



Application for Certificate of Public Need
to Establish Coronary Artery Calcium Scoring Services
(Manassas)

COPN Request No. VA-8813

Carient Heart & Vascular, LLC

Establishment of Coronary Artery Calcium Score Services in Planning District 8

PROJECT NARRATIVE

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OVERVIEW OF THE PROJECT

We are seeking approval to establish a Coronary Artery Calcium (CAC) Scoring service within our facility. CAC scoring is a non-invasive, low-dose CT scan that detects and quantifies calcified plaque in the coronary arteries. This diagnostic tool is instrumental in assessing the risk of coronary artery disease (CAD), facilitating early intervention, precise risk stratification, and enhanced patient outcomes.

PROJECT JUSTIFICATION

Heart disease continues to be the leading cause of death in the United States, with CAD as a major contributor. Traditional risk assessment models, such as cholesterol levels and blood pressure measurements, often do not fully capture an individual's cardiovascular risk. CAC scoring provides direct, quantifiable evidence of coronary atherosclerosis, enabling physicians to tailor preventive and therapeutic strategies more effectively.

According to major global guidelines, CAC scoring is particularly recommended for asymptomatic individuals aged over 40 who are at intermediate risk, as it can significantly influence management decisions. For instance, a CAC score of zero may lead to downgrading risk and withholding statin therapy, while a score above 100 suggests the initiation of statins.

By integrating CAC scoring into our practice, we aim to improve accessibility, reduce healthcare disparities, and ensure that high-risk patients receive timely evaluations.

SCOPE OF SERVICES

The proposed project will establish a dedicated CAC Scoring service within our imaging department. The service will:

- Utilize a low-dose CT scanner optimized for coronary calcium assessment.
- Be operated by certified technologists, with images interpreted by trained cardiologists.
- Be available to our patients for risk assessment and early detection of CAD.
- Provide rapid interpretation and reporting to referring providers, ensuring timely clinical decision-making.

EQUIPMENT AND FACILITY REQUIREMENTS

We plan to utilize the CT component of our existing PET-CT scanner to perform CAC scoring, thereby leveraging current equipment without the need for additional resources. Dedicated scheduling slots will be allocated to reduce wait times and enhance patient convenience.

The implementation of CAC scoring requires minimal staff training and workflow integration. The long-term benefits, including early detection of CAD, can lead to significant reductions in hospital admissions, emergency interventions, and long-term treatment expenses.

The demand for CAC scoring has been increasing due to growing awareness of its benefits among physicians and patients. Many individuals seeking proactive cardiac screening would benefit from a local, convenient option.

ALIGNMENT WITH COMMUNITY NEEDS AND COPN CRITERIA

This project aligns with value-based care initiatives, emphasizing prevention rather than reactive treatment. While not universally covered by insurance, CAC scoring is cost-effective, particularly in patients at intermediate risk, where the results can guide more personalized treatment decisions and reduce the need for more expensive interventions down the line. It is an out-of-pocket service for patients with a modest fixed fee.

The establishment of a CAC Scoring service aligns with public health priorities by:

- Addressing an unmet need for accessible, non-invasive cardiac risk assessment.
- Reducing cardiovascular morbidity and mortality through early detection and preventive care.
- Enhancing the continuum of care within our cardiology network by offering a seamless diagnostic pathway for patients at risk of CAD.

CONCLUSION

In summary, our proposed CAC Scoring service will fill a critical gap in preventive cardiology, providing accessible, cost-effective, and potentially life-saving diagnostic capabilities to our community. This initiative will enhance early detection efforts, support evidence-based cardiovascular risk management, and ultimately reduce the burden of CAD on both patients and the healthcare system. We respectfully request approval to proceed with this project under the Certificate of Public Need (COPN) framework to better serve our patient population.

Golub, I, Termeie, O, Kristo, S. et al. Major Global Coronary Artery Calcium Guidelines. J Am Coll Cardiol Img. 2023 Jan, 16 (1) 98–117.

<https://doi.org/10.1016/j.jcmg.2022.06.018>

SECTION I FACILITY ORGANIZATION AND IDENTIFICATION

A. Carient Heart & Vascular, LLC

Official Name of Facility

8100 Ashton Avenue, Suite 200

Address

Manassas

VA

20109

City

State

Zip

571-581-1771

Telephone

B. Carient Heart & Vascular, LLC

Legal Name of Applicant

8100 Ashton Avenue, Suite 200

Address

Manassas

VA

20109

City

State

Zip

C. Chief Administrative Officer

Merdod Ghafouri, DO

Name

8100 Ashton Avenue, Suite 200

Address

Manassas

VA

20109

City

State

Zip

571-581-1771

Telephone

D. Person(s) to whom questions regarding application should be directed:

Lauri Garrett

Name

8100 Ashton Avenue, Suite 200

Address

Manassas

VA

20109

City

State

Zip

571-217-7103

Telephone

N/A

Facsimile

lgarrett@carient.com

E-Mail

E. Type of Control and Ownership (Complete appropriate section for both owner and operator.)

Will the facility be operated by the owner? Yes X No

Owner of the Facility
(Check one)

Proprietary

Operator of Facility
(Check one)

(1)

(1) Individual

(1)

(2) X

(2) Partnership-attach copy of Partnership Agreement and receipt showing that agreement has been recorded

(2) X

See Attachments 1.E.1- Articles of Conversion

(3)

(3) Corporate-attach copy of Articles of Incorporation and Certificate of Incorporation

(3)

(4)

(4) Other Identify

(4)

Non-Profit

(5)

(5) Corporation-attach copy of Articles of Incorporation and Certificate of Incorporation

(5)

(6)

(6) Other Identify

(6)

Governmental

(7)

(6) State

(7)

(8)

(8) County

(8)

(9)

(9) City

(9)

(10)

(10) City/County

(10)

(11)

(11) Hospital Authority or Commission

(11)

(12)

(12) Other Identify

(12)

F. Ownership of the Site (Check one and attach copy of document)

- (1) _____ Fee simple title held by the applicant
- (2) _____ Option to purchase held by the applicant
- (3) _____ leasehold interest for not less than _____ years
- (4) X Renewable lease, renewable every 10 years-attach lease
- (5) _____ Other _____ Identify

See Attachment I.F - Copy of Renewable Lease

G. Attach a list of names and addresses of all owners or persons having a financial interest of five percent (5%) or more in the medical care facility.

(a) In the case of proprietary corporation also attach:

Not Applicable

- (1) A list of the names and addresses of the board of directors of the corporation.
- (2) A list of the officers of the corporation.
- (3) The name and address of the registered agent for the corporation.

(b) In the case of a non-profit corporation also attach:

Not applicable.

- (1) A list of the names and addresses of the board of directors of the corporation
- (2) A list of the officers of the corporation
- (3) The name and address of the registered agent for the corporation

(c) In the case of a partnership also attach:

See Attachment I.G.C Carient Heart & Vascular Sole Member Consent

- (1) A list of the names and addresses of all partners.

US Health Virginia, LLC (Sole Member/Manager)
2000 Tower Oaks Blvd
Suite 480
Rockville, MD 20852

- (2) The name and address of the general or managing partner.

US Health Virginia, LLC (Sole Member/Manager)
2000 Tower Oaks Blvd
Suite 480
Rockville, MD 20852

- (d) In the case of other types of ownership, also attach such documents as will clearly identify the owner.

Not applicable.

- H. List all subsidiaries wholly or partially owned by the applicant.

Not applicable.

- I. List all organizations of which the applicant is wholly or partially owned subsidiary.

Carient Heart & Vascular, LLC is wholly owned by US Health Virginia, LLC

- J. If the operator is other than the owner, attach a list of the names(s) and addresses of the operator(s) of the medical care facility project. In the case of a corporate operator, specify the name and address of the Registered Agent. In the case of the partnership operator, specify the name and address of the general or managing partner.

Not applicable.

- K. If the operator is other than the owner, attach an executed copy of the contract or agreement between the owner and the operator of the medical care facility.

Not applicable.

ARCHITECTURE AND DESIGN

1. Size of site:

Carient Heart & Vascular's long-range plan is to provide the most innovative cardiovascular care in Northern Virginia and set the industry standard for quality of care, clinical outcomes, and patient experience.

Carient's expert team offers comprehensive cardiac and vascular care. As an industry leader, Carient attracts the best-qualified medical and support staff to achieve clinical outcomes and patient satisfaction above industry benchmarks.

Carient provides patients with access to a wide variety of innovative procedures and technology that, until now, only hospitals could offer. Providing patients with access to these procedures and tests in the office setting significantly reduces wait times, procedure times, and costs to patients. The addition of Coronary Artery Calcium Scoring directly aligns with Carient's long-range plan, as it will provide patients in the region with access to a non-invasive and highly reliable method for assessing cardiovascular risk.

Its value lies in identifying subclinical atherosclerosis that traditional risk assessments may overlook, allowing for early intervention and personalized care. By guiding more accurate risk stratification, CAC Scoring supports both improved patient outcomes and cost-effective care by preventing over- or under-treatment.

- (2) Briefly describe the proposed project with respect to location, style and major design features, and the relationship of the current proposal to the long range plan.

Carient would utilize the CT portion of their current PET-CT camera to perform Coronary Artery Calcium Scoring. This is a specific and focused screening, leveraging existing equipment, without the need for new resources. Currently the CT is being used in conjunction with the PET, and to perform CACS, the CT would be utilized alone for this very narrow purpose.

The camera is located at 8100 Ashton Avenue, Ste 200, Manassas, VA 20109 (COPN VA-04642), and no additional construction is needed.

The current technologists will be credentialed as radiologic technologists, limited, which allows the technologists to perform radiologic procedures on patients limited to the chest for review by the physician.

CAC scoring is performed using non-invasive CT scans without the need for contrast agents, making it a safe and accessible method for routine risk assessment. The cost of CAC screening is relatively low compared to the potential costs associated with treating heart attacks or other major cardiovascular events. While not universally covered by insurance, CAC scoring is cost-effective, particularly in patients at intermediate risk, where the results can guide more personalized treatment decisions and reduce the need for more expensive interventions down the line.

- (3) Describe the relationship of the facility to public transportation and highway access.

Patients are able to easily access Carient at 8100 Ashton Avenue, Ste. 200 from VA Rt. 234 (also known as Sudley Road). The facility is conveniently located less than 2 miles from Exit 47 on Interstate 66W.

There is an abundance of parking on site for patients, with numerous handicapped spaces located nearest to the building.

Access to Carient's Cardiac PET-CT services can be easily gained via public transportation on OmniRide taking the Manassas Local North route. This route runs Monday through Friday, consistent with Carient's office hours. For a visual representation of the ease of access of this facility, please see Attachment II.C.3- Visual Representation of the Ease of Access of the Facility.

- (4) Relate the size, shape, contour and location of the site to such problems as future expansion, parking, zoning and the provision of water, sewer and solid waste services.

There are no anticipated problems pertaining to future expansion, parking, zoning and the provision of water, sewer and solid waste services.

The Cardiac PET-CT scanner is located in an existing 2 story, 54,000 square foot medical office building. The building is zoned as B-1 zoned general commercial office. The building has 4,000 square feet of parking space.

Water (Prince William County Service Authority), sewer and solid waste (American Disposal) services are all currently supplied by Prince William County, and the project will not increase demand on these services.

- (5) If this proposal is to replace an existing facility, specify what use will be made of the existing facility after the new facility is completed.

Not applicable.

- (6) Describe any design features which will make the proposed project more efficient in terms of construction costs, operating costs, or energy conservation.

The CT portion of the current PET-CT camera would be utilized to perform Coronary Artery Calcium Scoring without the need for new resources.

- D. Describe and document in detail how the facility will be provided with water, sewer and solid waste services. Also describe power source to be used for heating and cooling purposes. Documentation should include, but is not limited to:

- (1) Letters from appropriate governmental agencies verifying the availability and adequacy of utilities,
- (2) National Pollution Discharge Elimination System permits,
- (3) Septic tank permits, or
- (4) Receipts for water and sewer connection and sewer connection fees.

Not applicable due to prior existence. The current PET-CT scanner is located within a 54,000 square foot medical office building. This building is already serviced by all necessary utilities, including water, power, and gas.

E. Space tabulation – (show in tabular form)

1. If Item #1 was checked in II-B, specify:

- a. The total number of square feet (both gross and net) in the proposed facility.
- b. The total number of square feet (both gross and net) by department and each type of patient room (the sum of the square footage in this part should equal the sum of the square footage in (a) above and should be consistent with any preliminary drawings, if available).

Not applicable as the current site will not be modified.

2. If Item #2 was checked in II-B, specify:

- a. The total number of square feet (both gross and net) by department and each type of patient room in the existing facility.
- b. The total number of square feet (both gross and net) to be added to the facility.
- c. The total number square feet (both gross and net) to be remodeled, modernized, or converted to another use.
- d. The total number of square feet (both gross and net) by department and each type of patient room in the facility upon completion. (The sum of square footage in this part should equal the sum of the square footages in parts (a) and (b) above and should be consistent with any preliminary drawings, if available. (The department breakdown should be the same as in (a) above.)

