MSAC Application 1815

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

Applicant: CAD FRONTIERS Pty Ltd

PICO Confirmation

Summary of PICO/PPICO criteria to define question(s) to be addressed in an Assessment Report to the Medical Services Advisory Committee (MSAC)

Table 1 PICO for non-contrast ECG-gated CT of the coronary arteries for the purpose of calcium scoring in asymptomatic patients with no known CVD/CAD: PICO Set 1

Component	Description

Population	Asymptomatic patients without known CVD or CAD and who are:
	• aged 45–79 years and at
	  ○ intermediate risk as categorised by the Aus CVD Risk calculator of experiencing a CV event (MI, stroke, CV death), or
	  ○ low risk using the Aus CVD Risk calculator, but who have specific CVD risk enhancers* in whom CT-CAC imaging evidence of coronary atherosclerosis may change management decisions, or
	• an Aboriginal and Torres Strait Islander person aged 30–44 years with low or intermediate CV risk according to the Aus CVD Risk calculator.

Prior tests	Estimation of 5-year CVD risk using Aus CVD Risk calculator Other tests: fasting cholesterol, glucose and HbA1c for Aus CVD Risk algorithm, Lp(a) and hs-CRP.
Intervention	Non-contrast ECG-gated CT of the coronary arteries on a minimum of a 64 slice (or equivalent) scanner for the purpose of calcium scoring (CT-CAC)
Comparator/s	CV risk assessment using the Aus CVD Risk calculator and where appropriate the assessment of Lp(a) and hs-CRP
Reference standard	Long term incidence of MACE
Outcomes	Clinical effectiveness • Test accuracy of CV risk stratification measured by sensitivity, specificity, PPV, NPV, PLR, NLR, diagnostic yield, net reclassification improvement • Reduction in MACE, morbidity and cardiovascular and overall mortality • HRQoL Patient management outcomes • Change in rate of prescribing appropriate lipid lowering medications • Patients adherent to lipid lowering therapy in short and long term • Change in CV risk factors (e.g. lipid levels, blood pressure) • Proportion of patients in whom CV risk stratification changes • Change in rates of adverse events associated with preventive pharmacotherapy Safety • Increases in radiation exposure • Change in rates of adverse events associated with preventive pharmacotherapy (including treatment associated morbidity, mortality, HRQoL) Value of knowing • Patient adoption, persistence and adherence to prevention management • Psychological impacts of knowledge of risk (both positive, such as reassurance or increased sense of control, and negative such as anxiety or distress following a non-zero CAC result or incidental findings such as pulmonary nodules)

	Health care resources • Costs of delivering the intervention (including costs of follow-up of incidental findings e.g. pulmonary nodules) • Costs of managing adverse events • Cost offsets • Costs per Quality Adjusted Life Year Total Australian Government healthcare costs • Total costs to the Commonwealth government • Total costs to other government health budgets Economic analysis • CEA • CUA
Assessment questions	What is the safety, effectiveness and cost-effectiveness of CT-CAC versus the contemporary risk calculators alone in asymptomatic patients with low or intermediate risk of CV events?

Abbreviations: CAD = coronary artery disease; CEA = cost effectiveness analysis; CT = computed tomography; CT-CAC = computed tomography coronary artery calcium; CUA = cost utility analysis; CV(D) = cardiovascular (disease); ECG = electrocardiogram; HbA1c = glycated haemoglobin; HRQoL = health-related quality of life; hs-CRP = high-sensitivity C reactive protein; Lp(a) = lipoprotein a; MACE = major adverse cardiovascular event; MI = myocardial infarction; NLR = negative likelihood ratio; NPV = negative predictive value; PICO = population, intervention, comparator, outcomes; PLR = positive likelihood ratio; PPV = positive predictive value

Notes:

* CV risk enhancers include elevated lipoprotein a (Lp(a)) and persistently elevated high-sensitivity C-reactive protein (hs-CRP) and the reclassification factors included in the Aus CVD Risk calculator

Purpose of application

An application requesting the Medicare Benefits Schedule (MBS) listing of non-contrast electrocardiogram (ECG)-gated computed tomography (CT) of the coronary arteries for the purpose of coronary artery calcium (CAC) scoring, referred to as CT-CAC hereafter, was received from CAD Frontiers Pty Ltd by the Department of Health, Disability and Ageing. CT-CAC is a non-invasive imaging technique and provides a quantitative measure of coronary atherosclerosis via a CAC score in Agatston units.

PICO criteria

Population

The target population is asymptomatic patients without known cardiovascular disease (CVD) or coronary artery disease (CAD) and who is:

a. aged 45–79 years and at
    i. intermediate risk as categorised by the Aus CVD Risk calculator of experiencing a cardiovascular (CV) event (myocardial infarction [MI], stroke, CV death), or
    ii. low risk of experiencing a CV event using the Aus CVD Risk calculator but has specific CVD risk enhancers[1] in whom CT-CAC imaging evidence of coronary atherosclerosis may change management decisions, or
b. an Aboriginal and Torres Strait Islander person aged 30–44 years with low or intermediate CV risk according to the Aus CVD Risk calculator.

[1] CV risk enhancers include elevated Lp(a) and persistently elevated hs-CRP and risk reclassification factors as per AUS CVD calculator

Thus, it is assumed that the target population has undertaken prior testing to enable CVD risk assessment using the Aus CVD Risk calculator. The Aus CVD Risk calculator produces a CVD risk estimate expressed as a percentage probability of dying or being hospitalised due to MI, angina, other coronary heart disease, stroke, transient ischaemic attack, peripheral vascular disease, congestive heart failure or other ischaemic CVD-related conditions within the next 5 years. According to the Aus CVD Risk calculator, a high CVD risk is defined as a ≥ 10% 5-year estimated risk of CV events, intermediate risk as between 5% and < 10%, and low risk as < 5%.[2] In addition to the CVD risk prediction from the Aus CVD Risk calculator, other reclassification factors may help refine the CVD risk categorisation (e.g. family history of premature CVD[3], chronic kidney disease, severe mental illness[4], elevated lipoprotein a (Lp(a)), persistently elevated high-sensitivity C-reactive protein (hs-CRP), history of pre-eclampsia or gestational hypertension, and ethnicities such as Aboriginal and Torres Strait Islander-status, Māori people, Pacific Islander people, and people of South Asian ethnicity)[5] (Agarwala et al. 2019; Jennings et al. 2021). For instance, for Aboriginal and Torres Strait Islander patients, the Aus CVD Risk calculator recommends consideration of reclassifying up a category after use of the risk assessment tool. Risk enhancers are further discussed below.

PASC noted that the subpopulation of patients of intermediate risk was the main target group of the intervention and was potentially a large cohort nationally.

In Aboriginal and Torres Strait Islander patients, CV events and related mortality occur about 10–20 years earlier than non-indigenous Australians (Agostino et al. 2020; Cheung et al. 2026). CVD risk assessment via the Aus CVD risk calculator is recommended for Aboriginal and Torres Strait Islander patients from age 30–79 years.[2] Consistent with this earlier assessment age, Heart Health Checks containing the Aus CVD risk calculator are Medicare-subsidised for patients aged 30 years or over (MBS items 177 and 699).[6,7] The applicant advised that the phenotype of CAD in the Aboriginal and Torres Strait Islander population was similar to the non-Indigenous population but occurs approximately 10 years earlier.[8] Although Australian real-world evidence is lacking, the applicant considers that CT-CAC in a younger Aboriginal and Torres Strait Islander population would reflect burden of disease in a similar way to the older non-Indigenous population, with prevalence of calcified coronary artery plaques occurring with a similar prevalence but approximately 10 years earlier. This supports the earlier use of CT-CAC as a risk stratification tool in this population (Agostino et al. 2020; Jennings et al. 2021).

Type 2 diabetes (T2D), especially if poorly controlled or long-standing, may also confer a higher risk of CVD (Dal Canto et al. 2019; de Jong, Woodward & Peters 2022; Joseph et al. 2022), and risk assessment for individuals with poorly controlled T2D is recommended from age 35–79 years.[2]

However, in the general population, coronary calcification is often low in patients younger than 45 years and CT-CAC has low specificity in this population (Mach, François et al. 2019). A limitation of CAC is the inability to detect non-calcified plaques, which are more prevalent in younger patients (Chaparala et al. 2025). Therefore, CT-CAC is considered less reliable in these patients (Jukema et al. 2025; Mortensen et al.

[2] https://www.cvdcheck.org.au/identify-risk-category
[3] Defined as CVD event occurring in a first-degree relative at < 60 years, or second degree relative at < 50 years.
[4] Defined as a current or recent mental health condition requiring specialist treatment, whether received or not, in the 5 years prior to the CVD risk assessment.
[5] https://www.cvdcheck.org.au/reclassification-factors-other-considerations
[6] https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=177&qt=item&criteria=177
[7] https://www9.health.gov.au/mbs/fullDisplay.cfm?type=item&q=699&qt=item&criteria=699
[8] Better Cardiac Care measures for Aboriginal and Torres Strait Islander people: eighth national report 2023 (Accessed 4 May 2026)

2022; Sheppard et al. 2022) and therefore the applicant considered that the proposed target population remain as those aged between 45 years and 79 years.

PASC considered that the eligible starting age for the Aboriginal and Torres Strait Islander population should reduce from 45 to 30 years, to reflect the higher prevalence and earlier onset of CVD in this population and to align with Aus CVD Risk calculator guidance. The applicant supported this suggestion, stating that CAD in the Aboriginal and Torres Strait Islander population is clinically similar to that seen in the non-Indigenous population but tends to occur approximately a decade earlier. PASC queried whether the age threshold for CAC testing in patient with diabetes should be reduced to 35 given the Aus CVD Risk calculator is recommended in patients with diabetes from 35 years of age, though it was noted that this was only validated for type 2 diabetes. The applicant did not support the suggestion to lower the age for patients with diabetes to 35 years, as there is less evidence to show that CAC testing in this younger population would be beneficial and PASC supported this approach.

The applicant had included patients with indeterminate risk as part of the requested population, with indeterminate risk defined as: (1) A calculated risk score that is close to recommended treatment thresholds, and in whom the initiation, intensification or deferral of preventative pharmacotherapy is clinically uncertain, or there is patient indecision, and for whom a CAC result could possibly change management (also referred to as 'borderline' risk); (2) The risk category assigned to those individuals for whom risk calculators are not applicable/accurate; and (3) The risk assigned to individuals for whom there are insufficient clinical datapoints to utilise a risk calculator (Blumenthal et al. 2026). However, due to the significant risk of use of CT-CAC outside the intended population, the applicant was agreeable to exclude indeterminate risk from the requested population.

PASC considered that the definition of the indeterminate-risk population is unclear and is open to significant risk of use outside the intended population and there may be a low likelihood of sufficient data for assessment. Therefore, PASC considered that this population should be excluded from the target population for the PICO and the applicant agreed with this.

<u>Traditional risk stratification</u>

Several CV risk calculators, apart from the Aus CVD Risk calculator, are available to estimate an individual's likelihood of experiencing a CV event over a 5- or 10-year period (Comparator(s)). These risk calculators include the Framingham risk score (FRS), QRESEARCH cardiovascular risk algorithm 2 (QRISK2), systematic coronary risk evaluation 2 (SCORE2), PREDICT-1 and PROCAM (Chaparala et al. 2025). Traditional risk stratification relies on the use of these risk calculators, which incorporate patient demographics and clinical characteristics, such as diabetes status, systolic blood pressure (SBP) and lipid profile, to classify patients as low, intermediate, or high risk. These tools provide an estimated probability of a future CV event based on established risk factors.

However, these calculators may not capture subclinical atherosclerotic burden (Chaparala et al. 2025). Traditional risk calculators also do not reflect prior exposure to risk factors or the biological susceptibility to atherosclerosis (Soh et al. 2026). As a result, risk may be overestimated in older patients and underestimated in younger patients, leading to potential overmedication of older patients and under-identification of younger patients (Chaparala et al. 2025).

Each CV risk calculator is likely to capture a different population. This is because they are valid for use in different age ranges, predict different outcomes and have been constructed from different parameters

(Chaparala et al. 2025). For example, the Framingham Heart Study does not consider socioeconomic status, BMI, HbA1c (for people with diabetes) or current pharmacological treatment for CVD, while the Aus CVD Risk calculator does take these factors into account. Therefore, these alternative calculators are unlikely to categorise risk in the same way that the Aus CVD Risk calculator does. If alternative CV risk calculators are used and patients are risk stratified differently to the Aus CVD Risk calculator, this has flow on effects for the clinical algorithm and clinical utility for CT-CAC, which are currently tailored to patients who have been assessed using the Aus CVD Risk calculator.

The applicant acknowledged that there are many CV risk calculators and the use of a specific CV risk calculator cannot be mandated. Therefore, the applicant considered the Aus CVD Risk calculator as the primary risk calculation tool for the purpose of a health technology assessment (HTA) because it is the only tool that has been calibrated for or validated in the Australian population. The applicant mentioned that the 2023 Australian Guideline for Assessing and Managing Cardiovascular Disease, endorsed by both the Royal Australian College of General Practitioners (RACGP) and the Cardiac Society of Australia and New Zealand (CSANZ), includes the use of Aus CVD Risk calculator. The applicant further mentioned that there are no methods for the translation or conversion of risk categories between risk calculators. The Aus CVD Risk calculator, and the New Zealand PREDICT CVD risk calculator both estimate 5-year CVD risk, however all other current major international risk calculation tools (SCORE2, SCORE2-OP, PREVENT-ASCVD, QRISK3) and older tools (Framingham Risk Equation, Pooled Cohort Equations) provide either 10-year (or 30-year) CVD risk estimates.

PASC considered the use of the Aus CVD Risk calculator to be an appropriate and pragmatic approach for initial CV risk stratification to determine eligibility for CT-CAC.

Use of CT-CAC across cardiovascular risk groups

Patients who are already classified as being at high risk of CV events, including those with moderate to severe CKD or familial hypercholesterolaemia, and those already on preventive medicines (lipid lowering medicines, antihypertensives and antiplatelet therapy in select cases), are recommended to commence or intensify preventive pharmacotherapy regardless of further risk stratification. In these patients, CT-CAC is unlikely to alter management and is therefore not recommended.

At the other end of the risk spectrum, patients classified as low risk are not routinely recommended for preventive treatment, and CT-CAC is unlikely to change management. An exception may apply to select low-risk patients with additional CVD risk enhancers that would lead to reclassification to intermediate risk level, where preventive treatment may be considered depending on the clinical context.

In contrast, CT-CAC has the greatest clinical utility in intermediate-risk patients, where preventive treatment decisions depend on more precise risk stratification. In these patients a CAC score may aid risk reclassification and guide management decisions (Liew et al. 2017). The applicant requests CT-CAC for patients at intermediate risk of CV events, as well as selected low-risk patients with risk enhancers where there is uncertainty regarding appropriate management.

CV risk enhancers relevant to CAC score-based risk management include ethnicity, a family history of premature CVD, elevated hs-CRP or Lp(a), chronic kidney disease (CKD), a history of pre-eclampsia or gestational hypertension, and severe mental illness[5]are included as reclassification factors in the Aus CVD Risk calculator.

