# MSAC application 1815

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

# Application for MBS eligible service or health technology

**HPP Application number:**

HPP200370

**Application title:**

New item number and reimbursement for coronary artery calcium scoring

**Submitting organisation:**

CAD FRONTIERS PTY LTD

**Submitting organisation ABN:**

93662094626

# Application description

**Succinct description of the medical condition/s:**

Coronary atherosclerosis is a disease in which cholesterol, and other substances accumulate in the walls of the blood vessels supplying the heart muscle, causing the vessels to harden and narrow, and increasing a person's risk of a heart attack. Subclinical atherosclerosis is a very common condition where these fatty deposits (atherosclerotic plaques) are present in the heart's blood vessels, but haven't yet caused any symptoms or signs of disease. Subclinical atherosclerosis affects people of any age, even young people, and if left untreated, can lead to a life-threatening heart attack.

**Succinct description of the service or health technology:**

A coronary artery calcium score is a number that indicates the amount of atherosclerotic plaque present in the walls of the blood vessels (arteries) supplying the heart muscle. A higher score indicates that more plaque is present, and that a person has a higher risk of having a heart attack or stroke. The score is measured using a quick, non-invasive computed tomography (CT) scan of the heart that does not require any injections of dye or contrast material. The scanner detects tiny calcium deposits, which are a sign of atherosclerotic plaque. A coronary artery calcium score can be used, along with other risk factors like high blood pressure, cholesterol, smoking, diabetes and family history to help a patient and their doctor decide on the medications and lifestyle changes that will work best for them.

## 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

**Applicant organisation name:**

CAD FRONTIERS PTY LTD

## 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 Prescribed List?**

No

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

New

**What is the type of service or health technology?**

Investigative

**Please select the type of investigative health technology:**

Computed tomography scans

## PICO sets

**Application PICO sets:**

New item number and reimbursement for coronary artery calcium scoring.

**State the purpose(s) of the health technology for this PICO set and provide a rationale:**

**Purpose category:**

Target testing

**Purpose description:**

To test currently unaffected or asymptomatic individual(s) identified as at increased risk for the condition. For example: cascade testing.

**Purpose category:**

Value of knowing

**Purpose description:**

Tests may also provide additional non-health value to patients or to their family members and carers, and discussion of these outcomes could supplement an assessment of the clinical utility of the technology.

## 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.

**Select the most applicable Medical condition terminology (SNOMED CT):**

Coronary atherosclerosis

## Intervention

**Name of the proposed health technology:**

Computed tomography of the coronary arteries for the determination of coronary artery calcium score (CACS)

## 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:**

Heart Health Check or equivalent consultation performed by a specialist physician

## Outcomes

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

Outcome 1: Reduction in Major Adverse Cardiovascular Events (MACE) – composite endpoint of acute myocardial infarction, stroke and cardiovascular death. CACS may change (initiate, intensify or cease) pharmacological management based on presence/absence of subclinical atherosclerosis

Outcome 2: Reduction in patient uncertainty. There may be considerable additional value for the patient in knowing that they have subclinical atherosclerosis, reducing the uncertainty that comes with risk estimates derived from standard cardiovascular risk tools (the comparator). 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 (planning value). However, knowing is not universally positive. For some individuals, knowing they have subclinical atherosclerosis can be adaptive, driving changes in lifestyle and increased adherence to prescribed medications, whereas in others in can lead to maladaptive feelings of hopelessness and distress.

Outcome 3: Change in rate of prescribing of lipid-lowering medications (statins, ezetimibe, PCSK9 inhibitors, bile acid sequestrants) for primary prevention in patients. Using population-based risk calculators (the comparator) to guide pharmacotherapy exposes the estimated 45% - 55% of intermediate/moderate risk patients with a CAC score of zero to unnecessary financial costs, inconvenience, and to the risk of adverse drug effects

Outcome 4:  Incidental findings. CAC scoring is performed with a CT scan of the chest and may result in incidental findings. 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: Radiation exposure. CAC scoring using ECG-gated CT scanning typically exposes an individual to approximately 1mSv of radiation, compared with no exposure for the comparator.

## Proposed MBS items

**Please provide at least one proposed item with their descriptor and associated costs, for each population / intervention:**

**Proposed item:**

AAAAA

**MBS item number (where used as a template for the proposed item):**

NA

**Category number:**

DIAGNOSTIC IMAGING SERVICES

**Category description:**

COMPUTED TOMOGRAPHY

**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:**

$250.00

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

$250.00

**Please specify any anticipated out of pocket expenses:**

$0.00

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

Self-funded by patients

## 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)?**

Non-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.

## Estimated utilisation

**Estimate the prevalence and/or incidence of the proposed population:**

An estimated 26% of the Australian population are classified as at 'intermediate' 10 year risk of an acute cardiovascular event (stroke, myocardial infarction or cardiovascular death), based on data from 115,873 people aged 45-74 years without existing CVD from MedicineInsight, a longitudinal primary-care database covering 8% of Australian general practices

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

**Year 1 estimated uptake (%):**

10

**Year 2 estimated uptake (%):**

20

**Year 3 estimated uptake (%):**

30

**Year 4 estimated uptake (%):**

30

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

~247,000

**Optionally, provide details:**

Estimation of number of patients who will utilise the proposed technology in the first year based on March 2025 Australian Census figures for population:
Approximately 9,500,000 individuals aged  between 45 and 79 years
26% of these at intermediate cardiovascular risk: 2,470,000
Estimated 10% uptake in Year 1: 247,000

**Will the technology be needed more than once per patient?**

Yes, multiple times

**Over what duration will the health technology or service be provided for a patient? (preferably a number of years):**

5

**What frequency will the health technology or service be required by the patient over the duration? (range, preferably on an annual basis):**

1

## Consultation

**List all entities that are relevant to the proposed service / health technology. The list can include professional bodies / organisations who provide, request, may be impacted by the service/health technology; sponsor(s) and / or manufacturer(s) who produce similar products; patient and consumer advocacy organisations or individuals relevant to the proposed service/health technology.**

**Entities who provide the health technology/service:**

Royal Australian and New Zealand College of Radiologists (RANZCR)

Australian Diagnostic Imaging Association (ADIA)

**Entities who request the health technology/service:**

Royal Australian College of General Practitioners (RACGP)

Cardiac Society of Australia and New Zealand (CSANZ)

**Patient and consumer advocacy organisations relevant to the proposed service/health technology:**

National Heart Foundation

CAD Frontiers

**Entity who may be impacted by the health technology/service:**

Royal Australian and New Zealand College of Radiologists (RANZCR)

## 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?**

No