Not applicable.

3. Specify design criteria used or rationale for determining the size of the total facility and each department within the facility.

The rationale for designing the space as it is currently utilized was based on the requirements of the scanner, the guidelines provided by the manufacturer, and compliance with applicable codes. The space allocated for the camera and control room is approximately 400 sq. ft.

F. Attach a plot plan of the site which includes at least the following:

- 1. The courses and distances of the property line.
- 2. Dimensions and location of any buildings, structures, roads, parking areas, walkways, easements, right-of-way or encroachments on the site.

See Attachment II.F – General Plot Plan of Site

- G. Attach a preliminary design drawing drawn to a scale of not less than 1/16"-1'0" showing the functional layout of the proposed project which indicates at least the following:

Not applicable as no modifications will be made to the current site.

1. The layout of each typical functional unit.
2. The spatial relationship of separate functional components to each other.
3. Circulatory spaces (halls, stairwells, elevators, etc.) and mechanical spaces.

- H. Construction Time Estimates

Not applicable as no modifications will be made to the current site.

1. Date of Drawings: Preliminary _____ Final _____
2. Date of Construction: Begin _____ Completion _____
3. Target Date of Opening: _____

SECTION III

SERVICE DATA

- A. In brief narrative form describe the kind of services now provided and and/or the kind of services to be available after completion of the proposed construction or equipment installation.

Our facility currently provides Cardiac PET CT imaging, which combines positron emission tomography (PET) and computed tomography (CT) to assess myocardial perfusion and viability. Under our current COPN, the CT component is used in conjunction with PET imaging for cardiac assessments.

With the proposed addition of Coronary Artery Calcium (CAC) Scoring, we seek to utilize the CT component of our existing PET-CT system independently for cardiovascular risk assessment. CAC Scoring is a non-invasive, highly reliable method for detecting and quantifying coronary artery calcification, a key marker of subclinical atherosclerosis. Unlike traditional risk assessments that rely on factors such as cholesterol levels and blood pressure, CAC Scoring provides direct visualization of arterial plaque, allowing for more precise risk stratification, early intervention, and improved patient management.

This expansion will not require new construction or additional equipment purchases, as we will leverage our current PET-CT system to perform CAC Scoring. Additionally, CAC Scoring does not impose financial burdens on state insurance programs, as it is an out-of-pocket service for patients, with a modest, fixed fee that enhances accessibility while supporting proactive cardiovascular care.

By incorporating CAC Scoring, we aim to provide a cost-effective, evidence-based tool for early cardiovascular disease detection, ultimately improving patient outcomes while maintaining efficient use of existing healthcare resources.

- B. Describe measures used or steps taken to assure continuity of care.

The qualified physicians who interpret the studies will be able to communicate results electronically or by phone for referring physicians which would be especially useful in critical cases.

A copy of the medical record will be provided to the referring physician along with other providers as needed. Carient will provide copies of final reports and medical records to providers as necessary for appropriate follow-up and continuity of care as permitted by applicable health records and privacy laws. Carient Heart & Vascular has a policy of dictating and sending all referring physicians a copy of the nuclear report within 48 hours of the patient's testing.

- C. What procedures are utilized in quality care assessment?

Carient has implemented a comprehensive quality care assessment process to ensure excellence in patient care. Our imaging modalities are accredited by the Intersocietal Accreditation Commission (IAC), which sets rigorous standards for facilities performing nuclear cardiology, nuclear medicine, and PET imaging. IAC accreditation serves as an industry benchmark, demonstrating our commitment to maintaining high-quality patient care. Our Cardiac PET program is included in this

accreditation, and we consistently perform ongoing quality assurance to uphold IAC standards and maintain our accreditation status.

In addition to accreditation, Carient has established robust policies and procedures for quality control testing, ensuring adherence to appropriate use criteria. With over 10,000 Cardiac PET imaging procedures performed, we continue to provide individualized, compassionate care to every patient. Our nuclear technologists hold NMTCB certifications, reinforcing our commitment to clinical excellence.

Over the past five years, Carient has built a strong track record of delivering high-quality imaging at a lower cost while maintaining an outstanding patient experience. Our experience with Cardiac PET has resulted in significantly improved diagnostic accuracy for coronary artery disease compared to SPECT imaging, further supporting our dedication to high-quality, patient-centered care.

- D. Describe the plan for obtaining additional medical, nursing and paramedical personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.

Carient plans to utilize existing personnel and does not anticipate the need to hire additional staff for the proposed Coronary Artery Calcium Scoring tests.

- E. Facilities and Services to be Provided (Check)

	<u>Existing</u>	<u>This Project To be Added</u>	<u>This Project to be Discontinued</u>
1. Outpatient Surgery	_____	_____	_____
2. Post Operative Recovery Room	_____	_____	_____
3. Pharmacy with full-time pharmacists part-time pharmacists	_____ _____	_____ _____	_____ _____
4. Diagnostic Radio- logical Services x-ray radioisotope CT scanning	_____ X _____	_____ X _____	_____ _____ _____
5. Therapeutic Radio- logical Services Specify Source(s) or Type(s) or Equipment Used	_____ _____	_____ _____	_____ _____
6. Clinical Pathology Laboratory	_____	_____	_____

7.	Blood Bank	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.	Electroencephalo- graphy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9.	Electrocardiography	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10.	Ultrasonography	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11.	Respiratory Therapy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12.	Renal Dialysis chronic outpatient home dialysis training	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
13.	Alcoholism Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14.	Drug Addiction Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
15.	Physical Therapy Department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
16.	Occupational Therapy Department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17.	Medical Rehabilitation outpatient	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18.	Psychiatric Service outpatient emergency service	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
19.	Clinical Psychology	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20.	Outpatient Emergency Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21.	Social Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22.	Family Planning Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23.	Genetic Counseling Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24.	Abortion Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25.	Pediatric Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26.	Obstetric Service	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

- | | | | | |
|-----|------------------------------|---------------------|-------|-------|
| 27. | Gynecological Service | _____ | _____ | _____ |
| 28. | Home Care Service | _____ | _____ | _____ |
| 29. | Speech Pathology Service | _____ | _____ | _____ |
| 30. | Audiology Service | _____ | _____ | _____ |
| 31. | Paramedical Training Program | _____ | _____ | _____ |
| 32. | Dental Service | _____ | _____ | _____ |
| 33. | Podiatric Service | _____ | _____ | _____ |
| 34. | Pre-Admission Testing | _____ | _____ | _____ |
| 35. | Pre-Discharge Planning | _____ | _____ | _____ |
| 36. | Multiphasic Screening | _____ | _____ | _____ |
| 37. | Other (Identify) | | | |
| | Office Based Lab | <u> X </u> | _____ | _____ |

F. Program

1. Is (will) this outpatient facility (be) a department, unit or satellite of a hospital?
 _____ Yes (Give name of hospital) _____
 X No

2. Is this outpatient facility affiliated with or does it have a transfer agreement with a hospital?
 _____ Yes (Give name of hospital) _____
 X No (**Not applicable**)

3. Is (will) there (be) an arrangement whereby medical records can readily be transferred between this outpatient facility and an inpatient facility (ies)?

 X Yes (give name of facility)

We send medical record requests electronically via fax through our EMR to all of the local hospital systems – UVA Health Prince William Medical Center, UVA Health Haymarket Medical Center, Inova Health System, Sentara Northern Virginia Medical Center, Reston Hospital Center, Fauquier Health

 No

4. Outpatient services are (will be) available from 7:00 a.m. to 5:00 p.m. 6 days of week.

5. Does (will) the facility operate scheduled clinics?

 X Yes (Attach clinic schedule list)

Carient has a daily schedule for Cardiac PET-CT patients, generally in accordance with the below chart. If Coronary Artery Calcium Scoring is added, they would be added at the end of the day as shown below.

MANASSAS					
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
1st PET-CT Patient 6:40 AM	1st PET-CT Patient 6:40 AM	1st PET-CT Patient 6:40 AM	1st PET-CT Patient 6:40 AM	1st PET-CT Patient 6:40 AM	1st PET-CT Patient 6:40 AM
Appointments every 40 minutes	Appointments every 40 minutes	Appointments every 40 minutes	Appointments every 40 minutes	Appointments every 40 minutes	Appointments every 40 minutes
Last PET-CT Patient 4:00 PM	Last PET-CT Patient 4:00 PM	Last PET-CT Patient 4:00 PM	Last PET-CT Patient 4:00 PM	Last PET-CT Patient 4:00 PM	Last PET-CT Patient 4:00 PM
CACS 4:30, 4:15, 5:00	CACS 4:30, 4:15, 5:00	CACS 4:30, 4:15, 5:00	CACS 4:30, 4:15, 5:00	CACS 4:30, 4:15, 5:00	CACS 2:45, 3:00, 3:15

VIENNA				
Monday	Tuesday	Wednesday	Thursday	Friday
1st PET-CT Patient 6:40 AM		1st PET-CT Patient 6:40 AM		1st PET-CT Patient 6:40 AM
Appointments every 45 minutes		Appointments every 45 minutes		Appointments every 45 minutes
Last PET-CT Patient 4:00 PM		Last PET-CT Patient 4:00 PM		Last PET-CT Patient 4:00 PM
CACS 4:30, 4:15, 5:00		CACS 4:30, 4:15, 5:00		CACS 4:30, 4:15, 5:00

 No

6. Are there other organized outpatient services in your primary service area?

 X Yes No

7. The outpatient facility is (will be) staffed:
- (a) Only by physicians on call: _____ Yes _____ No
- (b) By full time physicians: _____ **X** Yes _____ No
- (c) By physicians who limit their practice to this outpatient service? _____ Yes _____ No
8. State specifically any limitations or restrictions for participation in the services of the facility.

Carient foresees no restrictions for participation in the service, unless the patient does not exhibit the clinical indication supporting the medical necessity for the testing.

Clinical limitations include patient body habitus, inability to fit in the camera gantry. Patients who do not meet appropriate use criteria will have limitations in participating in the services.

See Attachment III.F - Clinical Indication and Appropriate Use Criteria

- G. Please provide historical and/or project utilization statistics for the facility including number of patients, number of patient visits and number of patient services.

SERVICE VOLUME	2023	2024
New Patient	10,757	11,745
Office Visit, Tele & VV	52,041	58,550
SPECT	1,248	1,329
PET-CT	4,302	4,549
Echo/S.Echo	13,629	14,780
ETT	1,074	1,585
Vascular	8,786	8,759

- H. Staffing of Existing and/or Proposed Facility

In the following categories, indicate the number of full time equivalent personnel (at least 35 hours per week).

Carient has 194 staff members across the practice. This includes twenty (20) medical doctors, fifteen (15) advanced practice providers, four (4) registered nurses, sixty-one (61) clinical staff (licensed practical nurses, medical assistants, Cardiac Device Technicians, Telemetry Technicians, Clinical Research Coordinators, Phlebotomist, Scribes, Clinical Techs, Cath Lab Techs), seventeen (17) echo/vascular technologists, five (5) full-time radiologic technologists and several administrative staff.

Carient's Manassas office has Forty-Nine (49) staff members. This includes seven (7) providers (physicians and nurse practitioners), two (2) scribes, eleven (11) nursing staff, two (2) echo technologists, two (2) Vascular Sonographers, three (3) radiologic technologists (NUC), two (2) stress technologists, one (1) Phlebotomist, six (6) clinical research, three (3) schedulers, two (2) authorization specialists, one (1) Medical Records specialist, two (2) administration, and five (5) front desk/receptionists. As reflected in table below, no additional staff are needed to staff Carient's proposed project.

Carient's Vienna office has thirteen (13) staff members. This includes three (3) providers (physicians and nurse practitioners), one (1) scribe, three (3) nursing staff, one (1) echo technologist, one (1) radiologic technologist (NUC), one (1) stress technologist, one (1) Vascular Sonographer and two (2) front desk/receptionists. As reflected in table below, no additional staff are needed to staff Carient's proposed project.