The applicant had also listed polygenic risk scores (PRS) as a marker of increased risk. PRS is the weighted contribution of multiple disease-associated single nucleotide variants (SNV) across the genome (O'Sullivan et al. 2022), and may help identify patients with a high genetic risk profile for CVD. However, PRS is not included in the Aus CVD Risk calculator as a CV risk enhancer. Including PRS as a risk enhancer may encourage unnecessary genetic testing that falls outside the scope of this PICO. As such, PRS is not included as a risk enhancer as part of the proposed MBS item descriptor (see Proposal for public funding).

Elevated Lp(a) levels are known to contribute to the baseline risk of CVD. Although Lp(a) levels vary by ethnicity and gender, the increase in CVD risk associated with higher Lp(a) levels appears consistent across ethnic groups after adjusting for traditional risk factors, with CVD risk increasing with increasing Lp(a) levels (Sosnowska et al. 2025). Clinically, Lp(a) levels >125 nmol/L are considered to confer high CVD risk, while concentrations >450 nmol/L confer very high risk (Blumenthal et al. 2026; Sosnowska et al. 2025).

The role of hs-CRP as a CV risk enhancer is unclear. Evidence from the Physicians' Health Study demonstrated a strong association between elevated hs-CRP and incident CVD, with levels ≥2.11 mg/L linked to an approximate threefold increase in MI risk ($p<0.001$) and twofold increase in stroke risk ($p=0.02$) (Mehta et al. 2025). In primary prevention, hs-CRP may support risk stratification as higher levels have been associated with increased risk of ASCVD, even in individuals without known atherosclerosis (Mehta et al. 2025). However, findings are not uniform across studies. The SCAPIS study reported only modest associations between elevated hs-CRP (≥2.3 mg/L) and coronary atherosclerosis (OR 1.15, 95% CI 1.07–1.24), coronary diameter stenosis ≥50% (OR 1.27, 95% CI 1.09–1.47), ≥4 segments involved (OR 1.13, 95% CI 1.01–1.26) and severe atherosclerosis (OR 1.33, 95% CI 1.05–1.69) after adjustment for age, sex and traditional risk factors (Cederström et al. 2023). Nevertheless, the 2026 ACC/AHA guidelines for the management of dyslipidaemia considers hs-CRP >2 mg/L on two successive occasions to be a risk enhancer in determining the need for high intensity statin therapy in reducing ASCVD event risk (Blumenthal et al. 2026).

A history of adverse pregnancy outcomes in women is increasingly recognised as sex-specific risk enhancers for future CVD. Among women with a history of adverse pregnancy outcomes, an absolute 3.8% prevalence of coronary atherosclerosis was reported (Bello 2023). Specifically, pre-eclampsia was associated with a 3.1% absolute increase in significant coronary stenosis with similar findings for gestational hypertension. Notably, women with prior pre-eclampsia who were categorised as low risk by traditional risk calculators demonstrated a burden of coronary stenosis comparable to women without adverse pregnancy outcomes but classified as intermediate risk (Bello 2023; Sederholm Lawesson et al. 2023).

PASC noted the subpopulation of low-risk individuals with specific CVD risk enhancers was proposed to include individuals who do not reach the intermediate risk level based on the standard assessment but have other factors known/thought to increase the risk into the intermediate group. PASC noted that while risk enhancers are typically used in guidelines to personalise discussion/therapy in lower risk individuals, in this application they were being used to upscale risk score to justify CT-CAC. PASC noted that several proposed CV risk enhancers (family history of premature CVD, severe mental illness, chronic kidney disease, Aboriginal and Torres Strait Islander population, Māori people, Pacific Islander people and people of South Asian ethnicity) used to determine eligibility for CT-CAC for patients who are low risk, are already incorporated within the Aus CVD Risk calculator as factors that may be considered to "reclassify a patient up a category" and should be excluded from the MBS item descriptor. PASC considered that risk enhancers retained in the subgroup of low-risk patients should be limited to those with evidence demonstrating that

their presence would have the potential to result in reclassification to the intermediate-risk category. PASC did not consider PRS appropriate for inclusion. PASC noted additional issues regarding PRS, including that it has so far not been subject to HTA and there was a lack of population-level evidence, the association between PRS and cardiovascular risk may vary by age, challenges in standardisation and access and the additional cost implications in the economic analysis given that it was not MBS listed. PASC also noted that some proposed risk enhancers, such as Lp(a) and PRS, are also not currently MBS listed, which may raise equity and access issues.

PASC queried whether the economic evaluation included in the assessment report should group together the intermediate-risk and low-risk population with any CV risk enhancers into the one group or whether each low-risk group with a specific risk-enhancer should be assessed separately.

Management of CVD risk

Gupta et al. (2017) reported that a non-zero CAC score is associated with an increased likelihood of individuals initiating or continuing preventive pharmacotherapies and adopting lifestyle modifications. Several randomised controlled trials have compared CT-CAC guided management with standard care, including DANCAVAS (Lindholt et al. 2022), CAC-WOMEN trial (Marschner et al. 2022), CorCal (Muhlestein et al. 2022), EISNER (Rozanski et al. 2011) and ROBINSCA (Moldovanu et al. 2024). Although not exhaustive, these trials suggested that CT-CAC informed management is associated with favourable changes in surrogate and intermediate outcomes, such as plaque progression and control of CAD risk factors, and no clear adverse effects on health-related quality of life (HRQoL) or increases in downstream testing over the duration of follow-up.

Additional supportive evidence is provided by the CAUGHT-CAD trial (Nerlekar et al. 2025), which offers Australian specific data. In this trial, patients with a CAC score greater than 0 and less than 400 were randomised to usual care or CAC-informed care. Patients in the CAC-informed arm received lipid-lowering therapy and education around life-style/risk modification using CT-CAC images as evidence to support shared decision-making. The study demonstrated that combining CAC scoring with primary prevention therapy reduced atherogenic lipid levels and slowed plaque progression compared with usual care.

Treatment recommendations as per risk categories assigned by the Aus CVD Risk calculator are summarised in Table 2. A healthy lifestyle is encouraged for all patients irrespective of the risk category. In patients at low CVD risk, preventive pharmacotherapy is not routinely recommended. For patients at intermediate CVD risk, preventive pharmacotherapies such as blood pressure lowering medicines and lipid modifying medicines may be considered depending on the clinical context. In patients at high CVD risk, blood pressure lowering medicines and lipid modifying medicines should be prescribed in accordance with clinical guidelines.

Table 2 Treatment recommendations based on risk stratification as calculated by the Aus CVD Risk calculator

Risk Category	Estimated 5-Year CVD risk	Management	Reassessment Interval
Low	< 5%	• Encourage, support and advise a healthy lifestyle • Pharmacotherapy not routinely recommended	• Reassess every 5 years • Assess sooner if close to intermediate-risk threshold, if risk factors worsen, or new risk factors develop • Aboriginal and Torres Strait Islander: reassess every year (annual health check or opportunistically) or at least every 2 years
Intermediate	5% to < 10%	• Encourage, support and advise a healthy lifestyle • Consider blood pressure-lowering and lipid-modifying pharmacotherapy depending on clinical context	• Reassess every 2 years if not receiving pharmacotherapy • Assess sooner if close to high-risk threshold, if risk factors worsen, or new risk factors develop • Aboriginal and Torres Strait Islander: reassess every year (annual health check or opportunistically) or at least every 2 years
High	≥ 10%	• Encourage, support and advise a healthy lifestyle • Prescribe blood pressure-lowering and lipid-modifying pharmacotherapy	• Formal reassessment of CVD risk is not generally required • High-risk status requires ongoing clinical management, follow-up, and communication

Abbreviations: Aus = Australian; CVD = cardiovascular disease
Source: https://www.cvdcheck.org.au/managing-cvd-risk

With the application of CT-CAC, patients with a CAC score of zero may be reclassified to low risk, and management should focus on lifestyle modification without routine pharmacotherapy as per the guidelines. For those with CAC score 1–99 and < 75th percentile for age and sex, risk reclassification is uncertain and benefits and harms of therapy should be discussed with the patient. Patients with a CAC score > 99 or ≥ 75th percentile for age and sex should be considered for upward reclassification to high risk and managed according to guideline-recommended care (Jennings et al. 2021).

Overall, PASC proposed the following updates to the requested population of the PICO:

1. *Intermediate-risk population: to be retained and expanded to include Aboriginal and Torres Strait Islander people of a younger age range (30–44 years)*
2. *Low-risk population with CV risk enhancers should exclude PRS and limit the inclusion of risk enhancers to those that have robust evidence supporting the potential re-classification of patients to a CV risk level consistent with the intermediate risk category.*
3. *Low-risk population with risk enhancers already included in the Aus CVD Risk calculator are considered to already have evidence supporting their use and therefore these risk enhancers do not require further HTA. These risk enhancers do not need to be explicitly listed in the MBS item. However, for the purposes of the financial and economic evaluation it is presumed that this population will be reclassified by clinicians as intermediate-risk population and proceed to CT-CAC.*
4. *Indeterminate-risk population: to be excluded from the requested population.*

Intervention

CT-CAC is a non-invasive imaging technique for quantifying the burden of calcified plaque within the coronary arteries. The intervention involves an ECG-gated non-contrast CT scan of the heart, performed on a multi-detector CT scanner to minimise cardiac motion artefact. Coronary calcium is visualised on CT as > 1 mm^2 areas of hyper attenuation within the coronary arteries (> 130 Hounsfield units) and is quantified using dedicated software to generate an Agatston score (Chua, Blankstein & Ko 2020). A typical radiation dose for CT-CAC is approximately 1 mSv. While coronary calcium can be identified on non-ECG-gated chest CT and shows reasonable correlation with gated CAC scores, non-gated imaging is generally used for incidental or qualitative assessment and is not considered equivalent to ECG-gated CT for formal CAC measurement (Zhu Y., 2024). ECG-gated CT-CAC differs from non-ECG gated CT in that ECG-gated CT is less affected by cardiac motion. Non-ECG gated CT is typically performed for non-cardiac indications and may identify coronary calcium incidentally (Foraker et al. 2025). In a meta-analysis, evidence showed that while CAC severities assessed on non-ECG gated CT correlates with ECG-gated CT, agreement varies with technical parameters such as slice thickness and reconstruction kernel. A scoping review identified no studies evaluating dedicated non-ECG gated CT for CAC scoring. Studies of CAC scoring from non-ECG gated CTs were largely incidental findings from scanning performed for other medical conditions (Kim, JY et al. 2021).

PASC noted the CAC score is most commonly reported using Agatston units in Australian clinical practice and proposed that CAC scores should be defined using these units. The specification for Agatston units should be included in the proposed MBS item descriptor.

PASC noted that the application specifies CT-CAC as an ECG-gated non-contrast CT and proposed using a minimum 64-slice CT scanner. PASC also noted that the existing MBS items 57630 and 57364 require a 64-slice scanner and the existing 16- and 32-slice machines will be phased out in the next few years. The applicant clarified that the 64-slice CT scanner is not strictly necessary for provision of a CAC score.

CT-CAC provides a quantitative measure of coronary atherosclerosis and may be used to refine CV risk classification when population-based risk calculators provide uncertain or borderline estimates (Jennings et al. 2021; Liew et al. 2017). CT-CAC enables the identification of subclinical atherosclerotic CVD and may inform decisions regarding initiation, intensification or de-escalation of preventive pharmacotherapy (Jennings et al. 2021; Liew et al. 2017; Mach, F. et al. 2025). The identification of ASCVD also has an inherent 'value of knowing' for the patient and caregivers.

As previously discussed, CT-CAC may be requested following a CV risk assessment undertaken during a range of MBS attendance items. This may include, but is not limited to, General Practice items (Group A1), Other Medical Practitioner items (Group A2), Specialist Attendance Items (Group A3), Consultant Physician Attendance items (Group A4), Health Assessment items (Group A14), GP Chronic Conditions management plans (Group A15) Geriatric Medicine items (Group A28) and telehealth items (Groups A40 and A48). CT-CAC is intended for patients at intermediate risk and low risk in the presence of CVD risk enhancers in whom CT-CAC imaging evidence of coronary atherosclerosis will change management decisions. The Aus CVD Risk calculator is the recommended first-line tool for CV risk assessment in individuals without known atherosclerotic cardiovascular disease, including all people aged 45–79 years, people with diabetes aged

35-79 years, and Aboriginal and Torres Strait Islander peoples aged 30-79 years (with individual risk factor assessment from 18-29 years)[9].

CAC scoring independently predicts CV event risk and mortality and provides risk information beyond that captured by traditional CVD risk calculators and biomarkers, allowing for more individualised assessment of coronary risk (Liew et al. 2017). Both the CSANZ and Heart Foundation position statements on risk assessment recommend CT-CAC for appropriate populations, such as individuals aged 45–75 years at intermediate CVD risk or those at lower CVD risk with CVD risk enhancers, to improve risk precision and better guide management decisions regarding preventive pharmacotherapy (Jennings et al. 2021; Liew et al. 2017). The proposed population is consistent with these recommendations.

Risk stratification by CAC score is presented in Table 3. A CAC score of 0 can be used to re-classify patients from intermediate to low risk, potentially avoiding unnecessary or de-escalating preventive treatment. Based on the CSANZ position statement, patients with a CAC score between 0 and 100 have very low to low 10-year risk of CVD events occurring, and maintenance of a healthy diet and lifestyle should be encouraged (Liew et al. 2017). Patients with a CAC score between 101 and 400 are considered to have intermediate or moderately high (if >75th percentile for age and sex) risk and should be managed with aspirin and statin therapy accordingly. A CAC score > 400 indicates a high 10-year risk of CVD event occurrence and aspirin and intensive lipid-lowering therapy is recommended. The National Heart Foundation recommendations are similar, with a slight difference in the CAC cut-off at 99 rather than 100. The 2019 European Society of Cardiology (ESC)/European Atherosclerosis Society (EAS) guidelines consider that patients with a CAC score >300 have a risk of CV event similar to patients with known clinical ASCVD (Mach, F. et al. 2025), and may be used to guide more intensive treatments. Overall, guideline recommendations are largely aligned.

[9] Australian cardiovascular disease risk calculator | AusCVDRisk

Table 3 Interpretation of CAC score

CSANZ			National Heart Foundation	
CAC score	**10-year risk**	**Management**	**CAC score**	**Management**
0	Very low risk of death (< 1%)	Maintenance of healthy diet and lifestyle	0	Consider reclassifying as low risk and manage as per guideline recommendations
1–100	Low risk (< 10%)	Maintenance of healthy diet and lifestyle	1–99 and < 75th percentile for age and sex	Reclassification of risk status is uncertain. Discuss risk and benefits of management strategies with patient
101–400	Intermediate risk (10–20%)	Aspirin recommended Statins considered reasonable	> 99 or ≥ 75th percentile for age and sex	Consider reclassifying as high risk and management as per guideline recommendations
101–400 and > 75th percentile	Moderate high risk (15–20%)	Reclassify as high risk Aspirin recommended Statins considered reasonable		
> 400	High risk (> 20%)	Aspirin recommended Statin recommended, to achieve target LDL-C <2.0 mmol/L Consider functional assessment.		

