HTE10085 CaRi-Heart for predicting cardiac risk in adults with suspected coronary artery disease

Protocol

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1. Decision problem

The purpose of this routine use assessment is to review and appraise new evidence on the clinical effectiveness and cost-effectiveness of CaRi-Heart (Caristo diagnostics Ltd, Oxford, UK), an artificial intelligence (AI)-based analysis of computed tomography coronary angiography (CTCA) images that estimates an individualised risk score for cardiac mortality within 8 years based on quantification of coronary inflammation and characterization of plaque and stenosis. The main output includes measurements of the fat attenuation index (FAI) at vessel level, the FAI score, and the CaRi-Heart risk estimate. CaRi-Heart is used as an adjunctive investigation for the assessment of cardiac risk in people with stable chest pain and/or suspected coronary artery disease (CAD) who are undergoing CTCA. This assessment aims to inform the guidance on the use of CaRi-Heart in the NHS by answering the research question:

Is offering CaRi-Heart for predicting cardiac risk in adults with suspected CAD a clinically and cost-effective use of NHS resources?

Table 1 summarises the decision problem to be addressed in this assessment. Further detail on each element can be found in the scope for the assessment.

Table 1. Summary table of the decision problem

Item	Description
Population(s)	Adults with suspected CAD who are referred for CTCA as part of NHS chest pain assessment pathways.
Subgroups	If the evidence allows, the following subgroups may be considered: • People with no CAD on CTCA • People with non-obstructive CAD on CTCA • People with obstructive CAD • Evidence should be considered that evaluates prognostic performance based on the following characteristics:Age • Sex • Ethnicity • Socioeconomic status
Intervention(s)	CaRi-Heart software used as an add-on to routine CTCA scan interpretation and clinical assessment.

Item	Description
Comparators	Standard care: • Current NHS practice without CaRi-Heart: routine CTCA interpretation and clinical assessment.
Setting	Secondary care chest pain assessment pathways
Outcomes eligible for inclusion	Intermediate outcomes: • Prognostic performance of risk prediction (e.g. discrimination, calibration, reclassification) • Changes to clinical management following CaRi-Heart reporting (e.g. initiation or intensification of lipid-lowering therapy and other preventive therapies) • Adherence to or uptake of lifestyle changes or drug treatment • Number of downstream investigations and referrals • Test failure rate • Time to test results Clinical outcomes: • Major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke) • Cardiovascular mortality and all-cause mortality • Stroke, heart failure events • Adverse events associated with downstream treatments (e.g. statin intolerance or myositis) Patient-reported outcomes: • Health-related quality of life • Anxiety or reassurance related to risk results (where measured) • Acceptability and understanding of risk information (e.g. treatment uptake) Costs and resource use: • Costs of CaRi-Heart testing (including implementation cost, test cost, time to interpret results, and staff training costs). • Downstream costs from changes in prescribing, follow-up (including primary care management), referrals, and further testing • Costs associated with cardiovascular events avoided or incurred • Costs of managing major adverse cardiovascular events • Costs of repeat imaging tests • NHS resource use across the care pathway (including primary care follow-up, preventive management, prescribing, monitoring, and secondary care services)
Economic analysis	A health-economic model will be developed comprising a cost-utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services (PSS) perspective.

Item	Description
	Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared. For cardiovascular risk prediction and prevention, a lifetime horizon is likely required.

1.1 Objectives

The following primary objectives are proposed based on the scope developed by NICE:

Clinical effectiveness

- Identification, assessment, and summary of relevant clinical evidence on the prognostic performance and clinical effectiveness of CaRi-Heart.
- Description of any potential safety concerns associated with the use of CaRi-Heart.
- Summary of gaps in the current evidence base and indication what further data may be required to address these uncertainties.

Cost effectiveness

- Identification and assessment of relevant health-economic models.
- Identification and assessment of available economic evidence relating to the use of CaRi-Heart.
- Development of a health-economic model to estimate the potential cost-effectiveness of CaRi-Heart compared with current care.
- Summary of available model inputs, identification of areas where evidence is lacking, and outline what data could be collected to address the evidence gaps.
- Description of key uncertainties within the economic model, their potential implications for decision-making, and exploration of the impact of alternative plausible assumptions using sensitivity and scenario analyses.
- Presentation of the estimated costs and effects of CaRi-Heart and indication of its potential cost-effectiveness compared to current care within the NHS.

2. Evidence review methods

The External Assessment Group (EAG) will perform an independent search to identify evidence relevant to the scope of this assessment. A systematic literature review will be conducted to identify and summarize published evidence on the clinical and cost-effectiveness of CaRi-Heart for people with suspected CAD as outlined in the scope. This review will follow the recommendations of the NICE HealthTech programme manual and the NICE technology appraisal and highly specialised technologies guidance manual.

