dispersion and Density Score to Predict Myocardial Infarction and Cardiovascular Mortality	Girish Dwivedi and Ben Chow co-lead this evaluation of a fully automated novel CAC-dispersion and density score to improve the prognostic ability of a non-contrast CACS study. They apply the score across an established cohort of ~950 individuals and show improvement in C statistic. The CAC-DAD score had a HR of 2.57 for MACE.	Recently accepted for publication - https://doi.org/10.1161/circimaging.125.018059 Ongoing efforts to evaluate in additional cohorts.	2025-current

	Type of study design*	Title of research (including any trial identifier if relevant)	Short description of research (max 50 words)**	Website link to research (if available)	Date***
5.	Prospective, multicentre implementation study incorporating polygenic risk scoring (PRS) into primary care cardiovascular risk assessments	Implementation Study of Incorporating a Polygenic Risk Score into Cardiovascular Disease **E**xaminations to Identify **S**ub**C**linic**AL** coron**A**ry ar**TE**ry Disease	Prospective multicentre implementation study incorporating PRS into standard primary care CVD risk assessments, to identify patients at increased lifetime CAD risk for **non-invasive coronary imaging.** 1000 participants, 45 to 65 years old will enter the study, which applies PRS to those considered low or moderate 5-year absolute CVD risk and triages those with CAD PRS ≥80% for a CAC scan. Primary outcome identification of subclinical CAD, defined as a coronary artery calcium score (CACS) >0.	Ongoing study, Principal Investigator Prof Gemma Figtree. Protocol available at: doi: 10.1016/j.ahj.2023.06.009.	Ongoing

References

1. Mach F, et al; ESC/EAS Scientific Document Group. 2025 Focused Update of the 2019 ESC/EAS **Guidelines for the management of dyslipidaemias**. Eur Heart J. 2025 Nov 7;46(42):4359-4378.

2. Commonwealth of Australia as represented by the Department of Health and Aged Care. **Australian Guideline for assessing and managing cardiovascular disease risk.** 2023. Available from: https://d35rj4ptypp2hd.cloudfront.net/pdf/Guideline-for-assessing-and-managing-CVD-risk_20230522.pdf

3. Liew G, Chow C, van Pelt N, Younger J, Jelinek M, Chan J, Hamilton-Craig C. **Cardiac Society of Australia and New Zealand Position Statement: Coronary Artery Calcium Scoring**. Heart Lung Circ. 2017 Dec;26(12):1239-1251.

4. Garg PK, Bhatia HS, Allen TS, Grainger T, Pouncey AL, Dichek D, Virmani R, Golledge J, Allison MA, Powell JT. **Assessment of Subclinical Atherosclerosis in Asymptomatic People In Vivo: Measurements Suitable for Biomarker and Mendelian Randomization Studies.** Arterioscler Thromb Vasc Biol. 2024 Jan;44(1):24-47. doi: 10.1161/ATVBAHA.123.320138. Epub 2023 Nov 21.

5. Detrano R, Guerci AD, Carr JJ, Bild DE, Burke G, Folsom AR, Liu K, Shea S, Szklo M, Bluemke DA, et al**. Coronary calcium as a predictor of coronary events in four racial or ethnic groups**. N Engl J Med. 2008;358:1336–1345. doi: 10.1056/NEJMoa072100

6. Fernandez-Friera L, Garcia-Alvarez A, Oliva B, Garcia-Lunar I, Garcia I, Moreno-Arciniegas A, et al. **Association between subclinical atherosclerosis burden and unrecognized myocardial infarction detected by cardiac magnetic resonance in middle-aged low-risk adults.** Eur Heart J Cardiovasc Imaging 2024;25:968–75.

7. Erbel R, Möhlenkamp S, Moebus S, Schmermund A, Lehmann N, Stang A, Dragano N, Grönemeyer D, Seibel R, Kälsch H, et al; Heinz Nixdorf Recall Study Investigative Group. **Coronary risk stratification, discrimination, and reclassification improvement based on quantification of subclinical coronary atherosclerosis: the Heinz Nixdorf Recall study**. J Am Coll Cardiol. 2010;56:1397–1406. doi: 10.1016/j.jacc.2010.06

8. Bhatia HS, McClelland RL, Denenberg J, Budoff MJ, Allison MA, Criqui MH. **Coronary artery calcium density and cardiovascular events by volume level: the MESA**. Circulation: Cardiovasc Imag. 2023;16:e014788. doi: 10.1161/CIRCIMAGING.122.014788

9. McClelland RL, Jorgensen NW, Budoff M, Blaha MJ, Post WS, Kronmal RA, Bild DE, Shea S, Liu K, Watson KE, et al. **10-year coronary heart disease risk prediction using coronary artery calcium and traditional risk factors: derivation in the MESA (Multi-Ethnic Study of Atherosclerosis) with validation in the HNR (Heinz Nixdorf Recall) study and the DHS (Dallas Heart Study).** J Am Coll Cardiol. 2015;66:1643–1653. doi: 10.1016/j.jacc.2015.08.035

10. Nasir K, Bittencourt MS, Blaha MJ, et al. **Implications of coronary artery calcium testing among statin candidates according to American College of Cardiology/American Heart Association cholesterol management guidelines: MESA (Multi-Ethnic Study of Atherosclerosis)**. J Am Coll Cardiol 2015; 66: 1657–1668.