Abbreviations: CAC = coronary artery calcium; CSANZ = Cardiac Society of Australia and New Zealand; LDL-C = low density lipoprotein cholesterol

Source: Liew et al. (2017); Jennings et al. (2021)

For the purposes of the MBS, the delivery of CT-CAC imaging includes:

1. Acceptance of request forms with required clinical information
2. Use of a Medicare-eligible CT equipment at a practice accredited under the Diagnostic Imaging Accreditation Scheme
3. Patient preparation and taking of the images under the supervision of a specialist in diagnostic radiology
4. Processing of appropriate information and images, including with calculated CAC score (Agatston score) using vendor-specific software, and forwarding for reporting
5. Standardised reporting of images, transfer and report delivery

The applicant stated that no additional formal training for radiographers is required to perform CT-CAC or for radiologists/cardiologists to interpret the CT-CAC results. Currently, a CAC score is provided with a CT coronary angiography (CTCA) (MBS Items 57360 and 57364). Therefore, radiologists and/or cardiologists who interpret CTCA results would not require additional formal recognition for interpreting CT-CAC results. The CTCA items must be performed under the supervision of a specialist or consultant physician who is recognised by the Conjoint Committee for the Recognition of Training in CT Coronary Angiography (ANZCTCA), and also reported on by a specialist or consultant physician who is recognised by the ANZCTCA Conjoint Committee. (See: Clause 2.2.1 of the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No 2) 2020*). The applicant advised that cardiologists (or other physicians such as Nuclear Medicine Physicians) recognised by the ANZCTCA Conjoint Committee should be eligible to provide the service, and that CT-CAC is a routine study that is within the scope of 'normal practice' for Medical Imaging Practitioners.

The CT vendor may provide training and ongoing support, where necessary. Local guidelines should be updated to reflect current evidence on the use of CT-CAC in asymptomatic populations, to ensure appropriate integration into clinical pathways and optimisation of preventive therapy. There should also be a focus on ensuring that education reaches clinicians equitably, particularly for rural and remote GPs.

PASC noted comments from the applicant that CAC scoring is already incorporated within CTCA imaging, and providers of CTCA would not require additional training to perform CT-CAC or interpret CT-CAC results.

Limitations of CT-CAC

CT-CAC quantifies calcified plaques only. The technique does not detect non-calcified plaque and may therefore underestimate total atherosclerotic burden, particularly in individuals whose coronary lesions are predominantly non-calcified (Chua, Blankstein & Ko 2020; Lim & Lim 2025; Mokhtar et al. 2025). In younger patients, early coronary lesions may be non-calcified and, a CAC score of 0 does not necessarily indicate the absence of atherosclerosis.

CT-CAC is limited to the coronary arteries and does not assess calcified atherosclerotic lesions in other vascular territories (Chua, Blankstein & Ko 2020; Ibanez et al. 2021). Therefore, absence of coronary calcification does not exclude atherosclerosis elsewhere in the body (Lim & Lim 2025; Mokhtar et al. 2025).

CAC score increases as a person ages (Lim & Lim 2025). Preventive pharmacotherapies such as statins may increase the calcified component of plaques thereby stabilising them, and CAC scores may rise over time even with effective therapy. Therefore, routine serial testing is not recommended for monitoring treatment response or therapy efficacy (Lim & Lim 2025).

Repeat testing

While the Aus CVD Risk calculator recommends reassessment of CV risk at 2-year intervals for individuals at intermediate risk, 5-year for those at low risk, and at least every one or two years for Aboriginal and Torres Strait Islander people, routine repeat CT-CAC is not generally recommended in clinical guidelines. Where repeat scanning is discussed, recommendations vary across organisations and are typically conditional on the initial CAC score and whether the rescanning is likely to alter risk classification or management decisions.

According to the CSANZ, repeat CT-CAC may be considered after a minimum of 5 years in patients with a CAC score of 0. In patients with a CAC score of 1–100, repeat scanning may be considered if evidence of progression would be expected to influence preventive therapy. For patients with diabetes or those with a CAC score of 101–400, repeat CT-CAC may be considered at approximately 3 years. In patients with a CAC score of > 400, repeat scanning is not recommended as these patients are typically already managed with preventive therapy and imaging is unlikely to change treatment (Table 4).[10] The applicant agreed that the proposed minimum of 5-years for a repeat scan in patients with a CAC score of 0 is reasonable. The applicant stated that repeat CT-CAC in patients with a previously high-risk score (>300) do not provide additional clinical value because these patients would already have commenced treatment and the CAC results is unlikely to change management decisions.

[10] https://www.cvdcheck.org.au/managing-cvd-risk

The potential value of repeat CT-CAC must be balanced against the risks of cumulative radiation exposure, limited utility in patients already at high risk or with high CAC scores, and the possibility of increased patient anxiety associated with repeated imaging.

Table 4 Recommendations for CT-CAC repeat testing from guidelines

Guidelines	Routine re-scanning	CAC score			
		0	1–100	101–400	> 400
CSANZ	Not recommended	5 years	May benefit if progression warrants change in therapy	3 years*	Not recommended
NHF	-	5 years	-	Not recommended	Not recommended
NLA	-	3–7 years depending on baseline ASCVD risk	3–5 years	3 years to assess for accelerated progression or an increase of CAC score > 300	3 years to assess for accelerated progression or an increase of CAC score > 300
SCCT	Recommended for patients in whom CAC progression would support intensification of preventive management	5 years	3–5 years	3-5 years	3-5 years
ACC/AHA	-	5–10 years	-	-	-
Golub et al. 2023	-	5–10 years	-	3 years	Not recommended

Abbreviations: ACC = American College of Cardiology; AHA = American Heart Association; ASCVD = atherosclerotic cardiovascular disease; CAC = coronary artery calcium; CSANZ = Cardiac Society of Australia and New Zealand; CT = computed tomography; NHF = National Heart Foundation; NLA = National Lipid Association; SCCT = Society of Cardiovascular Computed Tomography

Source: Liew et al. (2017); Jennings et al. (2021); Orringer et al. (2021); Grundy et al. (2019); Golub et al. (2023)

* For patients with diabetes (Liew et al. 2017)

PASC considered the frequency of rescanning, and proposed that repeat CT-CAC should either be limited to once per lifetime or not be performed earlier than 5 years after an initial scan if needed. The applicant proposed that rescanning no sooner than 5 years is reasonable for individuals with CAC scores 0–300, and that rescanning in patients with CAC scores >300 would be unlikely to provide additional clinical value.

Equity of access to the intervention

It was noted by the applicant that imaging services are largely concentrated in metropolitan centres, and the availability is limited in regional and remote areas.

CT-CAC can be used to detect subclinical coronary atherosclerosis. However, in this application it is positioned as a risk stratification tool rather than a diagnostic screening test. As the target population is broad, the widespread use of CT-CAC in this context may have substantial implications for healthcare resource utilisation and overall budget impact.

PASC queried whether the CT-CAC could be considered as a screening test, noting that the CT-CAC would be offered to the asymptomatic higher-risk population. PASC considered that while coronary atherosclerotic plaque detected by CT-CAC constitutes a disease risk marker for CVD, the use of CT-CAC in this application

aligns more closely with risk stratification than with the population-based or targeted screening. Under the 2018 Population-based Screening Framework[11], screening involves systematic testing of all individuals in a defined population to detect unrecognised disease or risk markers; however, CT-CAC is applied selectively following initial cardiovascular risk assessment to refine individual risk estimates and informed management decisions, rather than to establish a diagnosis of CVD or detect disease per se.

Comparator(s)

The comparator is a CVD risk assessment conducted by a medical practitioner. A CVD risk assessment includes taking a clinical history, a physical examination. As part of this assessment, clinicians may undertake a range of investigations including measurement of blood pressure, lipid levels, blood glucose, and use of a CVD risk assessment tool.

In Australia, the Aus CVD Risk calculator can potentially be used as part of the Heart Health Check toolkit[12] and is the current Australian standard for assessing an asymptomatic patient's CVD risk in primary care. The Aus CVD Risk calculator estimates the 5-year absolute risk of experiencing a CV event using patient demographics (age, gender) and clinical characteristics, including smoking status, blood pressure, and lipid ratios. The original Aus CVD Risk calculator was developed in 2012 based on the Framingham risk score (FRS) and was updated in 2023 using the NZ PREDICT-1 equation, which was developed from a large, contemporary New Zealand primary care cohort study and recalibrated to the Australian population, and modified for the Australian healthcare system (Barwick et al. 2026; Brown et al. 2023).[2] The Aus CVD Risk calculator has been shown to perform favourably compared with other contemporary risk equations (Kuo et al. 2025).

Use of the Aus CVD Risk calculator is not legislated in the MBS. Use of the assessment tool is recommended in the explanatory notes for MBS items 177 and 699, however the legislated requirements of these items is:

a. collection of relevant information, including taking a patient history; and
b. a basic physical examination, which must include recording blood pressure and cholesterol; and
c. initiating interventions and referrals as indicated; and
d. implementing a management plan; and
e. providing the patient with preventative health care advice and information.

Under these items patients are eligible for a Heart Health Check provided by a GP once every 12 months. Equivalent assessments may be undertaken by a specialist physician under MBS items 110 or 116. Other MBS items that may incorporate CVD risk assessments on a regular basis include MBS items 705 or 707 (for extensive health assessments) or MBS item 715 (for a patient who is of Aboriginal or Torres Strait Islander descent). However, when clinically relevant, CV risk assessment may be provided by any MBS eligible medical practitioner using any MBS attendance item.

The applicant acknowledges that other validated CV risk calculators exist, including SCORE2, SCORE2-OP, the pooled cohort equation (PCE), ASCVD Risk Estimator, Predicting Risk of cardiovascular disease EVENTs (PREVENT). These tools differ in their methodological approach and in the time horizon over which CV risk is estimated, with many international risk calculators reporting 10-year risk estimates rather than 5-year

[11] https://www.health.gov.au/sites/default/files/documents/2019/09/population-based-screening-framework_0.pdf

[12] https://www.heartfoundation.org.au/heart-health-check-toolkit/what-is-a-heart-health-check Accessed 23 February 2026

risk. However, the application does not specify a role for these alternative calculators within the Australian clinical pathway. It is therefore unclear whether in clinical practice CVD risk assessment of the proposed population may involve CV risk calculators other than the Aus CVD Risk calculator. If the use of other CV risk calculators in Australian clinical practice is significant, this may require changes to the proposed comparator and potentially even the current algorithm which is currently based on the use of the Aus CVD Risk calculator.

PASC agreed that for the purpose of this HTA, the Aus CVD Risk calculator be used for initial risk stratification to determine eligibility for CT-CAC. PASC noted that while alternative traditional risk calculators are available, the Aus CVD Risk calculator is embedded within several Australian clinical software programs used for electronic health records and is calibrated to the Australian population. PASC noted that there were difficulties in standardising event rates and definitions across the various calculators. Therefore, PASC considered that pragmatically, the Aus CVD Risk calculator as the most appropriate comparator for HTA purposes.

PASC also considered that CV risk stratification would be conducted during a routine clinical consultation and use of existing standard MBS-consultation items would be appropriate to capture the associated costs.

Reference standard (for investigative technologies only)

The reference standard is tests and investigations that may be associated with CV risk assessments, such as the Heart Health Check (MBS item 177 or 699), health assessment of a patient of Aboriginal or Torres Strait Islander descent (MBS item 715), or long health assessment by a GP (MBS items 705 or 707). The Aus CVD calculator as the mandated calculator under MBS item 177 and 699. Given that CT-CAC determines the presence or absence of calcified coronary artery plaque, the applicant considered that the reference standard is CTCA when used to assess plaque volume and not the degree of stenosis.

PASC considered that it was unclear what the most appropriate reference standard would be. PASC noted that invasive coronary angiogram is the gold standard for the diagnosis and quantification of CAD and CTCA also plays a role, however both are not recommended in asymptomatic populations. PASC noted that CTCA has the additional advantage of allowing detection of soft plaque, which CT-CAC does not have the ability to detect. To align with the MSAC Guidelines (Technical Guidance 2.4) which indicates that where 'the purpose of the test is to predict a future health outcome, the reference standard is likely to be the health outcome' itself, in the post-PASC phase, PASC recommended that the long term incidence of MACE should be considered the reference standard.

Clinical utility standard (for codependent investigative technologies only)

Initiation or intensification of preventive treatment in asymptomatic patients at risk of CVD is determined by the individual patient's estimated risk of experiencing a CV event over time. This risk is typically calculated using CV risk calculators that incorporate demographic and clinical characteristics.

The clinical utility of CT-CAC includes its role in guiding preventive pharmacotherapy and risk-based management in patients with an intermediate predicted risk of CV events. Noting that the majority of lipid modifying therapies, antihypertensives and antiplatelets have unrestricted listings on the Pharmaceutical Benefits Scheme (PBS), and that guidelines recommend treatment based on a patient's overall risk of CV events, CT-CAC is unlikely to lead to use of these treatments outside of that funded by the PBS. Therefore, a codependent submission is unlikely to be required. However, clarification is sought from the applicant.

Although Australian-specific data are lacking, a US-based population study found that patients with a CAC score >300 experienced future CV event rates similar to a post-MI cohort (Budoff et al. 2023). This suggests that these patients may benefit from more intensive lipid-lowering therapies to achieve a target LDL-C <1.4 mmol/L, consistent with secondary prevention thresholds. With suboptimal response or intolerance to standard lipid lowering therapies, newer agents (e.g. inclisiran) may be considered. The use of these newer agents in this context may fall outside current PBS restrictions. The applicant considered that the use of these newer medicines outside of PBS indications is unlikely to reach a threshold required for a codependent application.

PASC noted that initiation or use of other PBS-funded therapies beyond their accepted indications is not expected as a consequence of CT-CAC. PASC therefore considered that this application will not require a codependent submission.

Outcomes

Clinical effectiveness

- Test accuracy of CV risk stratification measured by sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR), negative likelihood ratio (NLR), diagnostic yield, net reclassification improvement
- Reduction in major adverse CV event (MACE), morbidity and cardiovascular and overall mortality
- HRQoL

Patient management outcomes

- Change in rate of prescribing appropriate lipid lowering medications
- Proportion of patients adherent to prescribed lipid lowering therapy in the short and long term
- Change in CV risk factors (e.g. lipid levels, blood pressure)
- Proportion of patients in whom CV risk stratification changes
- Change in rates of adverse events associated with preventive pharmacotherapy

Safety

- Increases in radiation exposure
- Change in rates of adverse events associated with preventive pharmacotherapy (including treatment associated morbidity, mortality, HRQoL)

Value of knowing

- Patient adoption, persistence and adherence to prevention management
- Psychological impacts of knowledge of risk (both positive, such as reassurance or increased sense of control, and negative such as anxiety or distress following a non-zero CAC result or follow-up incidental findings such as pulmonary nodules)

Health care resources

- Costs of delivering the intervention (including costs of follow-up of incidental findings e.g. pulmonary nodules)
- Costs of managing adverse events
- Cost offsets
- Costs per Quality Adjusted Life Year

Total Australian Government healthcare costs

- Total costs to the Commonwealth government
- Total costs to other government health budgets

Economic analysis

- CEA
- CUA

CT-CAC is used to reclassify the CVD risk status of a patient and may lead to subsequent changes in pharmacotherapy, which in turn leads to benefits or harms to the patient. A CAC score should be interpreted in conjunction with traditional risk assessment and other clinical risk factors. It provides additional information that may modify the estimated level of risk for an individual patient. In this way, CT-CAC provides refinement of risk, supporting more individualised risk stratification where uncertainty remains after conventional assessment.