If sufficient comparative evidence is identified, a pair-wise meta-analysis may be considered to pool effect sizes or to estimate the relative effects using data from published literature. This also depends on whether the evidence identified is suitable for meta-analysis; differences in populations and outcome reporting may prevent a meaningful and credible evidence synthesis using meta-analysis. Heterogeneity and consistency will be assessed to determine if a meta-analysis will be appropriate.

Missing or incomplete information may be supplemented with information available in the public domain, such as company websites or grey literature, or information provided by the companies or other stakeholders, such as unpublished studies if they are complete enough to enable critical appraisal.

2.1 Inclusion criteria

The selection criteria are outlined in Table 2. If the literature search does not identify sufficient evidence directly relevant to the decision problem for a given technology, the EAG will review whether elements of the selection criteria could be broadened. Should this become necessary, the decision will be justified and any changes made will be described in the assessment report. Furthermore, any evidence that is only partially within scope will be clearly labelled as such. The EAG will also consult with clinical experts to consider the extent to which the available evidence and findings may be generalisable to NHS practice.

Table 2. Inclusion and exclusion criteria

	Inclusion Criteria	Exclusion Criteria
Population	People undergoing CTCA for the investigation of stable chest pain/angina and/or suspected CAD.	People who are not undergoing CTCA, or are undergoing CTCA for reasons other than stable chest pain/angina or suspected CAD.
Intervention	CaRi-Heart software used as an add-on to routine CTCA scan interpretation and clinical assessment.	Technologies other than CaRi-Heart. Technologies that do not analyse CTCA images, or that do not provide outputs intended to support cardiovascular risk assessment using CTCA-derived measures of coronary inflammation. The technology is not disclosed in the full-text version of the manuscript, and cannot be inferred otherwise (e.g. from the company being a funding source or the reference being provided by the company).
Comparators	Current care for cardiac risk assessment: routine CTCA interpretation and clinical assessment.	No exclusion based on comparator.
Setting	Secondary care chest pain assessment pathways.	No exclusion based on setting.
Outcomes	See Table 1.	Evidence will be excluded if no relevant outcomes are reported. If a subsection of outcomes is relevant to the scope, these alone will be reported.

	Inclusion Criteria	Exclusion Criteria
Study design	• Systematic reviews • Meta-analyses • Randomized controlled trials • Case-control studies • Cross-sectional studies • Observational studies • Single-arm studies • Real-world studies • Database/registry data • Qualitative/mixed methods studies • Cost studies • Health-economic analyses • Study protocols • Trial registrations	• Narrative reviews • Animal studies • Comments • Editorials • Letters • Description of surgical technique • Retracted publications • Duplicate publications Unpublished evidence, abstracts, and conference presentations or posters may be considered for relevance to the scope if they are the only available source for a study, but may be deprioritized if published evidence is available. Case series and case reports may be considered for relevance to the scope if insufficient evidence is available from the preferred study designs.
Other	The literature review will be restricted to articles published in English	

2.2 Search strategy

A search strategy will be developed to identify articles reporting both clinical and health-economic outcomes for CaRi-Heart. Search terms will be structured around the population and intervention as detailed in the inclusion criteria (Section 2.1) and use controlled vocabulary from database thesauri such as MeSH (MEDLINE) or EMTREE (EMBASE), as well as free-text terms derived from target references and terms specific to the technology of interest (such as brand names, company names, and generic descriptors of CaRi-Heart and the parameters measured by CaRi-Heart).

Where appropriate, the EAG will consider applying limits to the literature search (for example English language publications and/or date of publication). Additional studies may be identified from hand searching relevant references of included papers.

The EAG may perform supplementary pragmatic searches of the broader literature on CAD for evidence on health-related quality of life (HRQoL), resource use, and treatment costs in order to inform the health-economic model.

The search strategies will be developed in MEDLINE (PubMed; see Appendix A for the search strings used) and translated specifically for each database, keeping as many of the key terms as possible while adapting database-specific keywords and thesaurus terms according to the configuration of each database. Filters may be applied to identify relevant clinical and health-economic publications, as appropriate.