11. Chou R, Dana T, Blazina I, Daeges M, Jeanne TL**. Statins for Prevention of Cardiovascular Disease in Adults: Evidence Report and Systematic Review for the US Preventive Services Task Force**. JAMA. 2016;316(19):2008–2024. doi:10.1001/jama.2015.15629

12. Bohula EA, Marston NA, Bhatia AK, et al. VESALIUS Investigators. **Evolocumab in patients without a previous myocardial infarction or stroke.** New Eng J Med. Epub 2025 Nov 8. doi0.1056/NEJMoa2514428

13. Soukup T, et al; NIHR HRC IVD PPIE Team. **Defining the value proposition in diagnostic technology: challenges and opportunities for its understanding and development - a review with a multi-perspective reflective analysis**. Front Med (Lausanne). 2025 Feb 20;12:1498618. doi: 10.3389/fmed.2025.1498618.

14. Lee DW, Neumann PJ, Rizzo JA. **Understanding the medical and nonmedical value of diagnostic testing**. Value Health. 2010 Mar-Apr;13(2):310-4. doi: 10.1111/j.1524-4733.2009.00597.x. Epub 2009 Sep 10. PMID: 19744295.

15. Mamudu HM, Paul TK, Veeranki SP, Budoff M**. The effects of coronary artery calcium screening on behavioral modification, risk perception, and medication adherence among asymptomatic adults: a systematic review.** Atherosclerosis. 2014 Oct;236(2):338-50. doi: 10.1016/j.atherosclerosis.2014.07.022.

16. Harry KM, Bennett KK, Marszalek JM, Eways KR, Clark JM, Smith AJ, Waters M, Bergland D, Umhoefer A, Wilson EJ. **Scale development and psychometric properties of the Cardiac Self-Blame Attributions scale in patients with cardiovascular disease.** Health Psychol Open. 2018 Jul 11;5(2):2055102918786865. doi: 10.1177/2055102918786865.

17. Schillinger D. **Social Determinants, Health Literacy, and Disparities: Intersections and Controversies**. Health Lit Res Pract. 2021 Jul;5(3):e234-e243. doi: 10.3928/24748307-20210712-01.

18. Amery R. **Recognising the communication gap in Indigenous health care**. Med J Aust. 2017 Jul 3;207(1):13-15. doi: 10.5694/mja17.00042. PMID: 28659103.

19. Nerlekar N, Vasanthakumar SA, Whitmore K, et al**. Effects of Combining Coronary Calcium Score With Treatment on Plaque Progression in Familial Coronary Artery Disease: A Randomized Clinical Trial**. JAMA. 2025;333(16):1403–1412. doi:10.1001/jama.2025.0584

20. Cholesterol Treatment Trialists' Collaboration. **Efficacy and safety of statin therapy in older people: a meta-analysis of individual participant data from 28 randomised controlled trials**. Lancet. 2019 Feb 2;393(10170):407-415. doi: 10.1016/S0140-6736(18)31942-1. PMID: 30712900; PMCID: PMC6429627.

21. Lee L, Kim H**. Exploring the Evolution of Statin Pricing in Australia: Observations of Price Disclosure Effects on Pharmaceutical Benefits Scheme Expenditure**. Value Health Reg Issues. 2024 Mar;40:27-34. doi: 10.1016/j.vhri.2023.10.004

22. Australian Institute of Health and Welfare. **Medicines in the health system [Internet]**. Canberra: Australian Institute of Health and Welfare, 2024 [cited 2025 Nov. 15]. Available from: https://www.aihw.gov.au/reports/medicines/medicines-in-the-health-system

23. Venkataraman P, Neil AL, Mitchell GK, Stanton T, Nicholls S, Tonkin AM, Watts GF, Marwick TH**. The cost-effectiveness of coronary calcium score-guided statin therapy initiation for Australians with family histories of premature coronary artery disease**. Med J Aust. 2023 Mar 20;218(5):216-222. doi: 10.5694/mja2.51860.

24. Lee CI, Tsai EB, Sigal BM et al. **Incidental extracardiac findings at coronary CT: Clinical and economic impact**. AJR Am J Roentgenol 2010;194(6):1531–38. doi: 10.2214/AJR.09.3587

25. Voros S, et al; Society for Atherosclerosis Imaging and Prevention Tomographic Imaging and Prevention Councils; Society of Cardiovascular Computed Tomography. **Guideline for minimizing radiation exposure during acquisition of coronary artery calcium scans with the use of multidetector computed tomography: a report by the Society for Atherosclerosis Imaging and Prevention Tomographic Imaging and Prevention Councils in collaboration with the Society of Cardiovascular Computed Tomography**. J Cardiovasc Comput Tomogr. 2011 Mar-Apr;5(2):75-83. doi: 10.1016/j.jcct.2011.01.003.