Clinical effectiveness

Test accuracy

Evidence on the diagnostic accuracy of CT-CAC for identifying obstructive CAD is limited, as the test is primarily intended for risk stratification rather than diagnosis of coronary stenosis. A cross-sectional study was conducted which assessed the diagnostic accuracy, NPV, PPV, specificity and sensitivity of CAC score less than 100 in predicting significant coronary artery stenosis in patients with risk of CAD (Hanifehpour et al. 2016). Notably, the study used CTCA to determine CAC score rather than ECG-gated non-contrast CT-CAC. The study reported high specificity (87%), sensitivity (79%), overall efficiency (84%), PPV (79%), and NPV (87%) on a vessel-based analysis. A CAC score of zero was observed in 59% of patients with no or nonsignificant stenosis, and in 7.6% of those with significant stenosis. The authors concluded that while a CAC score < 100 as determined by CTCA had a high NPV for excluding significant stenosis, it did not demonstrate sufficient diagnostic accuracy to reliably exclude coronary stenosis (Hanifehpour et al. 2016).

As CT-CAC is used as a risk stratification tool, test performance may be more appropriately assessed using measures such as net reclassification improvement and risk discrimination. Nevertheless, a false positive CAC score may lead to unnecessary downstream investigations or inappropriate changes in management, while a false negative result may delay further assessment and/or initiation of appropriate treatment.

Prevention of MACE

The CAC score is predictive of future events independent of traditional risk factors and improves risk prediction when added to traditional CVD risk stratification (Erbel et al. 2010). A zero CAC score is associated with < 0.5% per year risk of a subsequent CV event (Nasir et al. 2015). The 2023 ESC/EAS dyslipidaemia treatment guidelines consider a CAC score ≥ 300 as unequivocal evidence of documented ASCVD, placing these patients in the same ‘very high risk’ category as patients who have suffered a previous MI (Mach, F. et al. 2025). The prevalence of obstructive CAD was also shown to increase with higher CAC scores, rising from 4.1% in patients with a CAC score of zero to 76.1% in those with a CAC score ≥ 400 (Biavati et al. 2024).

Large prospective observational studies demonstrate a graded association between CAC score and future CV events. In the MESA study, the presence of CAC was associated with higher rates of CAD events across all levels of traditional risk factor burden, including patients with no conventional risk factors (Silverman et

al. 2014). Similarly, the Heinz Nixdorf Recall Study showed that incorporating CAC into traditional risk classification resulted in meaningful reclassification of intermediate risk patients, yielding a net reclassification improvement of 21.7% in those with CAC < 100 and 30.6% for CAC ≥ 400 when added to the FRS (Erbel et al. 2010). Additional cohort studies have confirmed that increasing CAC scores are associated with progressively higher rates of CVD events (Biavati et al. 2024; Peng et al. 2021).

Change in management of subclinical ASCVD

Change in rate of prescribing appropriate lipid lowering medications

CT-CAC has been shown to influence prescribing of lipid-lowering therapy by identifying individuals with subclinical ASCVD who are more likely to benefit from statins. In the NOTIFY-1 project, opportunistic identification of CAC followed by notification of both the primary care clinician and the patient, led to a substantial increase in statin initiation (Sandhu et al. 2023). The intervention also increased downstream coronary testing.

In Australia, this financial burden of pharmacotherapy is often shared with the community, through the PBS subsidisation of lipid-lowering medications, estimated at $167 million in 2022 (Lee, L & Kim 2024). Statins are the most commonly prescribed medication in Australia, with over 30 million prescriptions per year. Current Australian guidelines recommend statins for patients with 5-year risk of CV events ≥ 10%,[13] that is patients classified as high risk. A recent study found that it would be cost-effective to use a CT-CAC-guided strategy to prescribe statins to patients with a 5-year CVD risk ≥ 5% when a CAC score of 100 is the threshold for statin therapy, and for people with CVD risk of 8% when a CAC score > 0 is the criterion (Venkataraman et al. 2023). Much of the cost-benefit was driven by increased statin initiation and adherence rates associated with obtaining a CT-CAC (Venkataraman et al. 2023).

PASC considered that a change in CV risk score resulting from CT-CAC would primarily lead to changes in lipid-lowering therapy. PASC noted that the potential impact on aspirin use, if any, requires further clarification. PASC considered that changes in antihypertensive therapy were unlikely to be directly attributable to changes in CV risk scores resulting from CT-CAC, and noted that the use of antihypertensive therapy is usually driven by baseline blood pressure, tolerability, and clinical indication.

PASC considered that CT-CAC may result in initiation or intensification of lipid-lowering therapy in patients with a high CAC score, and de-escalation, deferral or discontinuation of lipid-lowering therapy in those with a low CAC score. However, PASC noted that evidence demonstrating a direct reduction in final outcomes, including MACE, morbidity and mortality, is limited.

PASC considered that changes in patient management resulting from CAC scores are an important outcome. Based on the MESA study reported by Silverman et al. (2014), approximately 5% of patients with no traditional risk factors had a high CAC score (>300 Agatston units) requiring initiation or intensification of therapy. Conversely, approximately 35% of patients with 3 traditional risk factors had a CAC score of 0, suggesting potential benefit from reduced treatment intensity, or from discontinuation or deferral of therapy.

Change in CV risk factors

The Aus CVD Risk calculator incorporates SBP, lipid levels and the presence of diabetes in its risk assessment. In patients who may benefit from CT-CAC for reclassification of risk, a CAC score can inform decisions to initiate or intensify preventive treatment with lipid modifying therapies or antihypertensives.

[13] https://www.cvdcheck.org.au/overview

Such treatment changes can, in-turn lead to improvements in risk factors such as lipid levels and blood pressure, which may reduce overall CVD risk and contribute to improved long term CV outcomes.

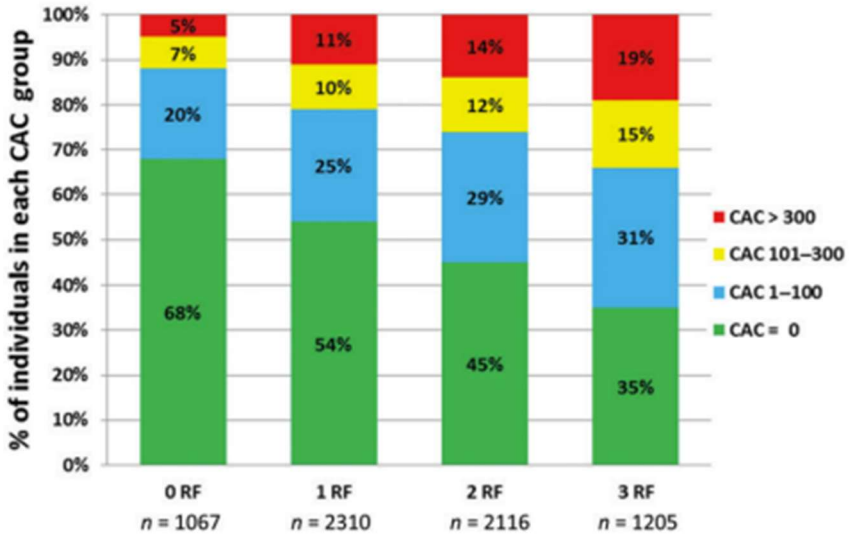
Evidence from the EISNER randomised controlled trial showed that patients allocated to CT-CAC scanning demonstrated net favourable changes in SBP, cholesterol and waist circumference at follow-up, along with a lower FRS compared with those receiving usual care (Rozanski et al. 2011).

Proportion of patients in whom CV risk stratification changes and change in rates of adverse events associated with preventive pharmacotherapy

Reclassification of a patient's CVD risk with the use of CT-CAC would likely lead to more appropriate use of antiplatelet, antihypertensive and lipid modifying pharmacotherapy (Chaparala et al. 2025). From CV risk stratification with traditional risk calculators, it is estimated that 45–55% of patients with intermediate CVD risk patients would have a CAC score of zero and thus be reclassified as low CVD risk (Nasir et al. 2015). Therefore, in the absence of CT-CAC, these patients may receive unnecessary treatment and be exposed to unnecessary financial costs, inconvenience, and risk of adverse drug effects (Nasir et al. 2015).

While CT-CAC may support de-escalation of preventive therapy in patients reclassified to low risk, it may also identify patients with a high CAC score (>300) who have markedly elevated CV risk and may benefit from more intensive therapies with lower cholesterol treatment targets. Based on the MESA study, approximately 5% of patients with no risk factors have a high CAC score (>300) and would benefit from lipid lowering therapy, while approximately 35% of patients with 3 risk factors have a CAC score of 0 and treatment deferral, discontinuation or deintensification may be considered (Figure 1).

Figure 1 Distribution of CAC by risk factor burden



Abbreviations: CAC = coronary artery calcium; RF = risk factor

Source: Silverman et al. (2014) Figure 1 p 4

PASC noted the applicant's advice that Australia-specific data on the proportion of patients who would experience reclassification following CT-CAC are limited. The applicant proposed that other population-based studies, including MESA (an American study) and SCAPIS (a Swedish study), may inform estimates of change in risk stratification for the purposes of the evaluation.

Change in HRQoL due to changes in health outcomes

The previous discussion outlined how improvements in accuracy of risk stratification of CVD risk can lead to changes in management (i.e. better management of underlying CVD) leading to improved health outcomes. The proposed linked evidence approach should also identify evidence demonstrating the extent to which improved CVD management can promote improvements in HRQoL. No other patient-reported outcomes were identified by the applicant.

Safety

Radiation exposure

CAC scoring using ECG-gated CT scanning typically exposes a patient to approximately 1 mSv of radiation, compared with no exposure for the comparator. Current international guidelines recommend minimisation of exposure to between 0.5 mSv and 1.5 mSv per CT scan (Jennings et al. 2021; Liew et al. 2017; Orringer et al. 2021). Radiation exposure may increase the risk of cancer development. A single CT-CAC scan at the age of 40 was estimated to result in a lifetime excess cancer risk of between 9 and 28 cancers per 100,000 persons for males and females, respectively (Kim, KP, Einstein & Berrington de González 2009). It is assumed that at a median exposure of 2.3 mSv every five years to age 75 years, would result in an estimated cumulative radiation-induced cancer risk of 42 per 100,000 for males and 62 per 100,000 for females (Kim, KP, Einstein & Berrington de González 2009). The potential benefit of utilising CT-CAC to guide management should be considered against the risks of radiation exposure, particularly with repeated scanning.

Change in rates of adverse events from pharmacotherapies (including treatment associated morbidity, mortality, HRQoL)

Preventive pharmacotherapy is not generally recommended for patients with a CAC score of 0, so potential adverse events from these treatments could be avoided in these patients. Conversely, those with a high CAC score (e.g. > 300) may initiate or intensify treatment with lipid lowering therapy and/or aspirin. In these cases, adverse events from these treatments could contribute to potential health harms (Cai et al. 2021).

Furthermore, while statins are generally well tolerated (Cheeley et al. 2022). statin intolerance has been associated with impaired quality of life (Peyrel et al. 2023; Stürzebecher et al. 2024), and may lead to poor adherence to therapy or treatment discontinuation (Grundy & Vega 2022).

Value of knowing

Support shared decisions and sense of control

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 termed "planning value" (Lee, DW, Neumann & Rizzo 2010). For some patients, knowing they have subclinical ASCVD may drive changes in lifestyle and increase adherence to prescribed medications, whereas in others in can lead to maladaptive feelings of hopelessness and distress (Mamudu et al. 2014). CT-CAC may also increase anxiety especially when non-zero results are returned (Moldovanu et al. 2024).

Patient persistence and adherence to prevention management

The knowledge of a patient's CAC score has been shown to influence behaviours and short-term management with preventive therapies (Johnson et al. 2015). CAC scores have been associated with the initiation of preventive pharmacotherapy, dietary changes and exercise (Orakzai et al. 2008). Evidence shows that persistence and adherence with CV medicines decline over time, with the steepest reduction occurring in the first few months after treatment initiation (Choudhry et al. 2022; de Oliveira Costa et al. 2023; Fuller et al. 2018). At one year, persistence has been reported to decreased by approximately 58% for antiplatelets, 51% for antihypertensives and anticoagulants, and 46% for statins (de Oliveira Costa et al. 2023), with further attrition observed with longer follow-up (de Oliveira Costa et al. 2023; Naderi, Bestwick & Wald 2012). Evidence suggests that disclosure of CAC results improves short-term persistence with preventive pharmacotherapy, particularly within the first year following testing (Nasir et al. 2010). However, the durability of this effect beyond the short term remains uncertain.

Psychological impact of CT-CAC

A scoping review on the psychological impact of CT-CAC was conducted by Anokye et al. (2023). Two RCTs reported outcomes relating to psychological distress, with one showing no significant effect of imaging on anxiety, depression, and stress scores measured at 12 months of post-screening. The other RCT showed no significant difference in perceived stress, anxiety, and depression scores in the imaging group versus the control group, and between those who had plaques or disease and those without plaques at 12-month follow-up.

In the same review, 3 before-and-after studies reported outcomes on psychological distress following screening. Results from these studies were mixed, with significant decrease in worry levels for patients with lower CAC scores reported in one study, no significant increases in depression scores, perceived stress, anxiety, and worry levels in higher CAC scores reported in three studies (Anokye et al. 2023).

Studies specifically examining CT-CAC also suggest that test results may influence emotional responses and illness perceptions. In a prospective study, patients with normal CAC results reported more positive illness perceptions following testing, including improvements in emotional impact, illness concern, perceived consequences and personal control (Devcich et al. 2012). Patients with positive CAC findings placed greater emphasis on treatment control. Intentions to engage in health promoting behaviours, such as adherence to medications and increased physical activity, rose among patients with positive CAC scores.

Overall, the evidence indicates that CT-CAC may influence psychological outcomes and HRQoL in both positive and negative directions.

Incidental findings

CAC scoring is performed with a CT scan of the chest and may result in incidental findings and may lead to downstream increase in health resource utilisation. Potential incidental findings on a CT-CAC may include pulmonary nodules, emphysema, hiatal hernia, vertebral haemangioma and degenerative bone changes (Sripariwuth, Kruamak & Xu 2021).