The following databases will be searched to identify published literature on clinical and health-economic evidence:

- MEDLINE (PubMed)
- EMBASE (Elsevier)
- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Central Register of Controlled Trials (CENTRAL)
- Epistemonikos
- International HTA database (INAHTA)

The following databases will be searched to identify unpublished and ongoing trials:

- ClinicalTrials.gov
- EU Clinical Trials Register
- International Clinical Trials Registry Platform (ICTRP)

The following sources will be checked to ensure that no relevant studies are missed:

- Reference lists of identified systematic reviews
- Published papers associated with any key trial registry entries or published protocols
- Relevant studies known to the guideline committee

2.3 Study selection

All references that were retrieved as part of the search strategy described in Section 2.2 will be imported into PICO Portal for deduplication and screening; the platform will record the screening decisions of all reviewers involved.

The titles and abstracts of all identified references will be screened by two independent reviewers against the pre-specified selection criteria (Section 2.1). Selection at title and abstract level will be more inclusive as the technologies used in the study are often not mentioned by name in the abstract but described in more generic terms. This approach will ensure that all relevant literature on the technologies included in the scope is identified.

Full-text articles will be obtained for all eligible references and screened by two independent reviewers. At full-text level, articles that do not explicitly name the technology or where the technology used cannot be inferred (for example from the manufacturing company sponsoring the study, or the paper being sent by the company) will be excluded.

All disagreements in screening decisions will be settled through discussion or by a third reviewer. All studies excluded during full-text screening will be presented in the appendix of the report, including the reason(s) for their exclusion.

PICO Portal includes an AI function that is meant to support the human reviewer and speed up the screening and data extraction processes but not replace the human researchers. During screening, it tries to recognize patterns in the studies that are included and excluded. After the first batch of abstracts (usually around 40 abstracts) have been screened, the AI predicts which articles are likely to be included and prioritises these. There is no risk associated with its use as all abstracts will be screened by human reviewers; the only impact the AI has is in the order in which the abstracts are screened.

Should a large volume of evidence be identified, the selection criteria may be further refined, prioritising comparative evidence over single-arm designs or studies with larger populations over smaller sample sizes. See TSD 27: Prioritising studies and outcomes for consideration in NICE HealthTech literature reviews for more details.

Unpublished evidence will be considered and handled according to the NICE HealthTech programme manual. Evidence provided by companies and other stakeholders will be considered and included if it is relevant to the decision problem (Section 1), fulfils the inclusion criteria (Section 2.1), and was submitted by 5 May 2026 at the latest. Any unpublished evidence should ideally be structured and presented in the form of a research publication and has to be accompanied by sufficient details to enable judgement on whether it meets the required standards and to determine potential sources of bias. Where published evidence is available, it will be prioritised over unpublished evidence. For more details, refer to Section 4.

2.4 Data extraction strategy

Data from the included studies will be extracted by one independent reviewer using a customised Microsoft Excel spreadsheet. A second reviewer will check the data extraction sheet. Any disagreements between the first and second reviewer will be settled either by consensus with a third reviewer or discussion. The extracted data will include the following information (if known, applicable, and relevant):

- Bibliographic information (e.g., authors, year, title)
- Study design
- Population (size, source, relevant subgroup)
- Study setting (e.g., country, hospital department)
- Intervention
- Comparator
- Length of follow-up (including loss to follow-up)
- Outcomes relevant to the decision problem, including their time points and their key results (e.g., effect sizes and confidence intervals or p-values, descriptive statistics, number needed to treat)
- Inadequately reported or missing data, or data that has been imputed (including method of imputation)

- Quality of evidence based on the critical appraisal
- Funding details
- Additional comments (such as study limitations not identifiable from the other data in the table, evidence gaps)

Any additional outcomes reported in the included evidence and relevant to the decision problem will be extracted.

The PICO Portal AI may be used to support data extraction, where the AI highlights potentially relevant text passages containing the data to be extracted, but the task will ultimately be performed and completed by human researchers.

2.5 Quality assessment strategy

The methodological quality of included studies will be appraised using appropriate checklists depending on study design. The checklists used for each study design are provided in Table 3, in accordance with NICE's health technology evaluations manual and Appendix H: Appraisal checklists, evidence tables, GRADE and economic profiles of Developing NICE guidelines: the manual. Where sufficient information is available for unpublished studies, the same checklists will be used for quality appraisal as for published studies. The certainty of findings for key outcomes will be assessed using GRADE (Guyatt et al. 2008).

Quality appraisal will be performed by one reviewer and confirmed by a second reviewer. Disagreements between the two reviewers will be resolved through discussion or by a third reviewer.

The report will summarize the overall quality of the evidence, describe potential sources of bias and confounding, and how these impact the certainty of the results.