	<u>Current</u>	<u>Additional</u>	<u>Needed</u>
	<u>Full Time</u>	<u>Vacant Positions</u>	<u>Full Time</u>
			<u>TOTAL</u>
Total number of Full-time staff	<u>49</u>	<u> </u>	<u> </u>
Administration-Business Office	<u>2</u>	<u> </u>	<u> </u>
Registered Nurses	<u> </u>	<u> </u>	<u> </u>
Licensed Practical Nurses, Nurses Aides, Orderlies/Attendants	<u>11</u>	<u> </u>	<u> </u>
Registered Medical Records Librarian	<u>1</u>	<u> </u>	<u> </u>
Registered Pharmacists	<u> </u>	<u> </u>	<u> </u>
Laboratory Medical Technologists	<u> </u>	<u> </u>	<u> </u>
ADA Dieticians	<u> </u>	<u> </u>	<u> </u>
Radiologic Technologists	<u> </u>	<u> </u>	<u> </u>
Occupational Therapists	<u> </u>	<u> </u>	<u> </u>
Physical Therapists	<u> </u>	<u> </u>	<u> </u>
Psychologists	<u> </u>	<u> </u>	<u> </u>
Psychiatric Social			

Workers	_____	_____	_____	_____
Recreational Therapists	_____	_____	_____	_____
Inhalation Therapists	_____	_____	_____	_____
Medical Social Workers	_____	_____	_____	_____
Other Health Professionals, Identify				
Scribes	<u>2</u>	_____	_____	_____
Front Desk/ Receptionists	<u>5</u>	_____	_____	_____
Authorization Specialists	<u>2</u>	_____	_____	_____
Schedulers	<u>3</u>	_____	_____	_____
Phlebotomist	<u>1</u>	_____	_____	_____
NP and PA	<u>3</u>	_____	_____	_____
Sonographers	<u>4</u>	_____	_____	_____
Nuclear/Stress Lab	<u>5</u>	_____	_____	_____
Research	<u>6</u>	_____	_____	_____

All Other Personnel (Exclude Physicians and Dentists)

- I. Present a plan for obtaining all additional personnel required to staff the project following completion and identify the sources from which such personnel are expected to be obtained.

No additional staff will be needed.

- J. Describe the anticipated impact that the project will have on the staffing of other facilities in the service area.

Carient anticipates no impact on staffing in other facilities since we will not need to hire any additional staff for this project.

- K. Attach the following information or documents:

1. Copy of most recent licensing report from State Agency (existing facilities, excluding public health centers).

See Attachment III.K.1 - RAM licensure

2. Current accreditation status and copy of latest accreditation report from Joint Commission on Accreditation of Hospitals (existing facilities excluding public health centers).

See Attachment III.K.2 - IAC Accreditation License

3. Roster of medical staff (existing facilities). Indicate their specialty, Board Certification, Board eligibility and staff privileges (active, associate, etc.).

See Attachment III.K.3 - Medical Staff Roster

4. Copies of letters of commitment or statement of intent from physicians indicating they will staff the proposed new facility or service upon completion (existing and proposed facilities).

See Attachment III.K.4 – Statement of Intent

SECTION IV PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED

A. Please provide a comprehensive narrative description of the proposed project.

OVERVIEW OF THE PROJECT

We are seeking approval to establish a Coronary Artery Calcium (CAC) Scoring service within our facility. CAC scoring is a non-invasive, low-dose CT scan that detects and quantifies calcified plaque in the coronary arteries. This diagnostic tool is instrumental in assessing the risk of coronary artery disease (CAD), facilitating early intervention, precise risk stratification, and enhanced patient outcomes.

PROJECT JUSTIFICATION

Heart disease continues to be the leading cause of death in the United States, with CAD as a major contributor. Traditional risk assessment models, such as cholesterol levels and blood pressure measurements, often do not fully capture an individual's cardiovascular risk. CAC scoring provides direct, quantifiable evidence of coronary atherosclerosis, enabling physicians to tailor preventive and therapeutic strategies more effectively.

According to major global guidelines, CAC scoring is particularly recommended for asymptomatic individuals aged over 40 who are at intermediate risk, as it can significantly influence management decisions. For instance, a CAC score of zero may lead to downgrading risk and withholding statin therapy, while a score above 100 suggests the initiation of statins.

By integrating CAC scoring into our practice, we aim to improve accessibility, reduce healthcare disparities, and ensure that high-risk patients receive timely evaluations.

SCOPE OF SERVICES

The proposed project will establish a dedicated CAC Scoring service within our imaging department. The service will:

- Utilize a low-dose CT scanner optimized for coronary calcium assessment.
- Be operated by certified technologists, with images interpreted by trained cardiologists.
- Be available to our patients for risk assessment and early detection of CAD.
- Provide rapid interpretation and reporting to referring providers, ensuring timely clinical decision-making.

EQUIPMENT AND FACILITY REQUIREMENTS

We plan to utilize the CT component of our existing PET-CT scanner to perform CAC scoring, thereby leveraging current equipment without the need for additional resources. Dedicated scheduling slots will be allocated to reduce wait times and enhance patient convenience.

The implementation of CAC scoring requires minimal staff training and workflow integration. The long-term benefits, including early detection of CAD, can lead to significant reductions in hospital admissions, emergency interventions, and long-term treatment expenses.

The demand for CAC scoring has been increasing due to growing awareness of its benefits among physicians and patients. Many individuals seeking proactive cardiac screening would benefit from a local, convenient option.

ALIGNMENT WITH COMMUNITY NEEDS AND COPN CRITERIA

This project aligns with value-based care initiatives, emphasizing prevention rather than reactive treatment. While not universally covered by insurance, CAC scoring is cost-effective, particularly in patients at intermediate risk, where the results can guide more personalized treatment decisions and reduce the need for more expensive interventions down the line. It is an out-of-pocket service for patients with a modest fixed fee.

The establishment of a CAC Scoring service aligns with public health priorities by:

- Addressing an unmet need for accessible, non-invasive cardiac risk assessment.**
- Reducing cardiovascular morbidity and mortality through early detection and preventive care.**
- Enhancing the continuum of care within our cardiology network by offering a seamless diagnostic pathway for patients at risk of CAD.**

CONCLUSION

In summary, our proposed CAC Scoring service will fill a critical gap in preventive cardiology, providing accessible, cost-effective, and potentially life-saving diagnostic capabilities to our community. This initiative will enhance early detection efforts, support evidence-based cardiovascular risk management, and ultimately reduce the burden of CAD on both patients and the healthcare system. We respectfully request approval to proceed with this project under the Certificate of Public Need (COPN) framework to better serve our patient population.

Golub, I, Termeie, O, Kristo, S. et al. Major Global Coronary Artery Calcium Guidelines. J Am Coll Cardiol Img. 2023 Jan, 16 (1) 98–117.
<https://doi.org/10.1016/j.jcmg.2022.06.018>

B. Identification of Community Need

- 1. Describe the geographic boundaries of the facility's primary service area. (Note: Primary service area may be considered to be geographic area from which 75% of patients are expected to originate.)**

The primary service area for Carient is the Northern Virginia area. While the PET-CT cameras that would be utilized for the CACS are located in Manassas and Vienna, patients from our other locations would utilize this service. We have locations in Woodbridge, Annandale, Vienna, Reston, Manassas, Warrenton, Haymarket, and Stafford.

2. Provide patient origin, discharge diagnosis or utilization data appropriate for the type of project proposed.

ICD-10	Common ICD-10 Diagnosis Codes- Cardiac PET (78492) with Supporting Medical Necessity
I20.0	Unstable Angina
I21.01	ST elevation (STEMI) myocardial infarction involving Left Main of coronary artery
I25.10	Atherosclerotic heart disease of native artery without angina pectoris
I42.0	Cardiomyopathy
I48.21	Chronic Atrial Fibrillation
R06.02	Shortness of Breath
R07.9	Chest Pain, Unspecified
R55.0	Syncope
R94.31	Abnormal Electrocardiogram
Z01.810	Encounter for preprocedural cardiovascular examination

- C. 1. Is (are) the service(s) to be offered presently being offered by any other existing facility(ies) in the Health Planning Region?

Yes.

2. If Yes,

- a. Identify the facility(ies).

Because this service is not a covered service, access to records as to current utilization are not available.

- b. Discuss the extent to which the facility(ies) satisfy(ies) the current demand for the service(s).

Currently, we believe access to calcium scoring in the area is limited, requiring patients to travel to facilities with dedicated cardiac CT programs. The integration of this service into an existing PET/CT unit will increase accessibility, particularly for individuals who may not seek specialty cardiac care but could benefit from early detection. This is especially relevant for middle-aged men and women without overt symptoms but who may still be at risk due to genetic, lifestyle, or undiagnosed metabolic factors.

- c. Discuss the extent to which the facility(ies) will satisfy the demand for services in five years.

Calcium scoring using CT technology is a fast, efficient, and non-invasive screening test that takes approximately 5-10 minutes per scan. Given the efficiency of the procedure and the existing PET/CT infrastructure, we anticipate having sufficient capacity to meet demand in the near term.

In the next five years, demand for calcium scoring is expected to grow due to several factors:

- **Aging Population & Increased Awareness:** As more individuals in their 40s and 50s become aware of the benefits of preventive cardiovascular screening, demand for calcium scoring will naturally increase.
- **Expanded Clinical Guidelines:** Recent research and evolving guidelines from the American College of Cardiology and the American Heart Association continue to support calcium scoring as a valuable risk stratification tool, leading to broader adoption by physicians and increased patient referrals.
- **Primary Care & Employer Wellness Programs:** As more primary care physicians and workplace wellness initiatives integrate calcium scoring into routine cardiovascular risk assessments, there will likely be a sustained increase in screening requests.
- **Advances in Insurance & Cost-Effective Pricing:** As insurers increasingly recognize the cost-saving benefits of early detection, coverage for calcium scoring may expand, removing financial barriers and further driving demand.

Given these factors, we believe the facility will have adequate capacity to handle projected growth over the next five years. However, if demand significantly increases beyond projections, we are prepared to expand capacity by either optimizing scheduling, adding dedicated CT time slots, and investing in additional imaging equipment as necessary to meet this demand.

- D. Discuss how project will fill an unmet need in the delivery of health care in the service area including, where applicable, geographic barriers to access.

The proposed project will fill an unmet need by providing low-cost, early detection of coronary artery disease (CAD) through calcium scoring using CT technology. CAD is a leading cause of heart attacks and sudden cardiac events, often in individuals who may not present with traditional risk factors. Calcium scoring allows for the identification of atherosclerosis at an early stage, enabling lifestyle modifications and medical interventions that can prevent more severe cardiovascular conditions.

Currently, access to calcium scoring in the Manassas area is limited, requiring patients to travel to facilities with dedicated cardiac CT programs. The integration of this service into an existing PET/CT unit will increase accessibility, particularly for individuals who may not seek specialty cardiac care but could benefit from early detection. This is especially relevant for middle-aged men and women without overt symptoms but who may still be at risk due to genetic, lifestyle, or undiagnosed metabolic factors.

By making calcium scoring available within the existing healthcare infrastructure, this project will address a gap in preventive cardiology and ensure that at-risk patients receive timely, cost-effective screening without the need for unnecessary referrals to higher-cost tertiary facilities.

- E. Discuss the consistency of the proposed project with applicable Regional Health Plan, State Health Plan, State Medical Facilities Plan, or other plans promulgated by State agencies.

The proposed project aligns with the goals of Virginia's State Medical Facilities Plan (SMFP) and Regional Health Plans, which prioritize access to preventive and diagnostic services to reduce long-term healthcare costs and improve population health outcomes.

Specifically, the Virginia SMFP emphasizes the need for accessible diagnostic imaging and cardiovascular screening services as a means to prevent chronic disease progression. Calcium scoring supports these objectives by identifying patients at risk for CAD before they develop symptomatic heart disease, thereby reducing the need for more expensive interventions such as emergency cardiac catheterization, bypass surgery, or intensive inpatient care.

Additionally, this project is consistent with the broader state and regional initiatives focused on enhancing cardiac care and reducing disparities in healthcare access. By offering calcium scoring through an existing PET/CT system, the project optimizes resource utilization, ensures cost-effective service delivery, and improves patient outcomes in line with state health objectives.

- F. Show the method and assumptions used in determining the need for additional beds, new services or deletion of service in the proposed project's service area.

The need for calcium scoring services in the Manassas area is based on multiple key indicators, including population demographics, prevalence of cardiovascular disease, and the current availability of comparable screening services.

i. Demographics and At-Risk Population

- **The Manassas region has a growing population of middle-aged adults, particularly men over 50, who are at increased risk for CAD.**
- **According to the CDC and American Heart Association, approximately one in three adults over the age of 45 has some degree of coronary artery calcification.**
- **The population of Northern Virginia is expanding, with a projected increase in the number of individuals at risk for cardiovascular disease over the next decade.**

ii. Existing Gaps in Service Availability

- **Currently, calcium scoring is not widely accessible in general diagnostic imaging settings in the Manassas area. Most patients must be referred to specialized cardiology centers, creating barriers in both cost and convenience.**
- **Patients without obvious cardiac symptoms may not be referred for calcium scoring, delaying early detection of cardiovascular disease.**

iii. Clinical and Economic Benefits

- **Calcium scoring is a well-documented, non-invasive tool for predicting cardiovascular risk and guiding preventive care strategies.**
- **Studies show that early detection through calcium scoring leads to a significant reduction in major cardiac events, lowering emergency department visits and hospitalizations.**

- **The availability of calcium scoring at a local PET/CT facility allows for cost-effective utilization of existing imaging infrastructure without the need for additional bed space or resource-intensive expansions.**

By incorporating calcium scoring into an established PET/CT service, this project meets a demonstrated need while maximizing efficiency, enhancing early diagnosis, and reducing the long-term burden of cardiac disease in the Manassas community.