In a study of 151 adults, 102 incidental extracardiac findings in 65 patients were identified (Lee, CI et al. 2010). Of these 53 (52%) findings were potentially clinically significant. However, only six (4%) patients underwent follow-up imaging or intervention. Incidental finding may, therefore, increase healthcare

resource use and may cause psychological distress due to the unexpected nature of the findings. However, incidental findings may also result in an earlier diagnosis and management.

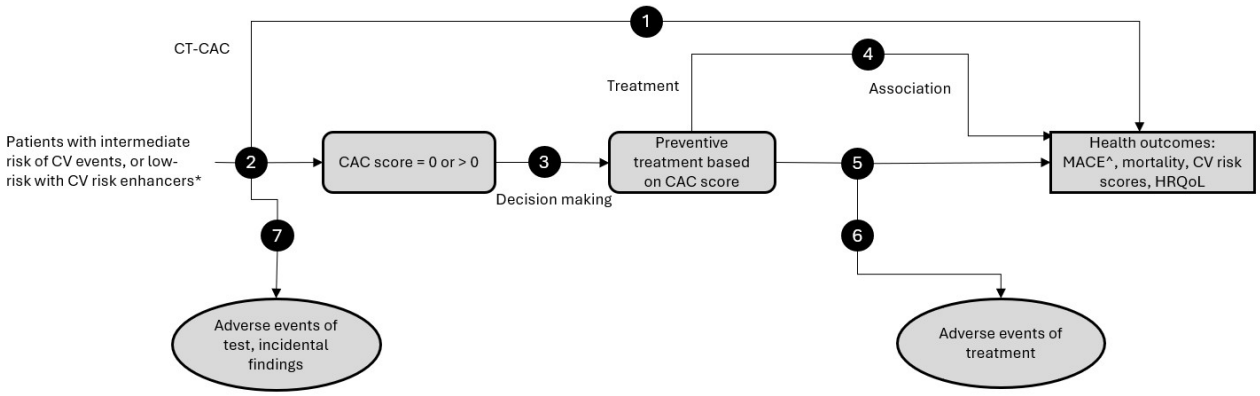
PASC noted that the applicant highlighted the value of knowing in patients classified as low risk using traditional risk calculators, who would typically not receive preventive treatment. The applicant also highlighted the proposed impact of CT-CAC on treatment intensity among individuals already receiving lipid-lowering therapy, including escalation to high-intensity treatment (e.g. to a low-density lipoprotein cholesterol [LDL-C] target <1.4 mmol/L).

Health care resources

The cost of CT-CAC is currently covered by patients out-of-pocket and cost approximately $150–200 per scan (Chua, Blankstein & Ko 2020).

Assessment framework (for investigative technologies)

Figure 2 Assessment framework showing the links from the test population to health outcomes



Abbreviations: CAC = coronary artery calcium; CV(D) = cardiovascular (disease); CT-CAC = computed tomography coronary artery calcium; HRQoL = health-related quality of life; hs-CRP = high-sensitivity C reactive protein; Lp(a) = lipoprotein a; MACE = major adverse cardiovascular event; MI = myocardial infarction; PRS = polygenic risk score

Figure notes: 1: direct from test to health outcomes evidence; 2: test accuracy; 3: change in diagnosis/treatment/management; 4: influence of the change in management on health outcomes; 5: influence of the change in management on intermediate outcomes; 6: adverse events due to treatment; 7: adverse events due to testing

* CV risk enhancers include elevated Lp(a) and persistently elevated hs-CRP

^ Includes CV death, myocardial infarction and stroke

Assessment questions linked to the assessment framework:

1. How does CT-CAC scoring compare with usual care (no CTC-CAC) in terms of CV risk stratification for CV events in patients with intermediate risk, or low risk with CV enhancers?
2. What is the prognostic value of CT-CAC results for future cardiovascular events in the proposed population?
3. How does CT-CAC-guided risk stratification influence downstream clinical treatment or management, including initiation, intensification, or de-escalation of preventive pharmacotherapy, compared with management guided by population-based risk assessment alone and what is the evidence base of the impact?
4. What is the impact of the CT-CAC guided changes in management versus usual management on health outcomes such as MACE, mortality and health-related quality of life (HRQoL)?

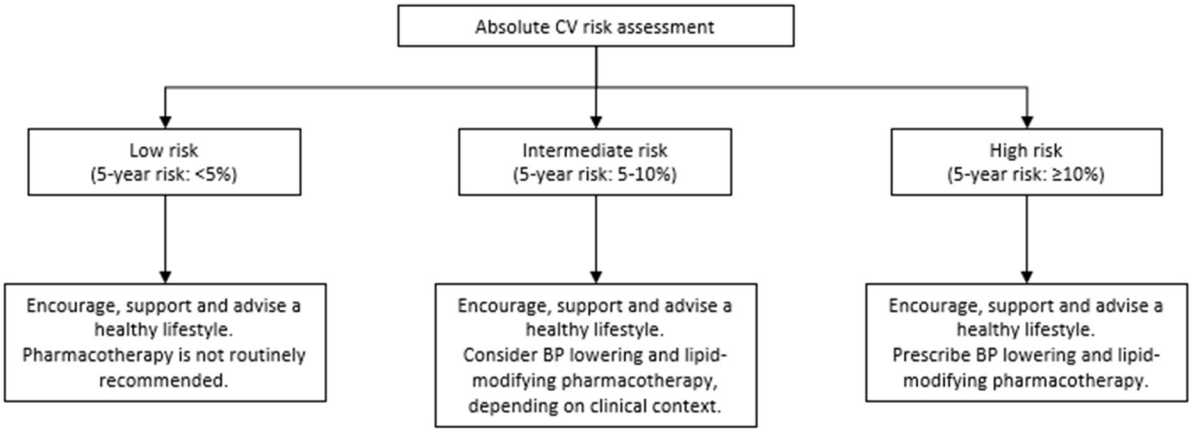
5. What are the treatment-related harms associated with changes in management following CT-CAC, including adverse events related to the initiation, intensification or de-escalation of preventive pharmacotherapy, and how do these compare to usual management?
6. How do treatment-related adverse events associated with CT-CAC guided management affect patient health outcomes (treatment-associated morbidity, mortality, HRQoL)?
7. What is the comparative safety of non-contrast ECG-gated CT for CAC scoring versus traditional risk assessments (i.e. no CT for CAC scoring)?

PASC considered the assessment framework is appropriate.

Clinical management algorithms

The current management algorithm provided by the applicant is presented in Figure 3. The management algorithm was adapted from the Australian Guideline for assessing and managing CVD risk[14] and the ACC/AHA guidelines (Arnett et al. 2019). The CVD risk of patients is assessed using traditional risk calculators, such as the Aus CVD Risk calculator in the Heart Health Check. The treatment employed depends on the risk level following management guidelines.[14]

Figure 3 Current management algorithm



Abbreviations: BP = blood pressure; CV = cardiovascular

Source: Adapted from https://www.cvdcheck.org.au/managing-cvd-risk and Arnett et al. (2019)

The proposed algorithm provided by the applicant was adapted from the NHF position statement (Jennings et al. 2021). In this framework, CT-CAC was recommended as an adjunct to absolute cardiovascular risk assessment in asymptomatic adults without known cardiovascular disease who are assessed as having intermediate cardiovascular risk or low cardiovascular risk with recognised risk enhancers, where uncertainty exists regarding the need for, or intensity of, subsequent risk management or preventive pharmacotherapy. CT-CAC is used in addition to traditional risk assessments to refine risk classification in patients whose absolute risk may be under- or over-estimated using population-based risk calculators alone.

Subsequent management is dependent on the reclassified risk status. A healthy diet and lifestyle should be recommended for all patients. In patients with a CAC score of 0, the patients' risk would be reclassified as

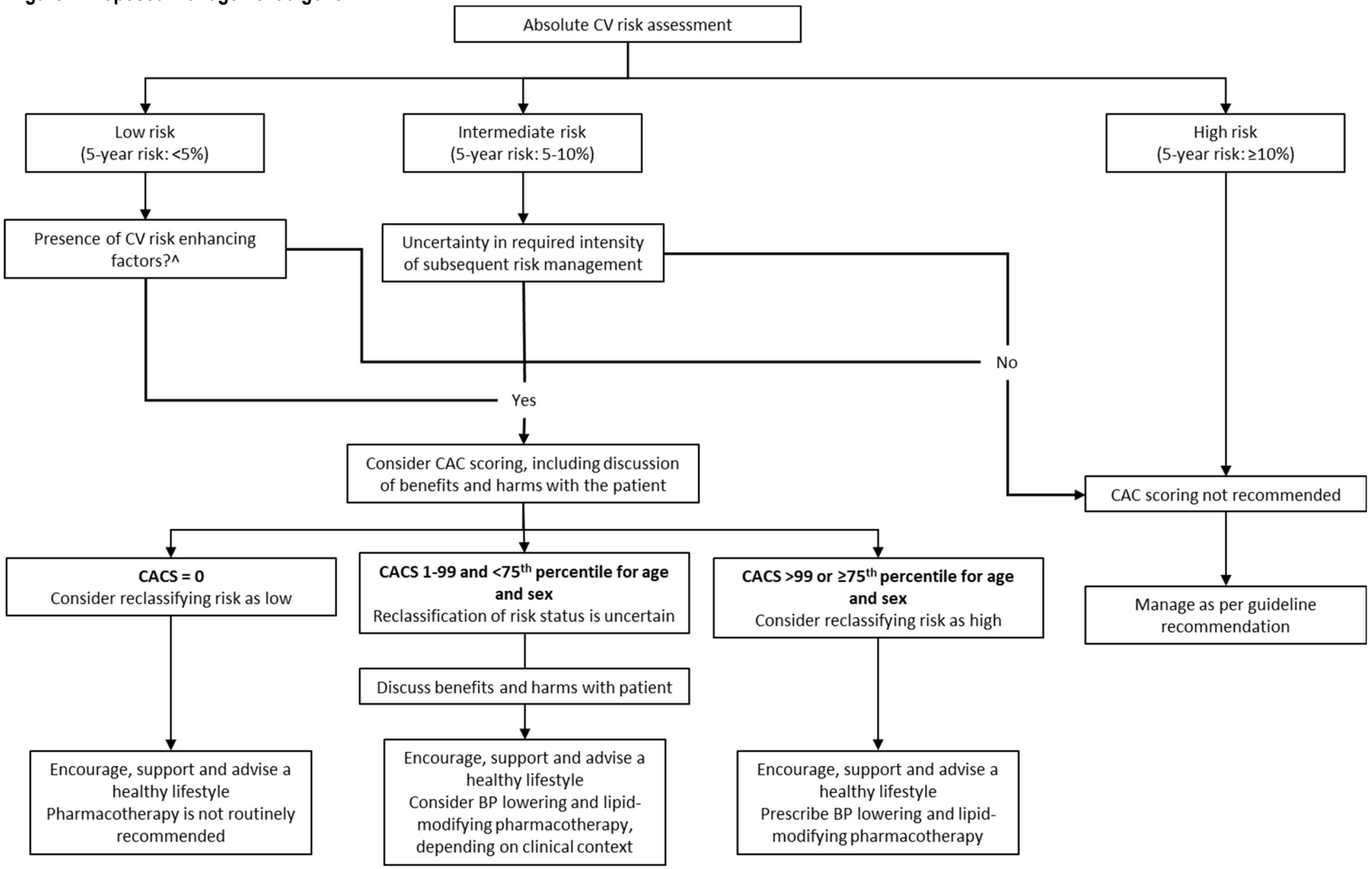
[14] https://www.cvdcheck.org.au/overview

low and preventive pharmacotherapy is generally not recommended but should be based on a patient's individual circumstances. In patients with a CAC score of 1–99 and <75th percentile for age and sex, reclassification of risk is uncertain. In this group, the potential benefits and harms of preventive pharmacotherapy should be discussed with the patient, with management decisions informed by individual patient preferences, values, and the overall clinical context. Patients with a CAC score > 99 or a risk profile ≥ 75th percentile for age and sex would likely be reclassified as high risk and be managed according to guideline-recommended therapy.

PASC recommended that the proposed algorithm should be amended to reflect the PASC recommendations on risk enhancers and the omission of patients of indeterminate risk as detailed in the population section of the PICO.

PASC sought comment from the applicant on what are the specific individual circumstances under which patients who have been reclassified by CT-CAC as being low-risk would continue their statin treatment or other preventive pharmacotherapy. For example, if patients are reclassified by CT-CAC as low-risk but they have other co-morbidities (e.g. diabetes or high lipid profile), would it be recommended that they continue statin treatment or other preventive pharmacotherapy or would it still be recommended that they cease treatment?

Figure 4 Proposed management algorithm



Abbreviations: BP = blood pressure; CAC(S) = coronary artery calcium (score); CV = cardiovascular

Notes:

^ CV risk enhancers include elevated Lp(a) and persistently elevated hs-CRP and the reclassification factors included in the Aus CVD Risk calculator

Source: Adapted from NHF position statement (Jennings et al. 2021).

Proposed economic evaluation

The application claims that the use of CT-CAC allows for the identification of subclinical ASCVD in asymptomatic patients and may be used in the reclassification of CVD risk to guide preventive treatment initiation, intensification or de-escalation. Patients originally classified as low risk with CV risk enhancers or intermediate risk may be re-classified as low risk based on a CAC score of 0, preventing the initiation of unnecessary treatment or allowing the de-escalation of preventive treatment. In patients with a CAC score >0, preventive treatment may be individualised depending on the reclassified risk, leading to more appropriate use of pharmacotherapy.

The application proposes that use of CT-CAC results in superior effectiveness and non-inferior safety compared with standard practice (including any MBS item that allows a CV risk assessment to be made either by a GP or equivalent consultation performed by a specialist consultant).

The applicant made an overall claim of non-inferior health outcomes for CT-CAC compared with traditional risk assessments. Nevertheless, the use of CT-CAC had been shown to improve reduction in atherogenic lipids, slow plaque progression, and improved patient compliance to treatment and lifestyle modifications compared with no CT-CAC (Muhlestein et al. 2022; Nerlekar et al. 2025; Venkataraman et al. 2021). A systematic literature review of several RCTs and prospective cohorts demonstrated that CT-CAC and associated treatment recommendations led to favourable risk factor control and improved adherence to CV medication and lifestyle modifications (Scheu et al. 2025). Improvement in these factors may in turn lead to improvement in long-term outcomes, e.g. a reduction in MACE. Therefore, it may be more appropriate for a claim of superior effectiveness and non-inferior safety to be made. The clinical claim leads to a cost-effectiveness or cost-utility analysis for the economic evaluation (Table 5). The applicant is agreeable to this.

Table 5 Classification of comparative effectiveness and safety of the proposed intervention and guide to the suitable type of economic evaluation

Comparative safety	Comparative effectiveness			
	Inferior	**Uncertain[a]**	**Noninferior[b]**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible: need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/CUA
Noninferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/CUA
Superior	? Likely CUA	? Likely CEA/CUA	CEA/CUA	CEA/CUA

Abbreviations: CEA = cost-effectiveness analysis; CMA = cost-minimisation analysis; CUA = cost-utility analysis

Notes:

? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis

[a] 'Uncertainty' covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations

[b] An adequate assessment of 'noninferiority' is the preferred basis for demonstrating equivalence

The applicant claimed that the use of CT-CAC will lead to superior effectiveness, though PASC was uncertain about the claim of non-inferior safety and supported a CEA/CUA.