Table 3. Checklists used for quality appraisal of included study types

Study type	Checklist for quality appraisal
Systematic reviews	ROBIS (Whiting et al. 2016)
Randomised controlled trials	Cochrane risk of bias (RoB) 2 tool (Sterne et al. 2019)

Study type	Checklist for quality appraisal
Non-randomised comparative studies	EPOC RoB Tool (Cochrane Effective Practice and Organisation of Care (EPOC) 2017)
Non-comparative studies	QuEENS (Quality of Effectiveness Estimates from Non-randomised Studies) – NICE Decision Support Unit Technical Support Document 17
Real-world evidence	NICE real-world evidence framework – Reporting on methods used to minimise risk of bias
Diagnostic accuracy studies	QUADAS-2 (Whiting et al. 2011)
Prediction model for a prognosis or diagnosis	PROBAST (Wolff et al. 2019)
Economic evaluation	Health technology assessment checklist for decision-analytic models (Philips et al. 2004)

2.6 Methods of synthesis and analysis

If sufficient data are available that are suitable for pooling, pair-wise meta-analysis of clinical effectiveness data will be considered. This synthesis is only possible if a sufficiently large number of studies report comparable evidence, regarding the comparator, included population, and outcome definition and reporting. If a meta-analysis is possible, heterogeneity due to differences in population characteristics or other known factors may be explored using subgroup analyses. Sensitivity analyses may be used to explore the impact of studies whose relevance to the scope is not clear.

Clinical effectiveness data where meta-analysis is not considered appropriate and cost-effectiveness data will be presented in tables and a structured narrative synthesis. The structure of the narrative synthesis will be based on potential sources of heterogeneity; these may include differences in populations, outcome types and definitions, or comparators.

Gaps in the evidence or evidence with limited certainty will be highlighted. If more than one source reports relevant data for the health-economic analysis, the EAG will consider criteria such as setting or pooled estimates to prioritise the most relevant input for the health-economic model.

3. Economic analysis methods

A cost-utility analysis will be undertaken from the NHS and Personal Social Services (PSS) perspective for adults undergoing CTCA for suspected CAD. The analysis will be performed as a decision-analytic model to compare the use of CaRi-Heart in addition to standard of care versus standard of care alone. Standard care comprises routine CTCA reporting and clinical assessment, alongside cardiovascular risk assessment using conventional risk factors. The model will capture prognostic classification, changes in treatment informed by the CaRi-Heart report, and long-term risks of CAD events. Development and reporting will be done according to the Good Practice Guidelines for Health-Economic Modelling and Reporting (Caro et al. 2012). The model will be developed *de novo* but may be adapted from previously published model structures, if an appropriate one is identified.

3.1 Model development

The model will be developed in Microsoft Excel, consisting of a short-term decision tree leading into a long-term state-transition model (Markov or microsimulation, depending on the granularity and available evidence). Given the chronic and progressive nature of CAD, a lifetime time horizon will be adopted, as relevant outcomes are expected to accrue over a person's lifetime. Costs will be expressed in 2025 prices and inflated using the NHS Cost Inflation Index (NHSCII) reported in the latest available Unit Costs of Health and Social Care Manual when needed. Benefits will be expressed using quality-adjusted life years (QALYs). Utilities and disutilities will be combined using a multiplicative approach. Costs and outcomes will be discounted at 3.5% per year, in line with the NICE reference case.

A decision tree will be used to model the short-term clinical prognostic pathway based on the CAD status determined by CTCA. In the intervention arm, the CaRi-Heart risk may be used to inform treatment decisions such as lifestyle and risk factor modification, initiation or intensification of statin therapy, initiation of other drugs, or no change to the initial therapy. The leaves of the decision tree will dictate where the cohorts/individuals enter the risk-stratified long-term state-transition model.

This state-transition model will simulate long-term CAD progression separately for each risk category. In each cycle, the model will update outcomes by moving

cohorts/individuals between defined health states depending on transition probabilities. Among others, these health states will include key clinical outcomes such as myocardial infarction, ischaemic stroke, heart failure, cardiac death, and background mortality. Depending on available evidence, the decision will be made whether the transition probabilities will remain constant over the time horizon or be adjusted according to the health state of the underlying cohorts/individuals (semi-Markov model).

3.1.1 Results and analyses

Results will be presented as incremental costs and incremental quality-adjusted life expectancy, measured in QALYs. The results will be summarised as the incremental cost-effectiveness ratio (ICER): the incremental cost per QALY gained, as well as net monetary benefit (NMB). Deterministic sensitivity analysis (DSA) and probabilistic sensitivity analysis (PSA) will be undertaken. DSA will vary key parameters such as CaRi-Heart test cost and risk-group distributions. PSA will use 1,000–10,000 Monte Carlo iterations to generate a cost-effectiveness plane and cost-effectiveness acceptability curve (CEAC). Subgroup analysis will be explored where evidence allows.