G. Coordination and Affiliation with Other Facilities.

Describe any existing or proposed formal agreements or affiliations to share personnel, facilities, services or equipment. (Attach copies of any formal agreements with another health or medical care facility.)

Not applicable.

H. Attach copies of the following documents:

1. A map of the service area indicating:

See Attachment IV.H.1 - Location Map

- a. Location of proposed project.
- b. Location of other existing medical facilities (by name, type (hospital, nursing home, outpatient clinic, etc.) and number of beds in each inpatient facility).

2. Any material which indicates community and professional support for this project; i.e. letter of endorsement from physicians, community organizations, local government, Chamber of Commerce, medical society, etc.

See Attachment IV.H.2 – Letters of Community Support

3. Letters to other area facilities advising of the scope of the proposed project.

Attachment IV.H.3 – Letters to Area Medical Facilities

SECTION V

FINANCIAL DATA

It will be the responsibility of the applicant to show sufficient evidence of adequate financial resources to complete construction of the proposed project and provide sufficient working capital and operating income for a period of not less than one (1) year after the date of opening:

- A. Specify the per diem rate for all existing negotiated reimbursement contracts and proposed contracts for patient care with state and federal governmental agencies, Blue Cross/Blue Shield Plans, labor organizations such as health and welfare funds and membership associations.

Per diem rates are not applicable to the project's reimbursement methodology.

- B. Does the facility participate in a regional program which provides a means for facilities to compare its costs and operations with similar institutions?

_____ Yes X No

If yes, specify program _____
Provide a copy of report(s) which provide(s) the basis for comparison.

- C. Estimated Capital Costs

No required capital costs for this project as the equipment is already installed and in use at the facility.

Please see "Instructions for Completing Estimated Capital Costs" Section of the Certificate of Need application for detailed instructions for completing this question (attached)

Part I – Direct Construction Costs – Not Applicable

1.	Cost of materials	\$ <u> 0 </u>
2.	Cost of labor	\$ <u> 0 </u>
3.	Equipment included in construction contract	\$ <u> 0 </u>
4.	Builder's overhead	\$ <u> 0 </u>
5.	Builder's profit	\$ <u> 0 </u>
6.	Allocation for contingencies	\$ <u> 0 </u>
7.	Sub-total (add lines 1 thru 6)	\$ <u> 0 </u>


- F. Describe in detail the proposed method of financing the proposed project, including the various alternatives considered. Attach any documents which indicate the financial feasibility of the project. – **Not Applicable**
- G. Describe the impact the proposed capital expenditure will have on the cost of providing care in the facility. Specify total debt service cost and estimated debt service cost per patient day for the first two (2) years of operation. (Total debt service cost is defined as total interest to be paid during the life of the loan (s). Estimate debt service cost per patient day by dividing estimated total patient days for year one into amount of debt service for that year. Repeat for year two.) Please attach an amortization schedule showing how the proposed debt will be repaid. – **Not Applicable**
- H. Attach a copy of the following information of documents. – **Not Applicable**
1. The existing and/or proposed room rate schedule, by type of accommodation.
 2. The audited annual financial statements for the past two (2) years of the existing facility or/if a new facility without operating experience, the financial state of the owner (s). Audited financial statements are required, if available.
 3. Copy of the proposed facility's estimated income, expense and capital budget for the first two years of operation after the proposed project is completed.

SECTION VI ASSURANCES

I hereby assure and certify that:

- a. The work on the proposed project will be initiated within the period of time set forth in the Certificate of Public Need; and
- b. completion of the proposed project will be pursued with diligence; and
- c. the proposed project will be constructed, operated and maintained in full compliance with all applicable local, State and Federal laws, rules, regulations and ordinances.

I hereby certify that the information included in this application and all attachments are correct to the best of my knowledge and belief and that it is my intent to carry out the proposed project as described.

Signed by:	
	8100 Ashton Avenue
Signature of Authorizing Officer	Address – Line 1
Merdod Ghafouri, DO	Suite 200
Type/Print Name of Authorizing Officer	Address – Line 2
President	Manassas, VA 20109
Title of Authorizing Officer	City/State/Zip
571-581-1771	3/27/2025
Telephone	Date

Copies of this request should be sent to :

- A. **Virginia Department of Health
Division of Certificate of Public Need
9960 Mayland Drive – Suite 401
Henrico, Virginia 23233**
- B. **The Regional Health Planning Agency if one is currently designated by the Board of Health to serve the area where the project would be located.**

Attachment III.F
Clinical Indication and
Appropriate Use Criteria

iREVIEW

STATE-OF-THE-ART REVIEW

Major Global Coronary Artery Calcium Guidelines



Ilana S. Golub, BS, Orly G. Termeie, BS, Stephanie Kristo, BS, Lucia P. Schroeder, BS, Suvasini Lakshmanan, MD, Ahmed M. Shafter, MD, Luay Hussein, MD, Dhiran Verghese, MD, Jairo Aldana-Bitar, MD, Venkat S. Manubolu, MD, Matthew J. Budoff, MD

ABSTRACT

This review summarizes the framework behind global guidelines of coronary artery calcium (CAC) in atherosclerotic cardiovascular disease risk assessment, for applications in both the clinical setting and preventive therapy. By comparing similarities and differences in recommendations, this review identifies most notable common features for the application of CAC presented by different cardiovascular societies across the world. Guidelines included from North America are as follows: 1) the 2019 American College of Cardiology/American Heart Association Guideline on the Primary Prevention of Cardiovascular Disease; and 2) the 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for Prevention of Adult Cardiovascular Disease. The authors also included European guidelines: 1) the 2019 European Society for Cardiology/European Atherosclerosis Society Guidelines for the Management of Dyslipidemias; and 2) the 2016 National Institute for Health and Care Excellence Clinical Guidelines. In this comparison, the authors also discuss: 1) the Cardiac Society of Australia and New Zealand Guidelines on CAC; 2) the Chinese Society of Cardiology Guidelines; and 3) the Japanese Atherosclerosis Society Guidelines for Prevention of Atherosclerotic Cardiovascular Diseases. Last, they include statements made by specialty societies including the National Lipid Association, Society of Cardiovascular Computed Tomography, and U.S. Preventive Services Task Force. Utilizing an in-depth review of clinical evidence, these guidelines emphasize the importance of CAC in the primary and secondary prevention of atherosclerotic cardiovascular disease. International guidelines all empower a dynamic clinician-patient relationship and advocate for individualized discussions regarding disease management and pharmacotherapy treatment. Some differences in precise coronary artery calcium score intervals, risk cut points, treatment thresholds, and stratifiers of specific patient subgroups do exist. However, international guidelines employ more similarities than differences from both a clinical and functional perspective. Understanding the parallels among international coronary artery calcium guidelines is essential for clinicians to correctly adjudicate personalized statin and aspirin therapy and further medical management. (J Am Coll Cardiol Img 2023;16:98-117) © 2023 by the American College of Cardiology Foundation.

Cardiovascular disease (CVD) is a leading cause of death worldwide, and accounts for over 30% of annual global fatality.¹ CVD is also the leading cause of disease burden worldwide. Prevalent cases of total CVD nearly doubled from 271 million in 1990 to 523 million in 2019, and the number of CVD deaths steadily increased from 12.1 million in

1990 to 18.6 million in 2019. Reducing coronary heart disease mortality and morbidity necessitates a highly sensitive risk assessment tool, followed by risk stratification and treatment strategies.² This paper compares guidelines from CV societies across the world to help encourage a homogeneous approach of CV risk adjudication: coronary artery calcium (CAC)

From the Lundquist Institute at Harbor-UCLA Medical Center, Torrance, California, USA.

The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

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screening. CAC is widely available, exhaustively studied, and a highly specific marker of subclinical atherosclerosis.³ It is a vital arbitrator of atherosclerotic cardiovascular disease (ASCVD) and accounts for both stroke and coronary heart disease.⁴ CAC testing facilitates the up- or down-risking of asymptomatic patients and provides a model for initiating or intensifying preventive statin pharmacotherapies. Uniting CAC risk stratification with cholesterol-modifying treatment promotes a model for individualizing primary ASCVD prevention and shared clinician-patient decision making.⁵

Clinical Practice Guidelines (CPGs) are vital for structuring systematic and universally applicable recommendations, to aid practitioner and patient decision making about appropriate health care.⁶ Empowering a thorough understanding of accessible clinical evidence and international recommendation is key. This facilitates specialists' ability to promote personalized decision making alongside patients and to better an equitable physician-patient dialogue.^{7,8} To simplify universal ASCVD risk assessment, it is incumbent on us to establish global solutions for CPGs on CAC scoring. In this review paper, we therefore explore 7 guideline statements by respective high-profile CV societies. From North America, we review the American College of Cardiology/American Heart Association (ACC/AHA)⁹ and Canadian Cardiovascular Society (CCS)¹⁰ guidelines. From Europe, we review the European Society for Cardiology/European Atherosclerosis Society (ESC/EAS)¹¹ and the UK National Institute for Health and Care Excellence (NICE)¹² guidelines. We also review Cardiac Society of Australia and New Zealand (CSANZ)¹³ as well as the Chinese¹⁴ and Japanese Atherosclerosis Society (JAS)¹⁵ guidelines. Last, we include statements made by specialty societies including the National Lipid Association (NLA),¹⁶ Society of Cardiovascular Computed Tomography (SCCT),¹⁷ and U.S. Preventive Services Task Force (USPSTF).¹⁸

After describing major societies' recommendations and scope of guidelines, we evaluate strength of recommendation in an evidence-level review. Next, this paper assesses guideline recommendations' comparison of risk scores in prediction of coronary and CV deaths. We also review coronary calcium guidelines within specific patient subgroups and ages. Furthermore, we examine international recommendations in utilizing CAC to guide statin, aspirin, antihypertensive therapy, and CAC rescanning time intervals. By summarizing the framework behind global guidelines of CAC in ASCVD risk assessment, this review paper helps advocate international synthesis and applications in both the clinical setting and

preventive therapy. Helping physicians understand universal differences and similarities is key to empower the most fitting choices in CVD prevention and management.

CLINICAL EVIDENCE AND STRENGTH IN GUIDELINE RECOMMENDATIONS

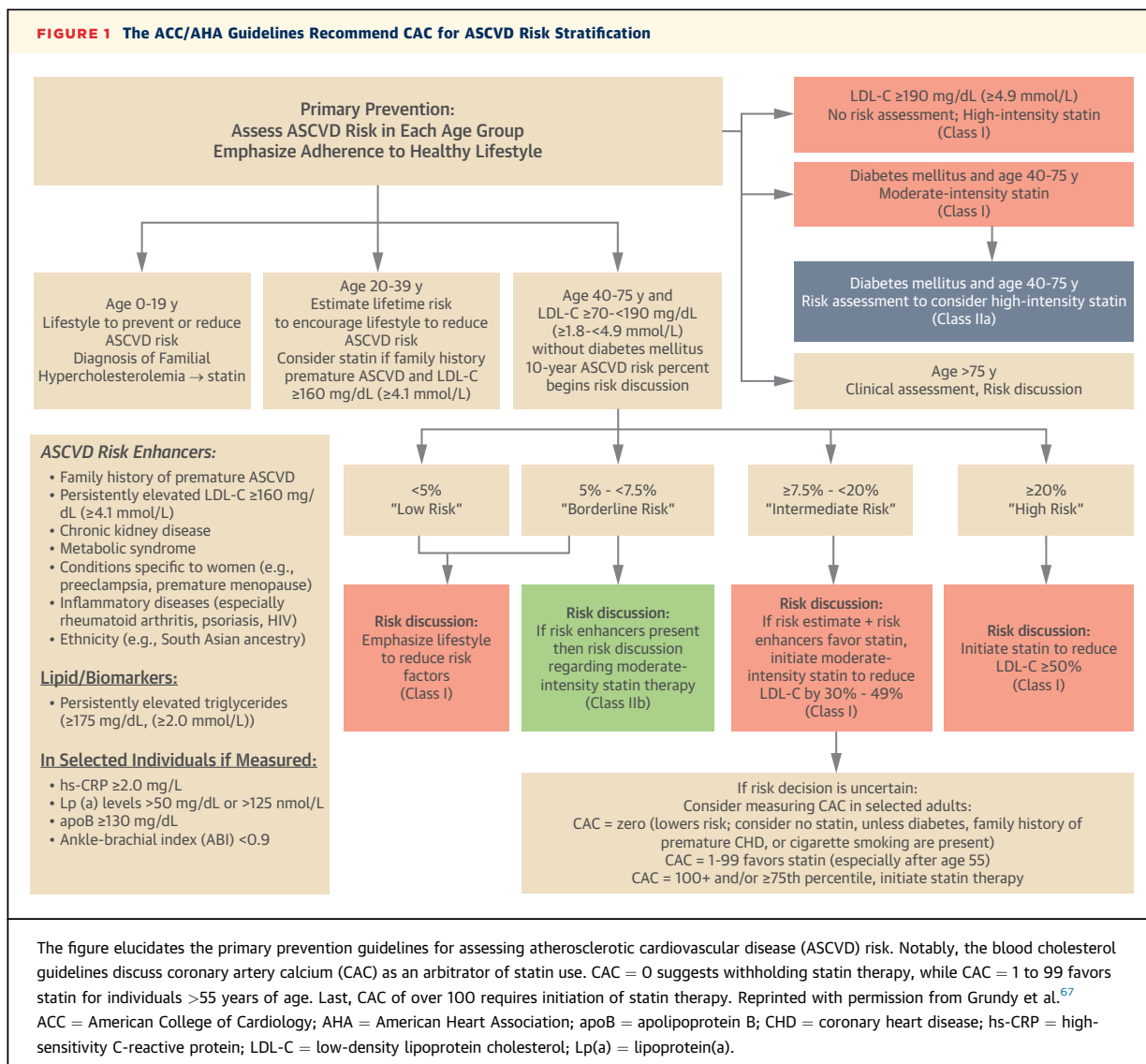
International CPGs are based on information from various sources. In preparing their recommendations, the ACC/AHA included only randomized controlled trials and their respective meta-analysis and systematic reviews. Studies of poor quality were rejected.⁹ Like the ACC/AHA, the NICE recommendations are determined from systematic reviews and randomized controlled trials.¹² The ESC/EAS and CCS, on the other hand, did not restrict the categories of studies. However, both European and Canadian agencies did apply rigorous analysis to published recommendations and data.^{10,11} Chinese guidelines were determined from a platform of clinical and epidemiological studies completed within the Chinese population. These studies were subsequently integrated with international research and recommendations.^{14,19} Each of these CPGs details the strength for every suggestion utilizing well-established recommendation classes (ie, I, IIa, IIb, and III) and evidence quality (ie, levels from A to C).^{9–12,20,21}