PASC noted that additional investigations and management, including additional imaging, that may be required following incidental findings would need to be factored into the economic analysis.

Proposal for public funding

The application proposed a new MBS item for non-contrast ECG-gated CT of the coronary arteries for the purpose of calculating the CAC score to identify subclinical atherosclerosis in asymptomatic patients without known CV or coronary artery disease. Currently, there is no MBS item number for this procedure. At present, CT-CAC is self-funded by the patient.

Two draft MBS item descriptors for CT-CAC are presented in Table 6 and Table 7. The draft MBS item descriptors for CT-CAC are also accompanied by a draft explanatory note to guide the claiming intervals as described in the PICO. That being: (1) Where a CT-CAC service demonstrates an Agatston score of 0, the patient is eligible to receive only one CT-CAC service under the CT-CAC items within a five-year period; (2a) Where a CT-CAC service demonstrates an Agatston score greater than 0, the patient remains eligible for both: (I) the initial CT-CAC item (claimable once within a five-year period), and (II) the subsequent CT-CAC item (claimable once within a five-year period); (2b) The five-year claiming restriction applies separately to each item. Where clinically appropriate a patient with an Agatston score greater than 0 may receive CT-CAC services more frequently than once every five years overall by claiming the two items at different time periods.

PASC noted the item descriptors be amended as follows:

- *exclude indeterminate-risk population*
- *update the list of risk enhancers in the low-risk population to exclude PRS and risk enhancers already included in the Aus CVD Risk calculator (risk enhancers should only be included if there is evidence that their presence would allow the re-stratification of low-risk patients to intermediate risk)*
- *inclusion of Agatston unit in the item descriptor*
- *update repeat scans to be accessible no earlier than 5 years from the initial scan*
- *specify that the risk calculator algorithm be based on the Aus CVD Risk calculator.*

The applicant considered it reasonable that a repeat scan should be accessible no earlier than 5 years for patients with a CAC score between 0 and 300, while a rescan is likely to be uninformative for those with a CAC score >300. PASC noted that evidence would need to be provided to support benefit for a repeat CT-CAC at this time interval.

PASC queried whether specific thresholds for Lp(a) and hs-CRP should be identified in the item descriptor and if so what the thresholds should be. PASC seeks clarification from the applicant on these points.

Table 6 Proposed MBS Item 1 – Initial scan where the CAC score is unknown

Category 5 – Diagnostic Imaging Servies
Group I2: Computed Tomography
Item XXXX1 ~~Non-contrast~~ ECG-gated computed tomography of the coronary arteries performed on a minimum 64-slice (or equivalent) scanner without intravenous contrast medium, to identify subclinical atherosclerosis in an asymptomatic patient with no known coronary artery disease or cardiovascular disease~~, and the patient~~ who is: a. aged 45 to 79 years~~, and the patient~~ who is: i. at intermediate cardiovascular risk **according to the Aus CVD Risk calculator**, or ii. at low cardiovascular risk **according to the Aus CVD Risk calculator** and has the following risk enhancers: lipoprotein(a), ~~family history of premature CVD~~, ~~or~~ persistently elevated hs-CRP, ~~and PRS indicating enhanced risk~~, ~~Aboriginal and Torres Strait Islander status, other,~~ or b. ~~**are at identified as having indeterminate risk and clinically require reclassification to stratify risk**~~ an Aboriginal and Torres Strait Islander patient aged 30 to 44 years with low or intermediate cardiovascular risk **according to the Aus CVD Risk calculator**. **The CAC score should be provided in Agatston units.** Once per lifetime.
Fee: ~~$200.00~~ $170.00 85% benefit = $144.50 75% benefit = $127.50

Source: Table 1, p 9 of the application. Departmental changes to the descriptor are in red. Assessment group changes to the descriptor are in blue. ***PASC changes to the descriptor are in bold.***

Abbreviations: Aus = Australian; CAC = coronary artery calcium; CVD = cardiovascular disease; ECG = electrocardiogram; hs-CRP = high-sensitivity C reactive protein; MBS = Medicare Benefits Schedule

*75% benefit applies to services provided in-hospital.

*85% benefit applies to services provided out-of-hospital.

Table 7 Proposed MBS Item 2 – Further scans where the CAC score is 0 (zero) to 300 Agatston unit

Category 5 – Diagnostic Imaging Servies
Group I2: Computed Tomography
Item XXXX2 ECG-gated computed tomography of the coronary arteries performed on a minimum 64□slice (or equivalent) scanner without intravenous contrast medium, to identify subclinical atherosclerosis in an asymptomatic patient who requires subsequent imaging where the coronary artery calcium score in Agatston units was 0 to 300, and the patient is: a. aged 45 to 79 years, ~~or an Aboriginal and Torres Strait Islander patient aged 30 to 44 years, with no known coronary artery disease or cardiovascular disease~~ and the patient is: i. at intermediate cardiovascular risk **according to the Aus CVD Risk calculator**, or ii. at low cardiovascular risk **according to the Aus CVD Risk calculator** and has the following risk enhancers: lipoprotein(a), ~~family history of premature CVD,~~ persistently elevated hs-CRP, ~~and PRS indicating enhanced risk~~, or b. ~~**identified as having indeterminate risk and clinically requires reclassification to stratify risk**~~ an Aboriginal and Torres Strait Islander patient aged 30 to 44 years with low or intermediate cardiovascular risk **according to the Aus CVD Risk calculator.** The CAC score should be provided in Agatston units. Once only in a 5-year period.
Fee: $170.00 85% benefit = $144.50 75% benefit = $127.50

Departmental changes to the descriptor are in red. Assessment group changes to the descriptor are in blue. ***PASC changes to the descriptor are in bold.***

Abbreviations: Aus = Australian; CAC = coronary artery calcium; CVD = cardiovascular disease; ECG = electrocardiogram; hs-CRP = high-sensitivity C reactive protein; MBS = Medicare Benefits Schedule

*75% benefit applies to services provided in-hospital.

*85% benefit applies to services provided out-of-hospital.

Draft Explanatory Note - CT coronary artery calcium (CT-CAC) services – Agatston Score and item frequency restrictions

This note applies to CT coronary artery calcium (CT-CAC) items [XXXX1 and XXXX2].

1. Agatston score >300
    a. Where a CT-CAC service demonstrates an Agatston score >300, the patient is eligible to receive only one CT-CAC service under the CT-CAC items.

2. Agatston score of 0 (zero) to 300
    a. Where a CT-CAC service demonstrates an Agatston score 0 to 300, the patient remains eligible for both:
        i. the initial CT-CAC item (claimable once per lifetime), and
        ii. the subsequent CT-CAC item (claimable once within a five-year period).

3. Independence of claiming limits
    a. Eligibility to claim the subsequent CT-CAC item (XXXX2) is not conditional on the timing of the initial CT-CAC item (XXXX1).

4. Per-patient application
    a. These restrictions apply per patient, regardless of the requesting practitioner, reporting practitioner, or location of service.

Based on the management algorithm, the only change to clinical management will be the inclusion of non-contrast ECG-gated CT to identify the presence of subclinical ASCVD. The cost of CT-CAC has been reported to be between $150 USD and $200 USD per scan (in 2016) (Chua, Blankstein & Ko 2020). Costs of $150[15,16] and $195[17] have been reported. The applicant has requested a cost of $250 with the breakdown presented in Table 8.

Table 8 Estimated cost breakdown for CT-CAC

Input	Description	Estimated median cost per patient
Imaging equipment costs	Includes capital cost, maintenance and depreciation	$80
Facility overheads	Includes non-clinical/administrative staffing & associated costs, rent, utility & non-imaging capital/infrastructure capital and maintenance costs, IT infrastructure, insurance, legal costs	$50
Imaging specialist	Radiologist or cardiologist supervision & reporting	$60
Medical consumables	Includes ECG dots, gowns	$20
Radiographer	Image acquisition & work up	$40
TOTAL		**$250**

Abbreviations: CAC = coronary artery calcium; CT = computed tomography; ECG = electrocardiogram; IT = information technology

The applicant noted that the range of estimated costs is wide, notably for imaging equipment and facility overheads. This variation is attributed to the significant variation in radiology practice contexts, geographical location and size.

PASC accepted the policy recommendation for a fee of $170, noting that that currently available commercial fees are in a range both lower and higher than this, and that CT-CAC is funded by the Department of Veteran's Affairs (DVA) at $280.

Summary of public consultation input

PASC noted and welcomed consultation input from 6 organisations and no individuals. The organisations that submitted input were:

- Heart Support Australia
- Cardiac Society of Australia and New Zealand (CSANZ)
- Royal Australian and New Zealand College of Radiologists (RANZCR)
- Hearts4heart
- Australasian Association of Nuclear Medicine Specialists (AANMS)
- Royal Australian College of General Practitioners (RACGP)

Consultation input was supportive of public funding for CT of the coronary arteries to determine CAC score. The consultation input raised a number of suggestions in relation to the proposed population, clinical management implications, and aspects of the MBS item descriptor and fee, including appropriate patient selection, downstream impacts on clinical pathways, and implementation considerations.

[15] https://www.harbour-radiology.com.au/services/low-dose-ct/ct-calcium-score-test
[16] https://gxu.com.au/services/calcium-score-test/
[17] https://www.prpimaging.com.au/ct-calcium-score-services/

Consumer Experience

Both Heart Support Australia and Hearts4heart highlighted the profound physical, emotional, psychological, and financial impacts experiencing a sudden cardiovascular event can have on asymptomatic individuals and their families. It was also noted that cardiovascular events result in a mix of patient outcomes. While some individuals may return to normal activities after an event, others may experience life-long disabilities requiring long-term physical support, placing significant financial strain on families.

Early detection was seen as having the potential to prevent or delay many of these impacts by allowing individuals to make informed decisions and act before a major event occurs, helping preserve both quality of life and long-term health. Both Heart Support Australia and Hearts4heart also emphasised that funding CT-CAC is important for ensuring equitable access to all individuals at risk, not just those who can currently afford to pay for the test.

Benefits and Disadvantages

The main benefit of public funding reported in the consultation input was to provide equitable access to a test that has the potential to identify coronary artery disease, in asymptomatic individuals, before a coronary event. Other benefits included improved cardiovascular risk stratification and enabling more personalised and evidence-based decision-making regarding preventive treatments.

Multiple stakeholders highlighted that CT-CAC may support more targeted use of lipid-lowering medications and improve shared decision-making between clinicians and patients. Several organisations also noted potential system-level benefits, including better alignment with contemporary cardiovascular guidelines and improved consistency of care across jurisdictions.

No clear disadvantages were identified in the consultation input, but there was a comment noting the importance of understanding that a zero-calcium score on this test does not exclude the possibility of coronary artery disease in a patient. Further to this, several pieces of input highlighted the importance of targeting the appropriate population for testing.

Population, Comparator (current management) and Delivery

The consultation input was largely supportive of the proposed population, with multiple stakeholders agreeing that CT-CAC is most appropriately targeted to asymptomatic individuals at intermediate cardiovascular risk. Some of the input emphasised the importance of clearly defining eligibility criteria to prevent low-value testing where other investigations are more appropriate, including high-risk patients, those with established CVD, general population screening or in symptomatic patients.

The consultation input was generally supportive of the proposed comparator, noting that current management relies on cardiovascular risk calculators and clinical assessment without imaging. Some stakeholders highlighted that while risk calculators remain appropriate first-line tools, CT-CAC may provide incremental value in refining risk classification and guiding preventive treatment decisions in selected patients.

Other services identified as being needed before or after the intervention included appropriate follow-up pathways for incidental non cardiac findings, access to cardiovascular risk counselling, and integration with primary care and specialist services.

MBS Item Descriptor and Fee

The consultation input was generally supportive of the proposed service descriptor, with several organisations agreeing that the description broadly reflects current clinical practice. Suggestions to strengthen the proposed item descriptor included explicitly stating that patients should be asymptomatic and not considered to be high-risk.

RANZCR considered that repeat CT-CAC should not be performed less than five years apart. RANZCR further advised that repeat CT-CAC provides no clinical value in the following circumstances:

- Individuals with a previous high-risk calcium score; and
- Individuals who are already receiving lipid-lowering therapy.

AANMS stated that current guidelines suggest that if a Total Coronary Calcium Score is zero, then the appropriate interval before a repeat study is performed would be 5 years. For patients with diabetes and those with positive calcium scores below 400 Agatston Units (AU), consideration of repeat testing at 3 years is suggested by current CSANZ guidelines but repeat testing for patients with scores greater than 400 AU is generally considered to have no clinical utility.

The RACGP supports further research synthesis to determine the optimal repeat frequency for CT-CAC with the exception of a repeat in 5 years if the patient remains at intermediate risk or if risk factors increase (e.g. diabetes, smoking, strong family history). In the interim, Medicare funding should be limited to a one-off CAC test for eligible patients, with no option for repeat testing.

The consultation input was mixed in relation to the proposed service fee, with some organisations considering the proposed fee reasonable, while others raised concerns about whether it would adequately cover the costs of service delivery and sustainability.

Additional Comments

Additional comments related to appropriately identifying eligible service practitioners. RANZCR stated that the claims section of the application focuses primarily on the reclassification of patients from intermediate to lower risk. RANZCR highlighted that it is important to note that CT-CAC can also reclassify patients from intermediate to high risk, which carries significant clinical benefit and should be acknowledged in the application.

PASC noted that consultation feedback was generally supportive or very supportive of CT-CAC. Consumer input, including from the Heart Support and Hearts4heart, highlighted the value of CT-CAC test results in improving patient's adherence to risk factor modification strategies and enabling more meaningful discussions between the patient and clinician about prevention.

The CSANZ considered CT-CAC is part of contemporary clinical practice and noted that CT-CAC is already incorporated within CSANZ guideline pathways. The RANZCR advised that all radiologists (not just those accredited with ANZCTCA) and approved cardiologists are able to provide CT-CAC, and restricting provision of CT-CAC to ANZCTCA accredited providers may limit access to the service. The AANMS supports the

proposed population and appropriate accreditation arrangements. Both RANZCR and AANMS advised that the repeat imaging should not be performed more frequently than every 5 years.

Next steps

The applicant indicated a likely request for a Department-contracted assessment report (DCAR) but confirmation would be provided at a later stage.

Applicant Comments on Ratified PICO

On PASC's recommended item descriptor fee of $170, the applicant notes that the current MBS rebate for a comparable service (non-contrast chest CT) is $332. The applicant is concerned that underfunding may result in providers charging a gap to patients, which will negate the equity of access we are seeking for disadvantaged populations.