3.1.2 Inputs

Model inputs, including baseline event risks, risk stratification distributions, transition probabilities, utilities, and costs will primarily be sourced from the evidence review described in this protocol, if sufficient evidence is available. Where necessary, additional sources of information such as pragmatic and targeted searches as well as expert input will supplement evidence gaps once preliminary model construction begins.

Model inputs will be preferentially taken from English and Welsh sources. Where these are not available, the data will be taken from wider UK sources, followed by European sources. Costs will be sourced from National Cost Collection Index (NCCI, the successor of NHS Reference Costs), Personal Social Services Research Unit (PSSRU) unit costs (Jones et al. 2025), the British National Formulary (BNF), published literature, and manufacturer (if needed and verifiable).

3.1.3 Technical validation

The model will undergo technical validation (formula checking, replication), internal validity testing (extreme values, transitions), external validity testing (comparison with event rates from published literature and databases), and clinical expert review. All modelling assumptions will be disclosed, and all limitations will be assessed in the report. Transparent reporting will be ensured through use of the Consolidated Health-Economic Evaluation Reporting Standards (CHEERS) checklist (Husereau et al. 2022).

4. Handling information from the companies and other stakeholders

All data submitted by the companies in evidence and information requests by NICE, or data submitted by other stakeholders will be considered by the EAG if received by 5 May 2026. Information arriving after this date will not be considered. If the data included in the information provided meets the inclusion criteria for the review, they will be extracted and quality assessed following the procedures outlined in this protocol. The EAG may seek clarification or additional information from companies and other stakeholders where necessary. All correspondence between the EAG and companies will happen through NICE.

Any 'commercial in confidence' data provided by a company and specified as such will be highlighted in blue and underlined in the assessment report. Any 'academic in confidence' data provided by a company, and specified as such, will be highlighted in yellow and underlined in the assessment report. If confidential information is included in the economic model, the EAG will provide a copy of the model with 'dummy variable values' for the confidential values (using non-confidential values) and ensure that back-calculation of the confidential values is not possible.

5. Additional information sources

The EAG will engage with clinical experts appointed by NICE in accordance with NICE's appointments to advisory bodies policy and procedure to provide clarification and guidance on interpreting and prioritising evidence, clarify issues related to model design and execution, including clinical pathways, model structure, model inputs,

and underlying assumptions. These experts will also provide feedback on the validity and suitability of the conceptual economic model.

6. Competing interests of authors

The authors declare no competing interests.

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Appendix A: Draft search strategy

The following search strategy (Table 4) is for illustrative purposes only and will be amended in line with input from clinical experts and the agreed scope.

Database: MEDLINE

Host: PubMed

Date of preliminary search: 26 February 2026

Table 4. Exemplary draft search strings for MEDLINE (PubMed)

#	Search string	Hits	Contextual detail
1	"CaRi Heart"[tiab:~3] OR CaRi-Heart*[tw] OR CaRiHeart*[tw] OR "CaRi Heart*"[tw] OR Caristo*[tw]	14	Search for brand names and manufacturers of the included technology
2	"coronary computed tomography angiography"[tw] OR CCTA[tw] OR "computed tomography coronary angiography"[tw] OR CTCA[tw] OR "coronary artery disease"[tw] OR "coronary artery disease"[majr] OR "chest pain"[tw] OR "chest pain"[majr]	207,995	Search for population (people undergoing CTCA for the investigation of stable chest pain/angina and/or suspected CAD)
3	"artificial intelligence"[tw] OR algorithm[tw] OR "risk prediction"[tw] OR prognostic[tw] OR prognosis[tw] OR prognostication[tw] OR "risk discrimination"[tw] OR "risk factor*"[tw] OR predict*[tw] OR cloud-based[tw] OR "medical device"[tw] OR measure[tw] OR mapping[tw] OR detect*[tw] OR quantif*[tw]	8,953,102	Search for generic descriptors of the included technology
4	"perivascular adipose tissue"[tw] OR PVAT[tw] OR "perivascular fat attenuation"[tw] OR "fat attenuation index"[tw] OR FAI[tw] OR FAI-score[tw] OR "FAI score"[tw] OR "perivascular fat composition"[tw] OR "perivascular fat imaging"[tw] OR "perivascular fat"[tw]	5,650	Search for generic terms of the parameters measured by the included technology
5	#2 AND #3 AND #4	289	Combining target population, generic technology descriptors, and measured parameters for the included technology
6	#1 OR #5	294	Relevant studies
7	English[la]	35,261,214	English language publications

#	Search string	Hits	Contextual detail
8	#6 AND #7	283	Relevant studies in English