COMMON ASPECTS AND SCOPE OF GUIDELINES

INTERMEDIATE-RISK COHORT. With regard to risk stratification, most CPGs agree that CAC scoring is vital to up- or down-classify intermediate risk individuals. As indicated in [Figure 1](#) and the [Central Illustration](#), the ACC/AHA recommend consideration of risk enhancing factors, to guide clinician-patient risk discussion for intermediate risk adults (7.5%–20% 10-year ASCVD risk) and adults at borderline risk (5%–7.5% 10-year ASCVD risk). These include family history of premature ASCVD, persistently elevated low-density lipoprotein cholesterol (LDL-C) ≥ 160 mg/dL or triglycerides ≥ 175 mg/dL, chronic kidney disease (CKD), metabolic syndrome, conditions specific to women (eg, preeclampsia, premature menopause), inflammatory diseases (rheumatoid arthritis, psoriasis, and HIV), high-risk race or ethnicity (eg, South Asian origin), and elevated high-sensitivity C-reactive protein or lipoprotein(a) in selected individuals. If risk-based choices for preventive interventions remain ambiguous, consider CAC as an adjudicator to upgrade risk (eg, young

ABBREVIATIONS AND ACRONYMS

ASCVD	= atherosclerotic cardiovascular disease
CAC	= coronary artery calcium
CAD	= coronary artery disease
CHD	= coronary heart disease
CKD	= chronic kidney disease
CPG	= Clinical Practice Guideline
CV	= cardiovascular
CVD	= cardiovascular disease
DM	= diabetes mellitus
LDL-C	= low-density lipoprotein cholesterol
PCE	= pooled cohort equations
SBP	= systolic blood pressure

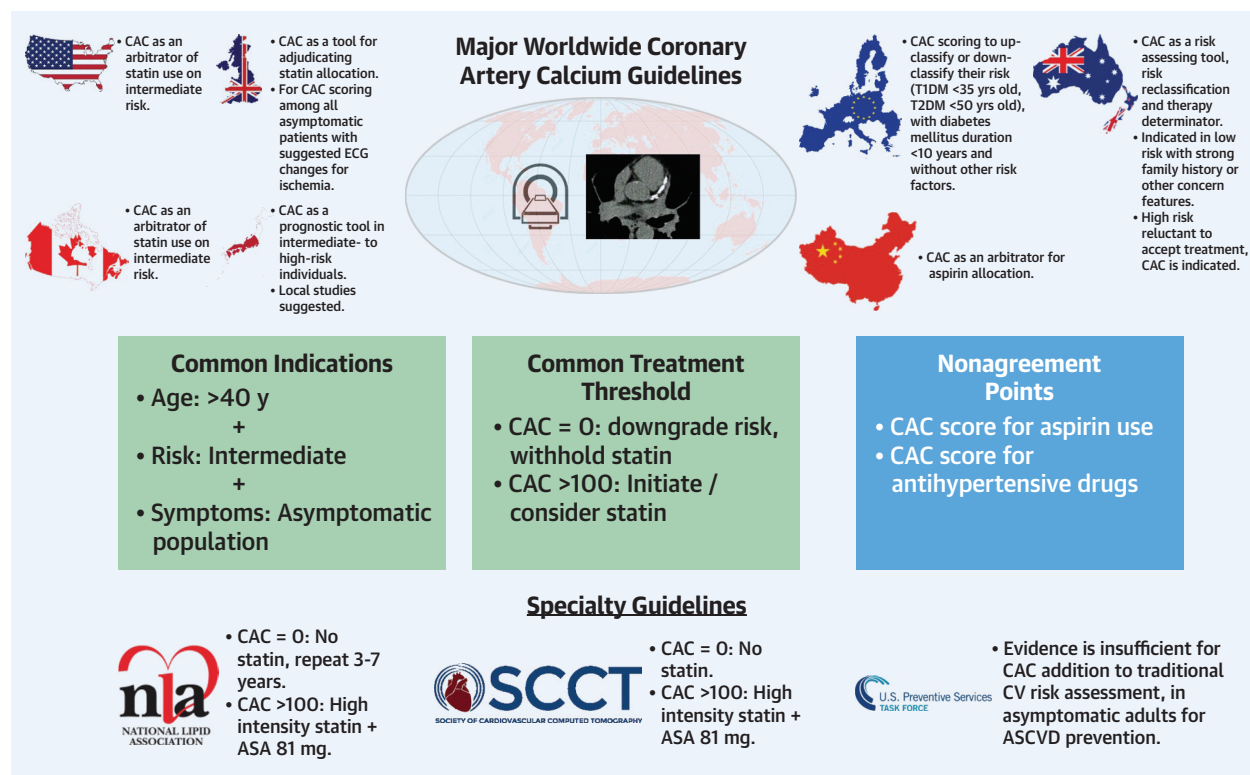
FIGURE 1 The ACC/AHA Guidelines Recommend CAC for ASCVD Risk Stratification

patients and women) or to de-risk (eg, elderly, diabetes).^{9,22} The CCS likewise recommends CAC screening for asymptomatic adults ≥40 years of age years and with intermediate risk based on the Framingham risk score (FRS) (10%-20%), for whom treatment choices are unclear (Figures 2 and 3).¹⁰ In the same regard, the CSANZ guidelines also recommend the CAC score for intermediate-risk individuals (10%-20% 10-year ASCVD risk) who are asymptomatic, without known coronary artery disease (CAD), and 45 to 75 years of age.^{13,23} The UK NICE guidelines are similar to those already discussed but allow instead for CAC scoring among all asymptomatic patients with suggested electrocardiography changes for ischemia.¹²

LOW-RISK COHORT. With respect to lower-risk individuals, the ACC/AHA note that CAC score will be

positive less often in this group than in those with higher levels of ASCVD risk. Thus, CAC is recommended for low-risk patients only when risk-enhancing factors are indicated.⁹ Similarly, the CCS suggests that CAC screening is not indicated for most asymptomatic low-risk adults.¹⁰ However, the CCS does indicate that CAC screening may be contemplated for a unique subset of low-risk individuals >40 years of age with a family history of premature ASCVD (men <55 years of age, women ≤65 years of age) and genetic ASCVD indicators (elevated lipoprotein[a] or familial hypercholesterolemia).¹⁰ The CSANZ similarly recommends that CAC can be examined for lower risk patients (absolute 10-year CV risk 6%-10%) with the following circumstances: family history of premature CVD and diabetic patients 40 to 60 years of age.^{13,23} Likewise, the ESC/EAS guidelines employ CAC

CENTRAL ILLUSTRATION Summary of Major Global CAC Guidelines



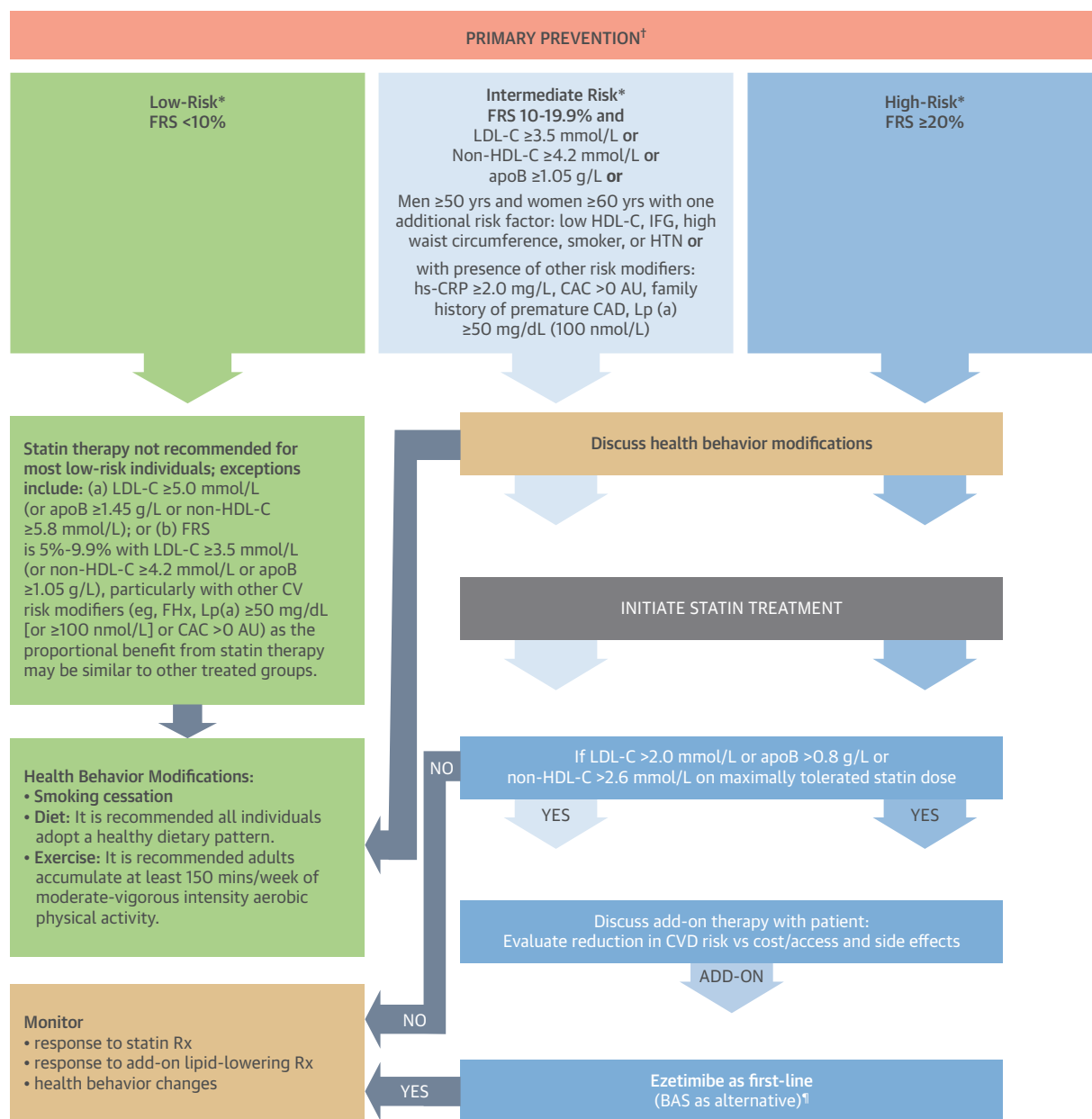
Golub IS, et al. J Am Coll Cardiol Img. 2023;16(1):98-117.