On PASC's enquiry regarding statin treatment in patients reclassified as low risk following CT-CAC but with comorbidities (e.g. diabetes or high lipid profile), the applicant refers to the AHA/ACC 2026 guidelines.[18] These guidelines indicate that, for primary prevention, in adults at intermediate risk or select adults at borderline risk who undergo CAC testing, if the CAC score is 0 Agatston units (AU), and there is preference to avoid LLT (lipid-lowering therapy) and focus on lifestyle management, and no higher risk conditions (FH [Familial Hypercholesterolaemia] or severe hypercholesterolemia >190 mg/dL [>4.9 mmol/L], diabetes and age >40 y, current cigarette smoking, strong family history of premature ASCVD) are present, it is reasonable to defer (lipid-lowering) therapy and reassess with repeat CAC testing in 3 to 7 y to personalize management.

On PASC's enquiry about appropriate thresholds for Lp(a) and hs-CRP, the applicant considered the following thresholds for Lp(a) and hs-CRP are appropriate to specify in the MBS descriptor:

Lp(a) ≥ 125 nmol/L

hs-CRP ≥ 2mg/L (persistently elevated).

[18] Blumenthal RS, et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ ADA/AGS/APhA/ASPC/NLA/PCNA *Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines*. J Am Coll Cardiol. 2026;87(19):2624-2757. doi: 10.1016/j.jacc.2025.11.016.

References

Agarwala, A, Liu, J, Ballantyne, CM & Virani, SS 2019, 'The Use of Risk Enhancing Factors to Personalize ASCVD Risk Assessment: Evidence and Recommendations from the 2018 AHA/ACC Multi-society Cholesterol Guidelines', *Curr Cardiovasc Risk Rep*, vol. 13, no. 7.

Agostino, JW, Wong, D, Paige, E, Wade, V, Connell, C, Davey, ME, Peiris, DP, Fitzsimmons, D, Burgess, CP, Mahoney, R, Lonsdale, E, Fernando, P, Malamoo, L, Eades, S, Brown, A, Jennings, G, Lovett, RW & Banks, E 2020, 'Cardiovascular disease risk assessment for Aboriginal and Torres Strait Islander adults aged under 35 years: a consensus statement', *Med J Aust*, vol. 212, no. 9, pp. 422-7.

Anokye, R, Jackson, B, Dimmock, J, Dickson, JM, Blekkenhorst, LC, Hodgson, JM, Lewis, JR & Stanley, M 2023, 'Psychological distress and quality of life in asymptomatic adults following provision of imaging results for prevention of cardiovascular disease events: a scoping review', *Eur J Cardiovasc Nurs*, vol. 22, no. 1, pp. 13-22.

Arnett, DK, Blumenthal, RS, Albert, MA, Buroker, AB, Goldberger, ZD, Hahn, EJ, Himmelfarb, CD, Khera, A, Lloyd-Jones, D, McEvoy, JW, Michos, ED, Miedema, MD, Muñoz, D, Smith, SC, Jr., Virani, SS, Williams, KA, Sr., Yeboah, J & Ziaeian, B 2019, '2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines', *Circulation*, vol. 140, no. 11, pp. e596-e646.

Barwick, G, Hancock, S, Ren, S, Hure, A & Attia, J 2026, 'External Validation of the 2023 Australian Cardiovascular Risk Calculator', *Heart Lung Circ*, vol. 35, no. 2, pp. 271-82.

Bello, NA 2023, 'Adverse Pregnancy Outcomes-Risk Enhancers Whose Time Has Finally Arrived', *Jama*, vol. 329, no. 5, pp. 373-5.

Biavati, F, Saba, L, Boussoussou, M, Kofoed, KF, Benedek, T, Donnelly, P, Rodríguez-Palomares, J, Erglis, A, Štěchovský, C, Šakalytė, G, Čemerlić Ađić, N, Gutberlet, M, Dodd, JD, Diez, I, Davis, G, Zimmermann, E, Kępka, C, Vidakovic, R, Francone, M, Ilnicka-Suckiel, M, Plank, F, Knuuti, J, Faria, R, Schröder, S, Berry, C, Ruzsics, B, Rieckmann, N, Kubiak, C, Hansen, KS, Müller-Nordhorn, J, Maurovich-Horvat, P, Sigvardsen, PE, Benedek, I, Orr, C, Valente, FX, Zvaigzne, L, Suchánek, V, Jankauskas, A, Ađić, F, Woinke, M, Cadogan, D, Lecumberri, I, Thwaite, E, Kruk, M, Neskovic, AN, Mancone, M, Kuśmierz, D, Feuchtner, G, Pietilä, M, Ribeiro, VG, Drosch, T, Delles, C, Cau, R, Fisher, M, Merkely, B, Kragelund, C, Aurelian, R, Kelly, S, García Del Blanco, B, Rubio, A, Szilveszter, B, Hove, JD, Rodean, I, Regan, S, Cuéllar Calabria, H, Édes, IF, Larsen, L, Hodas, R, Napp, AE, Haase, R, Feger, S, Mohamed, M, Serna-Higuita, LM, Neumann, K, Dreger, H, Rief, M, Wieske, V, Budoff, MJ, Estrella, M, Martus, P, Bosserdt, M & Dewey, M 2024, 'Coronary Artery Calcium Score Predicts Major Adverse Cardiovascular Events in Stable Chest Pain', *Radiology*, vol. 310, no. 3, p. e231557.

Blumenthal, RS, Morris, PB, Gaudino, M, Johnson, HM, Anderson, TS, Bittner, VA, Blankstein, R, Brewer, LC, Cho, L, de Ferranti, SD, Gianos, E, Gluckman, TJ, Gradney, KF, Isiadinso, I, Lloyd-Jones, DM, Marrs, JC, Martin, SS, McLain, KH, Mehta, LS, Mora, S, Mulugeta, WM, Natarajan, P, Navar, AM, Orringer, CE, Polonsky, TS, Reynolds, HR, Saseen, JJ, Shapiro, MD, Soffer, DE, Tynes, SA, Villavaso, CD, Virani, SS & Wilkins, JT 2026, '2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the

Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines', *J Am Coll Cardiol*.

Brown, S, Banks, E, Woodward, M, Raffoul, N, Jennings, G & Paige, E 2023, 'Evidence supporting the choice of a new cardiovascular risk equation for Australia', *Med J Aust*, vol. 219, no. 4, pp. 173-86.

Budoff, MJ, Kinninger, A, Gransar, H, Achenbach, S, Al-Mallah, M, Bax, JJ, Berman, DS, Cademartiri, F, Callister, TQ, Chang, HJ, Chow, BJW, Cury, RC, Feuchtner, G, Hadamitzky, M, Hausleiter, J, Kaufmann, PA, Leipsic, J, Lin, FY, Kim, YJ, Marques, H, Pontone, G, Rubinshtein, R, Shaw, LJ, Villines, TC & Min, JK 2023, 'When Does a Calcium Score Equate to Secondary Prevention?: Insights From the Multinational CONFIRM Registry', *JACC Cardiovasc Imaging*, vol. 16, no. 9, pp. 1181-9.

Cai, T, Abel, L, Langford, O, Monaghan, G, Aronson, JK, Stevens, RJ, Lay-Flurrie, S, Koshiaris, C, McManus, RJ, Hobbs, FDR & Sheppard, JP 2021, 'Associations between statins and adverse events in primary prevention of cardiovascular disease: systematic review with pairwise, network, and dose-response meta-analyses', *Bmj*, vol. 374, p. n1537.

Cederström, S, Lundman, P, Alfredsson, J, Hagström, E, Ravn-Fischer, A, Söderberg, S, Yndigegn, T, Tornvall, P & Jernberg, T 2023, 'Association between high-sensitivity C-reactive protein and coronary atherosclerosis in a general middle-aged population', *Sci Rep*, vol. 13, no. 1, p. 12171.

Chaparala, SP, Sampathkumar, N, Jonnadula, S, Chand, A & Chowdhury, D 2025, 'Beyond Traditional Risk Calculators: The Expanding Role of Coronary Artery Calcium Scoring in Preventive Cardiology', *Cureus*, vol. 17, no. 9, p. e93500.

Cheeley, MK, Saseen, JJ, Agarwala, A, Ravilla, S, Ciffone, N, Jacobson, TA, Dixon, DL & Maki, KC 2022, 'NLA scientific statement on statin intolerance: a new definition and key considerations for ASCVD risk reduction in the statin intolerant patient', *J Clin Lipidol*, vol. 16, no. 4, pp. 361-75.

Cheung, K, Pant, A, Dang, D, Ridsdill-Kenny, E, Marschner, S, Kuhn, L, Wing-Lun, E, Mitchell, J, Bittencourt, M & Zaman, S 2026, 'Prevalence and prognostic value of elevated computed tomography coronary artery calcium scores in Indigenous peoples globally: A systematic review', *Int J Cardiovasc Imaging*, vol. 42, no. 1, pp. 61-70.

Choudhry, NK, Kronish, IM, Vongpatanasin, W, Ferdinand, KC, Pavlik, VN, Egan, BM, Schoenthaler, A, Houston Miller, N & Hyman, DJ 2022, 'Medication Adherence and Blood Pressure Control: A Scientific Statement From the American Heart Association', *Hypertension*, vol. 79, no. 1, pp. e1-e14.

Chua, A, Blankstein, R & Ko, B 2020, 'Coronary artery calcium in primary prevention', *Aust J Gen Pract*, vol. 49, no. 8, pp. 464-9.

Dal Canto, E, Ceriello, A, Rydén, L, Ferrini, M, Hansen, TB, Schnell, O, Standl, E & Beulens, JW 2019, 'Diabetes as a cardiovascular risk factor: An overview of global trends of macro and micro vascular complications', *Eur J Prev Cardiol*, vol. 26, no. 2_suppl, pp. 25-32.

de Jong, M, Woodward, M & Peters, SAE 2022, 'Duration of diabetes and the risk of major cardiovascular events in women and men: A prospective cohort study of UK Biobank participants', *Diabetes Res Clin Pract*, vol. 188, p. 109899.

de Oliveira Costa, J, Lin, J, Pearson, SA, Buckley, NA, Schaffer, AL & Falster, MO 2023, 'Persistence and Adherence to Cardiovascular Medicines in Australia', *J Am Heart Assoc*, vol. 12, no. 13, p. e030264.

Devcich, DA, Ellis, CJ, Broadbent, E, Gamble, G & Petrie, KJ 2012, 'The psychological impact of test results following diagnostic coronary CT angiography', *Health Psychol*, vol. 31, no. 6, pp. 738-44.

Erbel, R, Möhlenkamp, S, Moebus, S, Schmermund, A, Lehmann, N, Stang, A, Dragano, N, Grönemeyer, D, Seibel, R, Kälsch, H, Bröcker-Preuss, M, Mann, K, Siegrist, J & Jöckel, KH 2010, 'Coronary risk stratification, discrimination, and reclassification improvement based on quantification of subclinical coronary atherosclerosis: the Heinz Nixdorf Recall study', *J Am Coll Cardiol*, vol. 56, no. 17, pp. 1397-406.

Foraker, R, Sperling, L, Bratzke, L, Budoff, M, Leppert, M, Razavi, AC, Rodriguez, F, Shapiro, MD, Whelton, S, Wong, ND & Yang, E 2025, 'Opportunistic Detection of Coronary Artery Calcium on Noncardiac Chest Computed Tomography: An Emerging Tool for Cardiovascular Disease Prevention: A Scientific Statement From the American Heart Association', *Circulation*, vol. 152, no. 19, pp. e391-e401.

Fuller, RH, Perel, P, Navarro-Ruan, T, Nieuwlaat, R, Haynes, RB & Huffman, MD 2018, 'Improving medication adherence in patients with cardiovascular disease: a systematic review', *Heart*, vol. 104, no. 15, pp. 1238-43.

Golub, IS, Termeie, OG, Kristo, S, Schroeder, LP, Lakshmanan, S, Shafter, AM, Hussein, L, Verghese, D, Aldana-Bitar, J, Manubolu, VS & Budoff, MJ 2023, 'Major Global Coronary Artery Calcium Guidelines', *JACC Cardiovasc Imaging*, vol. 16, no. 1, pp. 98-117.

Grundy, SM, Stone, NJ, Bailey, AL, Beam, C, Birtcher, KK, Blumenthal, RS, Braun, LT, de Ferranti, S, Faiella-Tommasino, J, Forman, DE, Goldberg, R, Heidenreich, PA, Hlatky, MA, Jones, DW, Lloyd-Jones, D, Lopez-Pajares, N, Ndumele, CE, Orringer, CE, Peralta, CA, Saseen, JJ, Smith, SC, Jr., Sperling, L, Virani, SS & Yeboah, J 2019, '2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines', *J Am Coll Cardiol*, vol. 73, no. 24, pp. 3168-209.

Grundy, SM & Vega, GL 2022, 'Statin Intolerance and Noncompliance: An Empiric Approach', *Am J Med*, vol. 135, no. 3, pp. 318-23.

Gupta, A, Lau, E, Varshney, R, Hulten, EA, Cheezum, M, Bittencourt, MS, Blaha, MJ, Wong, ND, Blumenthal, RS, Budoff, MJ, Umscheid, CA, Nasir, K & Blankstein, R 2017, 'The Identification of Calcified Coronary Plaque Is Associated With Initiation and Continuation of Pharmacological and Lifestyle Preventive Therapies: A Systematic Review and Meta-Analysis', *JACC Cardiovasc Imaging*, vol. 10, no. 8, pp. 833-42.

Hanifehpour, R, Motevalli, M, Ghanaati, H, Shahriari, M & Aliyari Ghasabeh, M 2016, 'Diagnostic Accuracy of Coronary Calcium Score Less than 100 in Excluding Coronary Artery Disease', *Iran J Radiol*, vol. 13, no. 2, p. e16705.

Ibanez, B, Fernández-Ortiz, A, Fernández-Friera, L, García-Lunar, I, Andrés, V & Fuster, V 2021, 'Progression of Early Subclinical Atherosclerosis (PESA) Study: JACC Focus Seminar 7/8', *J Am Coll Cardiol*, vol. 78, no. 2, pp. 156-79.

Jennings, GL, Audehm, R, Bishop, W, Chow, CK, Liaw, ST, Liew, D & Linton, SM 2021, 'National Heart Foundation of Australia: position statement on coronary artery calcium scoring for the primary prevention of cardiovascular disease in Australia', *Med J Aust*, vol. 214, no. 9, pp. 434-9.

Johnson, JE, Gulanick, M, Penckofer, S & Kouba, J 2015, 'Does knowledge of coronary artery calcium affect cardiovascular risk perception, likelihood of taking action, and health-promoting behavior change?', *J Cardiovasc Nurs*, vol. 30, no. 1, pp. 15-25.

Joseph, JJ, Deedwania, P, Acharya, T, Aguilar, D, Bhatt, DL, Chyun, DA, Di Palo, KE, Golden, SH & Sperling, LS 2022, 'Comprehensive Management of Cardiovascular Risk Factors for Adults With Type 2 Diabetes: A Scientific Statement From the American Heart Association', *Circulation*, vol. 145, no. 9, pp. e722-e59.