Among all discussed global coronary artery calcium (CAC) guidelines, common indications for CAC include the following: >40 years of age, intermediate level of risk, and among an asymptomatic population. Common treatment thresholds indicate that for CAC = 0, risk should be downgraded and statin withheld. For CAC >100, statins should be considered or initiated. Nonagreement points between major guidelines surround the CAC score's indication for aspirin use and antihypertensive medications. ASA = acetylsalicylic acid; ASCVD = atherosclerotic cardiovascular disease; CV = cardiovascular; ECG = electrocardiography; T1DM = type 1 diabetes mellitus; T2DM = type 2 diabetes mellitus.

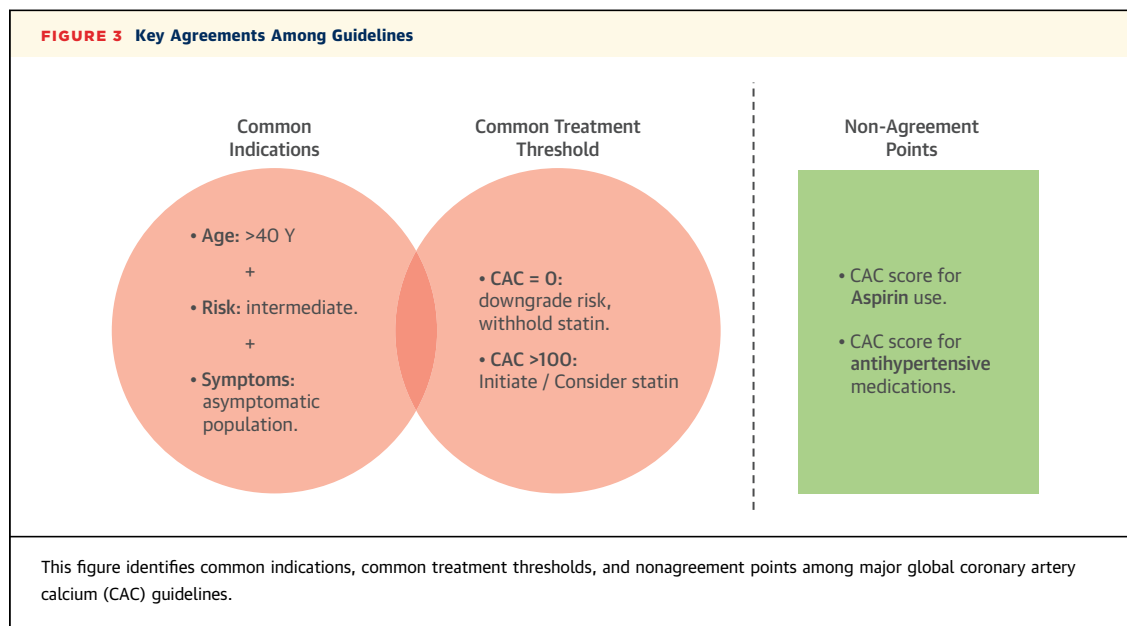
score assessment for risk modification in asymptomatic individuals of low to moderate risk who would be eligible for statin therapy.¹¹ For this cohort, ESC recommends CAC >100 for upward reclassification considering statin therapy.¹¹ CAC may also be explored in patients at low or moderate risk in whom the LDL-C goal is not reached with lifestyle intervention alone.¹¹ Recently updated 2021 ESC Prevention Guidelines restate that CAC may be considered to improve risk classification around treatment decision thresholds (Class IIb, Level of Evidence: B).²⁴

CAC RISK THRESHOLDS. With regard to calcium burden adjudicating statin therapy, international CPGs also tend to agree among CAC score cohorts. The ACC/AHA advocates CAC as an appropriate stratifier of statin use.⁹ For intermediate-risk individuals or selected borderline-risk adults (classified within the context of the AHA/ACC guidelines as statin suggested and statin recommended, respectively) with

CAC = 0 and no higher-risk conditions (ie, diabetes mellitus [DM], family history of premature coronary heart disease [CHD], smoking), American guidelines advise withholding statin therapy and reevaluating in 5 to 10 years.⁹ Similarly, the CCS reports that abstaining from statin therapy for CAC = 0 is reasonable, with reassessment during follow-up within 5 years for patients >40 years of age.¹⁰ Similar to the ACC/AHA guidelines, the CCS does note exceptions for intermediate-risk groups with high-risk features including smoking, diabetes, uncontrolled hypertension, and genetic dyslipidemias, and individuals with prominent family history of premature ASCVD events.¹⁰ For CAC subgroups 1 to 99, the ACC/AHA suggest that statin therapy is reasonable in those ≥55 years of age.⁹ With CAC ≥100 or ≥75th percentile, American guidelines endorse statin treatment for any age interval.⁹ Canadian recommendations employ CAC >100 as an indicator for

FIGURE 2 The CCS Guidelines Recommend CAC for ASCVD Risk Stratification

The figure elucidates the primary prevention guidelines for assessing ASCVD risk and discusses CAC as an arbitrator of statin use. CAC screening is strongly indicated for asymptomatic adults ≥40 years of age and with intermediate risk (Framingham risk score [FRS] 10%-20%), for whom treatment choices are unclear. CAC screening is not indicated for most asymptomatic, low-risk adults. For CAC >100, pharmacotherapy is reasonable regardless of FRS. However, for individuals with a CAC of 1 to 99, the Canadian Cardiovascular Society (CCS) suggests that individual decision making is necessary because risk remains intermediate. Reprinted with permission from Pearson et al.¹⁰ *Screening should be repeated every 5 years for men and women aged 40 to 75 years to reduce major cardiovascular events. A risk assessment might also be completed whenever a patient's expected risk status changes. †Calculate risk using the FRS. ‡Studies have evaluated the efficacy of BAS for the prevention of ASCVD, but results have been inconclusive. AU = arbitrary units; BAS = bile acid sequestrant; CAD = coronary artery disease; CV = cardiovascular; CVD = cardiovascular disease; FHx = family history; HDL-C = high-density lipoprotein cholesterol; HTN = hypertension; IFG = impaired fasting glucose; Rx = prescription; other abbreviations as in Figure 1.



pharmacotherapy regardless of FRS.¹⁰ However, for individuals with a CAC of 1 to 99, the CCS suggests that individual decision making is necessary because risk remains intermediate.¹⁰

The Australia and New Zealand guidelines, in contrast, utilize slightly different thresholds, as indicated in [Figure 4](#) and the [Central Illustration](#). The CSANZ indicates CAC = 0 for withholding statin therapy, while CAC = 1 to 100 favors lifestyle improvement. CAC of 101 to 400 uniquely indicates treatment for individuals >75th percentile, and CAC >400 requires initiation of statin therapy. Although patients with low CAC (1-100) have a 2-fold relative risk compared with those without CAC, the CSANZ asserts that evidence for pharmacotherapy is weak.¹³ However, in the MESA (Multi-Ethnic Study of Atherosclerosis) study, event rates varied from 1.3% to 5.6% for CAC = 0 and from 13.1% to 25.6% for CAC >300. With other risk factors held constant, the MESA study estimated a 14% relative increment in ASCVD risk for each doubling of CAC.²⁵ CAC of 101 to 400, in our perspective, is a high-risk population that could benefit from statin medication. The CSANZ instead recommends a healthy diet and lifestyle for maintaining a low 10-year risk, except when increased-risk clinical factors are present.¹³

NON-CAC ENDORSING. Chinese and Japanese agencies differ from the aforementioned CPGs ([Central Illustration](#), [Table 1](#)). Chinese guidelines appreciate the ACC/AHA guidelines that consider nontraditional risk factors like CAC scoring for risk assessment. In this regard, Chinese agencies plan to apply both traditional and nontraditional risk

factors (not limited to CAC score) to improve CVD assessment tools and primary prevention measures.¹⁹ However, current CPGs mainly focus on blood pressure and cholesterol levels, smoking status, and age for risk stratification.¹⁹ Therefore, the Chinese guidelines do not specifically discuss CAC score subgroups for ASCVD risk adjudication. Chinese CPGs suggest that enhancement factors (such as family history of premature CVD; inadequate regulation of cholesterol, blood pressure, and glucose level; or significantly higher CAC score) should be further explored, along with accepted risk stratification.¹⁹

Japanese guidelines similarly report that CAC has a high prognostic value for predicting CAD in intermediate- to high-risk individuals ([Central Illustration](#), [Table 1](#)). However, CPGs state that this finding may be swayed by Japan's lower rate of CAD morbidity and mortality when compared with the Western population's.²⁶ Therefore, Japanese guidelines suggest that additional longitudinal studies are needed to associate CAC score with CAD events within their population.²⁶

SPECIALTY GUIDELINES AND SOCIETIES. This review focuses primarily on international guidelines. Though this paper does not discuss them at length, many specialty societies in addition to those aforementioned also endorse the CAC score. Here, we therefore introduce recommendations by the NLA, SCCT, AACE, Endocrine Society, and USPSTF and refer to them throughout the paper ([Central Illustration](#), [Table 1](#)).

TABLE 1 Global CAC Guidelines Summary Table

Guideline	Summary
Country guidelines	
United States	CAC as an arbitrator of statin use on intermediate risk.
Canada	CAC as an arbitrator of statin use on intermediate risk.
United Kingdom	CAC as a tool for adjudicating statin allocation. For CAC scoring among all asymptomatic patients with suggested ECG changes for ischemia.
Europe	CAC scoring to up-classify or down-classify their risk (type 1 DM <35 years of age, type 2 DM <50 years of age), with DM duration <10 y and without other risk factors.
Australia	CAC as a risk-assessing tool, risk reclassification and therapy determinant. Indicated in low risk with strong family history or other concern features. High risk reluctant to accept treatment, CAC is indicated.
China	CAC as an arbitrator for aspirin allocation.
Japan	CAC as a prognostic tool in intermediate- to high-risk individuals. Local studies suggested.
Specialty guidelines	
NLA	CAC = 0: no statin, repeat 3-7 y. CAC >100: high-intensity statin + ASA 81 mg.
SCCT	CAC = 0: no statin. CAC >100: high-intensity statin + ASA 81 mg.
USPSTF	Evidence is insufficient for CAC addition to traditional CV risk assessment, in asymptomatic adults for ASCVD prevention.

This table indicates key points for CAC screening, per each country and specialty guideline reviewed.
ASA = acetylsalicylic acid; ASCVD = atherosclerotic cardiovascular disease; CAC = coronary artery calcium;
CV = cardiovascular; DM = diabetes mellitus; ECG = electrocardiography; NLA = National Lipid Association;
SCCT = Society of Cardiovascular Computed Tomography; USPSTF = U.S. Preventive Services Task Force.

One of the newest and most comprehensive guidelines, the NLA advocates CAC to guide preventive strategies for ASCVD risk reduction. The NLA explicitly categorizes CAC score as the best predictor of absolute 5- to 10-year ASCVD event risk (Figure 5, Central Illustration).¹⁶ Like most aforementioned international guidelines, the NLA does not recommend CAC scoring for adults with clinical ASCVD but notes immense use in stratifying borderline to intermediate- and low-risk adults. The NLA classifies borderline- to intermediate-risk adults as those 40 to 75 years of age, with LDL-C 70 to 189 mg/dL and a 10-year ASCVD of 5% to 19.9%. For this cohort, the NLA suggests that CAC scoring may aid clinicians in determining the need for and intensity of preventive therapies.¹⁶ The NLA classifies low-risk adults as those 40 years of age or older, with LDL-C 70 to 189 mg/dL and a 10-year ASCVD risk of <5%. For this cohort, the NLA states that CAC scoring is reasonable for selective patients with a strong family history of premature ASCVD, and may help adjudicate preventive therapy intensification or initiation.¹⁶

In tandem with American, Canadian, European, UK, and Australian and New Zealand CPGs, the NLA

also classifies specific CAC risk thresholds to adjudicate pharmacotherapy (Central Illustration, Table 1). In adults 40 to 75 years of age with LDL-C 70 to 189 mg/dL and without diabetes, active cigarette smoking, or a family history of premature ASCVD, the NLA recommends deferring statin initiation when CAC = 0. In adults 76 to 80 years of age for whom initiating statin therapy is uncertain, the NLA recommends CAC = 0 as a factor favoring avoidance of statin therapy.¹⁶ For adults with high CAC score, predominant left main coronary calcification, or multivessel coronary involvement, the NLA does not recommend stress testing or invasive coronary arteriography if clinically relevant symptoms remain absent. For patients with CAC ≥100, the NLA supports initiation of statin therapy. Specifically for CAC ≥300, and especially for CAC ≥1,000, the NLA recommends high-intensity statin therapy.¹⁶

Like the NLA and many aforementioned major CPGs, the SCCT similarly indicates CAC scoring in asymptomatic patients with unique clinical indications (Figures 6 and 7, Central Illustration, Table 1).¹⁷ Specifically, the SCCT endorses CAC screening for the following asymptomatic individuals without clinical ASCVD: those 40 to 75 years of age and within the 5% to 20% 10-year ASCVD risk group, and those in the <5% ASCVD risk group with a strong family history of premature CAD.¹⁷

The American Association of Clinical Endocrinology also emphasizes CAC measurement's high predictive value and utility in refining risk stratification to determine the need for more aggressive treatment strategies (Grade B, Best Evidence Level 2).²⁷ The 2020 Endocrine Society CPGs similarly discuss CAC at length, specifically for lipid management in patients with endocrine disorders.²⁸ For these adults at borderline or intermediate risk (defined as 10-year ASCVD risk 5%-19.9%), the Endocrine Society recommends CAC to inform shared decision making regarding statin treatment and preventive intervention.²⁸

In contrast, the USPSTF recommendations conflict entirely with those from the ACC, AHA, ESC, and SCCT, among others, all of which advise consideration of CAC testing in select populations.¹⁸ Instead, the 2018 USPSTF statement concludes that evidence is insufficient for CAC addition to traditional CV risk assessment, in asymptomatic adults for ASCVD prevention (Central Illustration, Table 1). The USPSTF asserts that the clinical meaning of any improvements found with risk reclassification by CAC remain largely unknown.¹⁸

TABLE 2 CAC in Guiding Statin Use

International Guideline	CAC Score			
	CAC = 0	CAC 1-99	CAC ≥100	CAC >400
ACC/AHA	Downgrade risk, withhold statin	Favors statin ≥55 years of age	Initiate statin therapy	—
ESC	—	—	Upward reclassification and consider statin therapy	—
CSANZ	Downgrade risk, withhold statin	Downgrade risk, withhold statin	CAC 101-400 and <75th percentile = consider statin treatment CAC score between 101 and 400 and >75th percentile = initiate statin therapy	Initiate statin therapy
CCS	Downgrade risk, withhold statin	Personal decision making needed	Initiate statin therapy	—
NICE	Downgrade risk, withhold statin	—	+ Statin	—
JAS	—	—	—	—
CSC	—	—	—	—

This table indicates statin pharmacotherapy recommendations per CAC score range, for each of the international guidelines reviewed.
ACC = American College of Cardiology; AHA = American Heart Association; CAC = coronary artery calcium; CCS = Canadian Cardiovascular Society; CSANZ = Cardiac Society of Australia and New Zealand; CSC = Chinese Society of Cardiology; ESC = European Society for Cardiology; JAS = Japanese Atherosclerosis Society; NICE = National Institute for Health and Care Excellence.

CAC RESCANING TIME INTERVALS

For the initial CAC = 0 cohort, CPG guidelines differ with regard to the timeline for repeating CAC assessment. For low-risk individuals or those with CAC = 0, the ACC/AHA and CSANZ recommend that CAC screening may be repeated in 5 to 10 years.^{4,13} The ESC guidelines recommend that for CAC = 0, repeat screening should not be performed <5 years from the initial scan.²⁹ The CSANZ also recommends that diabetic patients or those with CAC 101 to 400 should undergo repeat CAC at 3 years.¹³ However, individuals with high CAC (>400) may not require repeat CAC screening, seeing as these patients are often symptomatic and already vigorously treated.¹³ For this high-risk subgroup, the CSANZ does indicate functional testing on an individualized basis.¹³

Canadian guidelines, in contrast, do not recommend repeat scans after CAC = 0 unless personal risk factors are present, pharmacotherapy is deferred, or follow-up is warranted.¹⁰ The NICE guidelines also do not suggest a timeline for repeating CAC scans.

The NLA recommends that the timing for repeat CAC score depends on a patient's baseline estimated ASCVD risk, varying from 3 to 7 years.¹⁶ Specifically, for CAC = 0, the NLA advocates the following repeat scanning intervals: low-risk patients (<5% 10-year risk) warrant 5 to 7 years, borderline- to intermediate-risk patients (5%-19.9% 10-year risk) warrant 3 to 5 years, and high-risk or diabetes patients warrant 3 years.¹⁶ Specifically, for adults with CAC 1 to 99, the NLA advocates repeat CAC scoring in 3-5 years if the results might change treatment decisions.¹⁶ For adults with CAC scores ≥100 and an

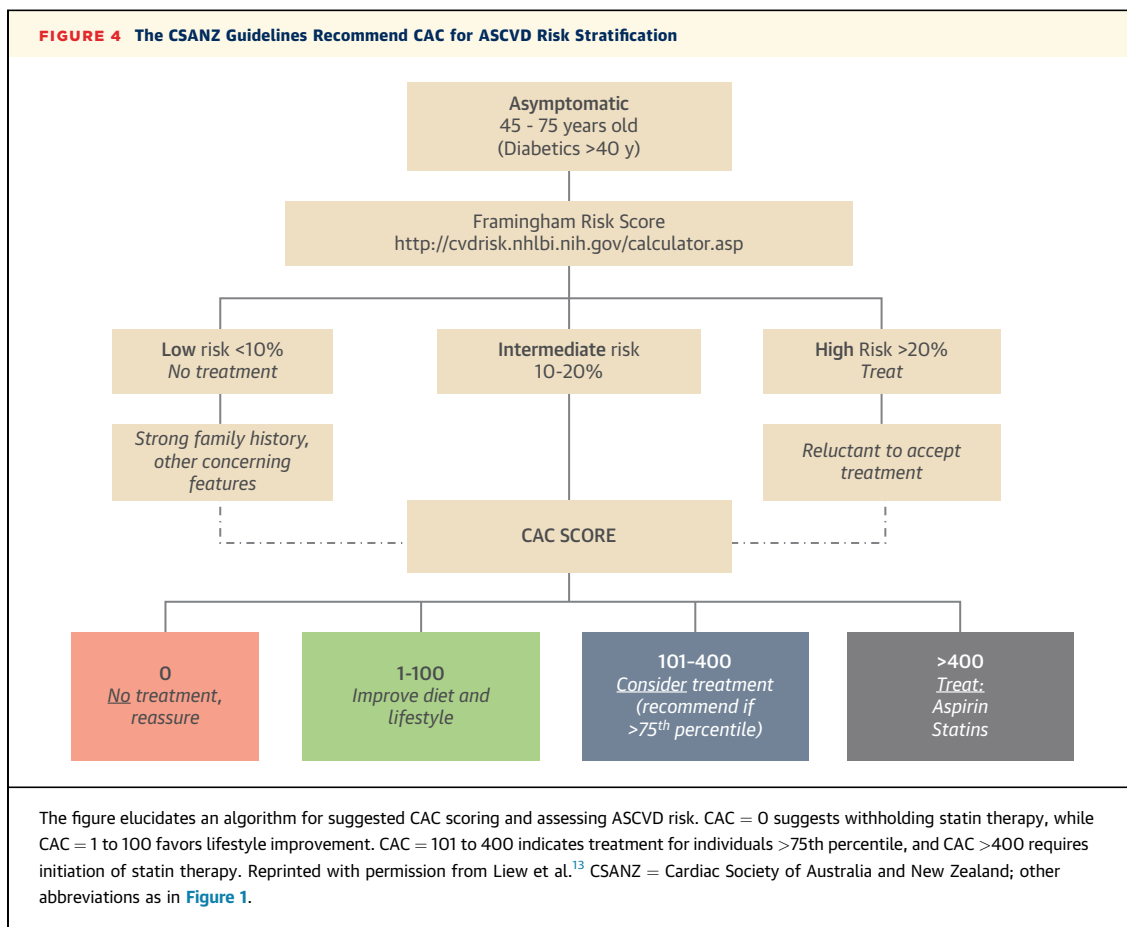
LDL-C ≥70 mg/dL, the NLA recommends repeat CAC scoring at 3 years to assess for accelerated progression (>20%-25% per year) or an increase to a CAC score >300.¹⁶

Less specific than the NLA perhaps, the SCCT recommends repeat scanning for patients in whom CAC progression would support intensification of preventive management. For these individuals, the SCCT advocates repeat screening every 5 years when CAC = 0 and every 3 to 5 years when CAC >0.¹⁷

COMPARISON OF RISK SCORES IN PREDICTION OF CORONARY AND CV DEATHS

Although this review focuses on international CAC recommendations, elucidating worldwide guidelines for noncalcium risk adjudicators (such as risk scores) is also important for completion and comprehension. As such, this paper briefly compares guideline recommendations of risk scores for predicting coronary and CV deaths.

International CPGs for pharmacotherapy decisions in ASCVD prevention rely heavily on CV risk assessment and stratification. Guidelines for use of statins, aspirin, and hypertension therapies are specifically risk based, and these CVD prediction estimators empower synergistic decision making in clinician-patient discussions.³⁰ The ACC/AHA, ESC/EAS, CCS, NICE, and Australian guidelines explicitly incorporate risk scores in CVD prediction and endorse CAC as a well-established arbitrator.^{9,10,20,31} The current international promotion of personalized risk-based approach not only increases the yield of treatment in high-risk patients, but also reduces potential harm

FIGURE 4 The CSANZ Guidelines Recommend CAC for ASCVD Risk Stratification

in low-risk patients that are less likely to encounter absolute risk reduction.³²

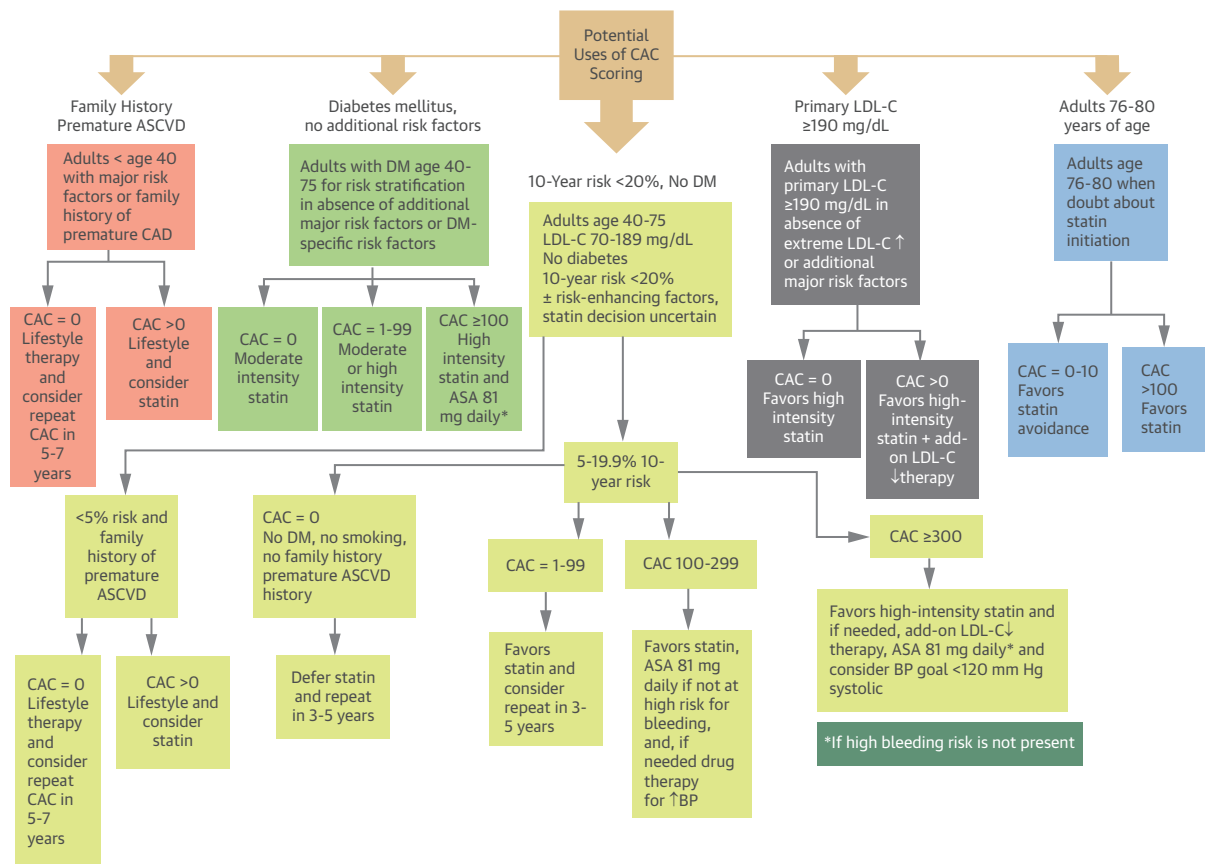
The utilization of clinical risk estimation tools in primary prevention has been widely examined and implemented in key guidelines worldwide.³³ In 2013, the ACC/AHA developed an updated risk predictor inclusive of CHD, CVD, and stroke events.³⁴ Known as the pooled cohort equations (PCE), this 10-year ASCVD Risk Estimator was also recommended for initial ASCVD risk assessment in the later 2018 and 2019 guideline updates.³¹ Dovetailing the PCE, the 2015 MESA study released a novel score for 10-year CHD event prediction that united traditional risk factors with CAC as a risk stratifier.³⁵ CAC has been widely indicated as the single best predictor of CVD and CHD events,³² and international guidelines have adopted recommendations as such. Guidelines worldwide recognize the inherent imprecision of multivariable CV event prediction tools and promote CAC as an arbitrator to improve discrimination, calibration, and net reclassification.³³ In intermediate-risk patients in whom management is uncertain after risk predictors like the PCE, the