Jukema, RA, Nasibi, N, Mueller, A, Kim, S, Argulian, E, Khoo, JK, Bin Zaid, AA, Rigby, H, Pashaee, B, Danad, I, Knaapen, P, Sellers, SL, Blanke, P, Parsa, A, Leipsic, JA, Narula, J & Ahmadi, A 2025, 'Analysis of the coronary artery calcium score for identifying coronary artery plaque in patients clinically referred for preventive screening with non-typical symptoms stratified by age and sex', *J Cardiovasc Comput Tomogr*, vol. 19, no. 5, pp. 585-91.

Kim, JY, Suh, YJ, Han, K & Choi, BW 2021, 'Reliability of Coronary Artery Calcium Severity Assessment on Non-Electrocardiogram-Gated CT: A Meta-Analysis', *Korean J Radiol*, vol. 22, no. 7, pp. 1034-43.

Kim, KP, Einstein, AJ & Berrington de González, A 2009, 'Coronary artery calcification screening: estimated radiation dose and cancer risk', *Arch Intern Med*, vol. 169, no. 13, pp. 1188-94.

Kuo, NI, Barbieri, S, Arnott, C, Gallego, B, Gandomkar, Z, Ferdousi, S, Douglas, K, Woodward, M & Jorm, L 2025, 'Estimating 5-year absolute risk of cardiovascular disease using routinely collected electronic medical records from Australian general practices', *Heart*.

Lee, CI, Tsai, EB, Sigal, BM, Plevritis, SK, Garber, AM & Rubin, GD 2010, 'Incidental extracardiac findings at coronary CT: clinical and economic impact', *AJR Am J Roentgenol*, vol. 194, no. 6, pp. 1531-8.

Lee, DW, Neumann, PJ & Rizzo, JA 2010, 'Understanding the medical and nonmedical value of diagnostic testing', *Value Health*, vol. 13, no. 2, pp. 310-4.

Lee, L & Kim, H 2024, 'Exploring the Evolution of Statin Pricing in Australia: Observations of Price Disclosure Effects on Pharmaceutical Benefits Scheme Expenditure', *Value Health Reg Issues*, vol. 40, pp. 27-34.

Liew, G, Chow, C, van Pelt, N, Younger, J, Jelinek, M, Chan, J & Hamilton-Craig, C 2017, 'Cardiac Society of Australia and New Zealand Position Statement: Coronary Artery Calcium Scoring', *Heart Lung Circ*, vol. 26, no. 12, pp. 1239-51.

Lim, ECN & Lim, CED 2025, 'The Power and the Limits of Zero: Strengths and Pitfalls of CT Coronary Artery Calcium Score in Risk Assessment.', *Journal of Biosciences and Medicines*, vol. 13, pp. 196-206.

Lindholt, JS, Søgaard, R, Rasmussen, LM, Mejldal, A, Lambrechtsen, J, Steffensen, FH, Frost, L, Egstrup, K, Urbonaviciene, G, Busk, M & Diederichsen, ACP 2022, 'Five-Year Outcomes of the Danish Cardiovascular Screening (DANCAVAS) Trial', *N Engl J Med*, vol. 387, no. 15, pp. 1385-94.

Mach, F, Baigent, C, Catapano, AL, Koskinas, KC, Casula, M, Badimon, L, Chapman, MJ, De Backer, GG, Delgado, V, Ference, BA, Graham, IM, Halliday, A, Landmesser, U, Mihaylova, B, Pedersen, TR, Riccardi, G, Richter, DJ, Sabatine, MS, Taskinen, M-R, Tokgozoglu, L, Wiklund, O & Group, ESD 2019, '2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk: The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS)', *European Heart Journal*, vol. 41, no. 1, pp. 111-88.

Mach, F, Koskinas, KC, Roeters van Lennep, JE, Tokgözoğlu, L, Badimon, L, Baigent, C, Benn, M, Binder, CJ, Catapano, AL, De Backer, GG, Delgado, V, Fabin, N, Ference, BA, Graham, IM, Landmesser, U, Laufs, U, Mihaylova, B, Nordestgaard, BG, Richter, DJ & Sabatine, MS 2025, '2025 Focused Update of the 2019 ESC/EAS Guidelines for the management of dyslipidaemias', *Eur Heart J*, vol. 46, no. 42, pp. 4359-78.

Mamudu, HM, Paul, TK, Veeranki, SP & Budoff, M 2014, 'The effects of coronary artery calcium screening on behavioral modification, risk perception, and medication adherence among asymptomatic adults: a systematic review', *Atherosclerosis*, vol. 236, no. 2, pp. 338-50.

Marschner, S, Wing-Lun, E, Chow, C, Maple-Brown, L, Graham, S, Nicholls, SJ, Brown, A, Wood, A, Ihdayhid, A, Von Huben, A & Zaman, S 2022, 'Randomised clinical trial using Coronary Artery Calcium Scoring in Australian Women with Novel Cardiovascular Risk Factors (CAC-WOMEN Trial): study protocol', *BMJ Open*, vol. 12, no. 12, p. e062685.

Mehta, A, Blumenthal, RS, Gluckman, TJ, Feldman, DI & Kohli, P 2025, 'High-sensitivity C-reactive Protein in Atherosclerotic Cardiovascular Disease: To Measure or Not to Measure?', *US Cardiol*, vol. 19, p. e06.

Mokhtar, J, Albaree, M, Battistin, V, Asbaita, M, Akbarpoor, F, Lakshmanan, J & El-Tamimi, H 2025, 'Inadequacy of coronary calcium scoring in evaluating coronary artery disease: A call to shifting to high-resolution CT coronary imaging', *Int J Cardiol Cardiovasc Risk Prev*, vol. 26, p. 200476.

Moldovanu, D, de Koning, HJ, Vonder, M, Gratama, JWC, Adriaansen, HJ, Roeters van Lennep, JE, Vliegenthart, R, van der Harst, P, Braam, RL, van Dijkman, PRM, Oudkerk, M & van der Aalst, CM 2024,

'Short-term impact of cardiovascular screening by traditional risk assessment or coronary artery calcium score on health-related quality of life: the ROBINSCA trial', *Eur Heart J Open*, vol. 4, no. 5, p. oeae080.

Mortensen, MB, Gaur, S, Frimmer, A, Bøtker, HE, Sørensen, HT, Kragholm, KH, Niels Peter, SR, Steffensen, FH, Jensen, RV, Mæng, M, Kanstrup, H, Blaha, MJ, Shaw, LJ, Dzaye, O, Leipsic, J, Nørgaard, BL & Jensen, JM 2022, 'Association of Age With the Diagnostic Value of Coronary Artery Calcium Score for Ruling Out Coronary Stenosis in Symptomatic Patients', *JAMA Cardiol*, vol. 7, no. 1, pp. 36-44.

Muhlestein, JB, Knowlton, KU, Le, VT, Lappe, DL, May, HT, Min, DB, Johnson, KM, Cripps, ST, Schwab, LH, Braun, SB, Bair, TL & Anderson, JL 2022, 'Coronary Artery Calcium Versus Pooled Cohort Equations Score for Primary Prevention Guidance: Randomized Feasibility Trial', *JACC Cardiovasc Imaging*, vol. 15, no. 5, pp. 843-55.

Naderi, SH, Bestwick, JP & Wald, DS 2012, 'Adherence to drugs that prevent cardiovascular disease: meta-analysis on 376,162 patients', *Am J Med*, vol. 125, no. 9, pp. 882-7.e1.

Nasir, K, Bittencourt, MS, Blaha, MJ, Blankstein, R, Agatson, AS, Rivera, JJ, Miedema, MD, Sibley, CT, Shaw, LJ, Blumenthal, RS, Budoff, MJ & Krumholz, HM 2015, '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*, vol. 66, no. 15, pp. 1657-68.

Nasir, K, McClelland, RL, Blumenthal, RS, Goff, DC, Jr., Hoffmann, U, Psaty, BM, Greenland, P, Kronmal, RA & Budoff, MJ 2010, 'Coronary artery calcium in relation to initiation and continuation of cardiovascular preventive medications: The Multi-Ethnic Study of Atherosclerosis (MESA)', *Circ Cardiovasc Qual Outcomes*, vol. 3, no. 3, pp. 228-35.

Nerlekar, N, Vasanthakumar, SA, Whitmore, K, Soh, CH, Chan, J, Goel, V, Ryan, J, Jones, C, Stanton, T, Mitchell, G, Tonkin, A, Watts, GF, Nicholls, SJ & Marwick, TH 2025, 'Effects of Combining Coronary Calcium Score With Treatment on Plaque Progression in Familial Coronary Artery Disease: A Randomized Clinical Trial', *Jama*, vol. 333, no. 16, pp. 1403-12.

O'Sullivan, JW, Raghavan, S, Marquez-Luna, C, Luzum, JA, Damrauer, SM, Ashley, EA, O'Donnell, CJ, Willer, CJ & Natarajan, P 2022, 'Polygenic Risk Scores for Cardiovascular Disease: A Scientific Statement From the American Heart Association', *Circulation*, vol. 146, no. 8, pp. e93-e118.

Orakzai, RH, Nasir, K, Orakzai, SH, Kalia, N, Gopal, A, Musunuru, K, Blumenthal, RS & Budoff, MJ 2008, 'Effect of patient visualization of coronary calcium by electron beam computed tomography on changes in beneficial lifestyle behaviors', *Am J Cardiol*, vol. 101, no. 7, pp. 999-1002.

Orringer, CE, Blaha, MJ, Blankstein, R, Budoff, MJ, Goldberg, RB, Gill, EA, Maki, KC, Mehta, L & Jacobson, TA 2021, 'The National Lipid Association scientific statement on coronary artery calcium scoring to guide preventive strategies for ASCVD risk reduction', *J Clin Lipidol*, vol. 15, no. 1, pp. 33-60.

Peng, AW, Dardari, ZA, Blumenthal, RS, Dzaye, O, Obisesan, OH, Iftekhar Uddin, SM, Nasir, K, Blankstein, R, Budoff, MJ, Bødtker Mortensen, M, Joshi, PH, Page, J & Blaha, MJ 2021, 'Very High Coronary Artery Calcium (≥1000) and Association With Cardiovascular Disease Events, Non-Cardiovascular Disease Outcomes, and Mortality: Results From MESA', *Circulation*, vol. 143, no. 16, pp. 1571-83.

Peyrel, P, Mauriège, P, Frenette, J, Laflamme, N, Greffard, K, Huth, C, Bergeron, J & Joanisse, DR 2023, 'Statin withdrawal and health-related quality of life in a primary cardiovascular prevention cohort', *Qual Life Res*, vol. 32, no. 7, pp. 1943-54.

Rozanski, A, Gransar, H, Shaw, LJ, Kim, J, Miranda-Peats, L, Wong, ND, Rana, JS, Orakzai, R, Hayes, SW, Friedman, JD, Thomson, LE, Polk, D, Min, J, Budoff, MJ & Berman, DS 2011, 'Impact of coronary artery calcium scanning on coronary risk factors and downstream testing the EISNER (Early Identification of Subclinical Atherosclerosis by Noninvasive Imaging Research) prospective randomized trial', *J Am Coll Cardiol*, vol. 57, no. 15, pp. 1622-32.

Sandhu, AT, Rodriguez, F, Ngo, S, Patel, BN, Mastrodicasa, D, Eng, D, Khandwala, N, Balla, S, Sousa, D & Maron, DJ 2023, 'Incidental Coronary Artery Calcium: Opportunistic Screening of Previous Nongated Chest Computed Tomography Scans to Improve Statin Rates (NOTIFY-1 Project)', *Circulation*, vol. 147, no. 9, pp. 703-14.

Scheu, V, Alwan, L, Gräni, C, Gencer, B, Rodondi, N & Blum, MR 2025, 'Coronary atherosclerosis screening in asymptomatic adults using coronary artery calcium for cardiovascular prevention: a systematic review of randomised controlled trials and prospective cohorts', *BMJ Open*, vol. 15, no. 7, p. e101472.

Sederholm Lawesson, S, Swahn, E, Pihlsgård, M, Andersson, T, Angerås, O, Bacsovics Brolin, E, Bergdahl, E, Blomberg, M, Christersson, C, Gonçalves, I, Gunnarsson, OS, Jernberg, T, Johnston, N, Leander, K, Lilliecreutz, C, Pehrson, M, Rosengren, A, Sandström, A, Sandström, A, Sarno, G, Själander, S, Svanvik, T, Thunström, E, Wikström, AK & Timpka, S 2023, 'Association Between History of Adverse Pregnancy Outcomes and Coronary Artery Disease Assessed by Coronary Computed Tomography Angiography', *Jama*, vol. 329, no. 5, pp. 393-404.

Sheppard, JP, Lakshmanan, S, Lichtenstein, SJ, Budoff, MJ & Roy, SK 2022, 'Age and the power of zero CAC in cardiac risk assessment: overview of the literature and a cautionary case', *Br J Cardiol*, vol. 29, no. 3, p. 23.

Silverman, MG, Blaha, MJ, Krumholz, HM, Budoff, MJ, Blankstein, R, Sibley, CT, Agatston, A, Blumenthal, RS & Nasir, K 2014, 'Impact of coronary artery calcium on coronary heart disease events in individuals at the extremes of traditional risk factor burden: the Multi-Ethnic Study of Atherosclerosis', *Eur Heart J*, vol. 35, no. 33, pp. 2232-41.

Soh, CH, Nerlekar, N, Whitmore, K, Salib, A, Watts, GF, Nicholls, SJ & Marwick, TH 2026, 'Association of Cardiovascular Risk Scores with Coronary Plaque and its Progression among Individuals with Family History of Coronary Artery Disease', *American Journal of Preventive Cardiology*, p. 101423.

Sosnowska, B, Toth, PP, Razavi, AC, Remaley, AT, Blumenthal, RS & Banach, M 2025, '2024: The year in cardiovascular disease - the year of lipoprotein(a). Research advances and new findings', *Arch Med Sci*, vol. 21, no. 2, pp. 355-73.

Sripariwuth, A, Kruamak, T & Xu, B 2021, 'Contemporary review: a clinically oriented interpretation of incidental radiological findings for common cardiovascular computed tomography scans', *AME Medical Journal; Vol 7 (March 25, 2022): AME Medical Journal*.

Stürzebecher, PE, Gouni-Berthold, I, Mateev, C, Frenzel, O, Erbe, S, Boeckel, JN, Scholz, M, Schatz, U, Weingärtner, O, Kassner, U & Laufs, U 2024, 'Quality of life in patients with statin intolerance: a multicentre prospective registry study', *Lancet Reg Health Eur*, vol. 43, p. 100981.

Venkataraman, P, Huynh, Q, Nicholls, SJ, Stanton, T, Watts, GF & Marwick, TH 2021, 'Impact of a coronary artery calcium-guided statin treatment protocol on cardiovascular risk at 12 months: Results from a pragmatic, randomised controlled trial', *Atherosclerosis*, vol. 334, pp. 57-65.

Venkataraman, P, Neil, AL, Mitchell, GK, Stanton, T, Nicholls, S, Tonkin, AM, Watts, GF & Marwick, TH 2023, 'The cost-effectiveness of coronary calcium score-guided statin therapy initiation for Australians with family histories of premature coronary artery disease', *Med J Aust*, vol. 218, no. 5, pp. 216-22.