American, European, Canadian, United Kingdom, and Australian and New Zealand guidelines all recommend CAC as an absolute risk stratifier for both cholesterol management and primary ASCVD prevention.^{9-13,32}

Alongside short-term risk prediction via PCE, the 2019 ACC/AHA guidelines also recommend 30-year risk evaluation by way of Lifetime Risk Estimation.^{33,36} With the goal of assessing long-term implications of risk factor aggregate burden, the Lifetime Risk Estimation tool is optimal for patients younger than 50 years of age with low short-term but elevated lifetime risk.³³

Like the ACC/AHA, European agencies similarly promote absolute risk prediction tools alongside CAC scoring. The 2019 European Guidelines specifically recommend the SCORE (Systemic COronary Risk Evaluation) model for the prediction of 10-year risk of CV death, and the UK NICE utilizes the QRISK algorithm to predict a composite outcome of CHD, ischemic stroke, or transient ischemic attack.^{33,37} The 2021 ESC guidelines have since upscaled the original SCORE to SCORE2, an improved algorithm now

FIGURE 5 The NLA Guidelines Endorse CAC

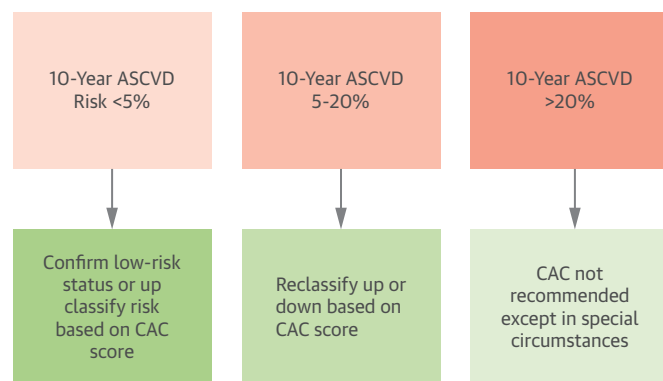


This figure shows a statement on CAC scoring to guide preventive strategies for ASCVD risk reduction and statin pharmacotherapy. Reprinted with permission from Orringer et al.¹⁶ ASA = acetylsalicylic acid; BP = blood pressure; DM = diabetes mellitus; LDL-C = low-density lipoprotein cholesterol; NLA = National Lipid Association; other abbreviations as in Figure 1.

estimating 10-year risk of combined fatal and nonfatal CVD events.²⁴ In contrast with SCORE's use of CVD mortality only, SCORE2 better estimates total CVD burden with included nonfatal myocardial infarction and stroke events.²⁴ SCORE2 may be used for populations without prior ASCVD 40 to 69 years of age, while SCORE2-OP (older persons) may be applied to those without ASCVD ≥70 years of age to estimate 5- and 10-year risk of CVD (including myocardial infarction and stroke).²⁴

Both American and European guidelines empower a targeted, personalized approach to estimating CVD risk. Unique to European preventive cardiology societies, however, is the push for CVD risk estimators specific to special populations. Within an elderly cohort, the JBS3 risk calculator and the elderly risk score account for competing nonvascular mortality are recommended.^{37,38} For patients with DM, the

ADVANCE (Action in Diabetes and Vascular Disease-PreterAx and DiamicroN Controlled Evaluation) risk score accounts for uniquely relevant variables such as hemoglobin A1c, albuminuria, retinopathy, and atrial fibrillation, in addition to traditional CV risk factors.^{33,39} The SMART (Second Manifestations of Arterial Disease) risk score for patients with vascular disease similarly includes unique variables (number of vascular disease locations, kidney function, high-sensitivity C-reactive protein, years since diagnosis) for increased specificity of CV risk stratification.^{33,38} Last, the MAGGIC (Meta-Analysis Global Group in Chronic Heart Failure) risk calculator is recommended uniquely for patients with heart failure.³³ Moreover, a key difference between the AHA/ACC and ESC/EAS risk estimation tools (PCE and SCORE, respectively) are their endpoints. While the AHA/ACC atherosclerotic risk adjudication utilizes the endpoint

FIGURE 6 The SCCT Guidelines Endorse CAC For 10-Year Risk Stratification

The figure indicates the role of CAC in guiding treatment for the 10-year ASCVD risk categories. Reprinted with permission from Hecht et al.¹⁷ SCCT = Society of Cardiovascular Computed Tomography; other abbreviations as in Figure 1.

of fatal and nonfatal myocardial infarction and stroke, the European SCORE CVD risk estimation employs a hard endpoint of CV death.³³

The JAS Guidelines for Prevention of Atherosclerotic Cardiovascular Diseases presented the NIPPON DATA80 Risk Chart in 2012 to estimate absolute risk of 10-year CVD mortality.¹⁵ Risk factors include gender-specific tables, age, serum total cholesterol, smoking, systolic blood pressure (SBP), and random blood glucose.^{15,40} Certain advantages were found in the NIPPON DATA80 Risk Chart, most notably: random sampling across Japan, distribution of a baseline survey conducted before statins were available, and high suitability for observation of natural disease course.¹⁵ Concerns with the NIPPON DATA80 Risk Chart include its lack of LDL-C or high-density lipoprotein cholesterol consideration and its employment of death as predicted outcome in place of CAD incidence. Also problematic is NIPPON's 1980 baseline year and its higher estimation of mortality than actualized when applied to more recent populations.^{15,41}

The Chinese Society of Cardiology notes that widely used prediction models (ie, European SCORE model and American pooled cohort studies equations) are based on European and American population data and thus cannot be fully extrapolated to Chinese cohorts.^{19,42} Instead, Chinese cardiology societies employ the 2016 Chinese Guidelines for the Management of Dyslipidemia in Adults for 10-year ASCVD risk assessment. These recommendations are rooted in long-term follow-up data from the Multi-provincial Cohort Study, and suggest that age is

a paramount risk factor in the predictive model of 10-year CV disease risk.^{19,43,44}

CAC RECOMMENDATIONS IN SPECIAL GROUPS OF PATIENTS

Next, this review examines international CAC recommendations with regard to special groups of patients, including individuals with CKD and DM, and gender differences.

CHRONIC KIDNEY DISEASE. In those with CKD, a significantly more pronounced, disseminated, and fast-progressing calcification of the vascular system (including the coronary arteries) is often present.⁴⁵ Coronary artery calcification develops early after the onset of CKD and is closely associated with mineral and bone disorders, which include but are not limited to secondary hyperparathyroidism.⁴⁵ Factors such as inflammation and obesity, commonly seen in CKD, lead to the acceleration of atherosclerotic plaques in the arteries.⁴⁵

Many of the CPGs discussed in this article therefore rate CKD on a very high risk level and agree that initiating statin therapy is warranted. CAC scoring is a valuable arbitrator, especially in cases in which intermediate risk patients may be up- or down-stratified for pharmacotherapy intervention.

The CCS defines the usage of statins in CKD to include the following: 1) patients with an estimated glomerular filtration rate <60 mL/min/1.73 m²; and 2) those patients with preserved estimated glomerular filtration rate in whom CKD is based on increased urinary albumin-to-creatinine ratio (≥3 mg/mmol) for at least 3 months; duration, all exempting patients on chronic dialysis.¹⁰ The CSANZ adds that CKD patients classified as extremely high risk may be exempted from CAC screening because it is unlikely to alter the recommended management of the disease.¹³ The ESC/EAS adds that active management instead of risk assessment by CAC is of more vital importance for those with CKD.¹¹ The ACC/AHA note that CKD is already a risk enhancer. If there is still uncertainty regarding risk estimate, American guidelines allow for reclassifying up or down with CAC.⁹

DIABETES MELLITUS. Another special group of patients are those with DM, a cohort thoroughly discussed by the CPGs included in this paper. Individuals with diabetes present with a risk for CV events comparable to those for patients with an actual ASCVD history. Thus, the presence of any CAC in individuals with DM equates with a higher risk of all-cause mortality, and CAC scoring becomes of vital importance as a risk stratifier.⁴⁶

FIGURE 7 The SCCT Guidelines Endorse CAC in the 5% to 20% ASCVD Risk Group

Score	Risk	Treatment Recommendation
0	very low	statin not recommended ^a
1-99	mildly Increased	moderate intensity statin if <75th%; moderate to high intensity if >75th%
100-299	moderately increased	moderate to high intensity statin + ASA 81 mg
>300	moderate to severely increased	high intensity statin + ASA 81 mg

This figure endorses CAC score-determined risk classifications and treatment recommendations in the 5% to 20% ASCVD risk group.

^aExcluding familial hypercholesterolemia. Reprinted with permission from Hecht *et al*.¹⁷ Abbreviations as in [Figures 1, 5, and 6](#).

The ESC/EAS guidelines indicate that young patients (type 1 DM <35 years of age, type 2 DM <50 years of age), with DM duration <10 years and without other risk factors, are considered at low-moderate risk for ASCVD.¹¹ Within this patient segment, European guidelines suggest that individuals may benefit from CAC scoring to up- or down-classify their level of risk standing.¹¹ The CSANZ describes parallel recommendations: lower-risk patients between 40 and 60 years of age with DM may similarly benefit from CAC scoring.¹³ The CCS echoes the ACC/AHA and denotes that intermediate risk factors, including impaired fasting glucose (in men at or older than 50 years of age and women at or older than 60 years of age) along with a risk modifier of CAC >0, favor the use of statins.¹⁰ The ACC/AHA further elaborate that clinicians should not down-classify risk in diabetic patients who have a CAC of zero due to the potential presence of noncalcified plaques.⁹ Consensus among international guidelines supports that, in patients with DM that are determined to be low-to-moderate risk, CAC is importantly indicated to further stratify atherosclerotic risk assessment.

In more severe and high-risk DM patients, however, the CPGs described previously trend toward immediate statin therapy as opposed to preventive CAC score assessment. The CCS recommends that patients with DM over 40 years of age (or over 30 years of age with at least 15 years' duration) should initiate statin therapy immediately.¹⁰ Similarly, the CSANZ defines this group as diabetics over 60 years of age or diabetics with albuminuria, and also echoed the

initiation of statin therapy.¹³ The ESC/EAS indicate that patients with DM and target organ damage, DM >10 years, or early onset of type 1 DM of long duration (>20 years) should receive immediate attention that does not stipulate preventive calcium scoring.¹¹ In instances of longstanding or more severe forms of diabetes, immediate treatment is deemed the most necessary course of action, and CAC remains a vital adjudicator for up- or down-risking intermediate-group patients.

The NLA similarly offers detailed recommendations for CAC in patients with DM, stratified uniquely by age, risk severity, and lipid thresholds. The NLA's guidelines are highly specific. For adults 40 to 75 years of age with DM and an LCL-C 70 to 189 mg/dL, the NLA indicates a moderate- or high-intensity statin regardless of CAC score.¹⁶ For adults 40 to 75 years of age with DM who are preparing to initiate statin therapy, a CAC >100 helps adjudicate high-intensity statin use.¹⁶ For adults 30 to 39 years of age with long-standing DM (type 1 diabetes of >20 years or type 2 diabetes of >10 years) and risk factors or microangiopathy, the NLA advocates CAC scoring to facilitate ASCVD risk stratification and shared decision making with regard to statin treatment. Last, in adults older than 75 years with type 2 diabetes (for whom whether to employ a statin for primary prevention remains uncertain), the NLA recommends CAC scoring to aid statin adjudication.¹⁶

GENDER DIFFERENCES. In the last few decades, significant sex-specific differences in the epidemiology of CVD have also been studied and established.^{47,48} Although they develop CVD approximately 10 years

FIGURE 8 The ACC/AHA Recommendations for Aspirin Use

COR	LOE	Recommendations
IIB	A	1. Low-dose aspirin (75-100 mg orally daily) might be considered for the primary prevention of ASCVD among select adults 40 to 70 years of age who are at higher ASCVD risk but not at increased bleeding risk. ^{54,6-1-54,6-8}
III: Harm	B-R	2. Low-dose aspirin (75-100 mg orally daily) should not be administered on a routine basis for the primary prevention of ASCVD among adults >70 years of age. ^{54,6-9}
III: Harm	C-LD	3. Low-dose aspirin (75-100 mg orally daily) should not be administered for the primary prevention of ASCVD among adults of any age who are at increased risk of bleeding. ^{54,6-10}

The figure elucidates American recommendations for aspirin use. Notably, aspirin pharmacotherapy is only recommended for adults 40 to 70 years of age, with high ASCVD risk but no increased bleeding risk. Referenced studies that support recommendations are summarized in [Online Data Supplements 17 and 18](#). Reprinted with permission from Cainzos-Achirica et al.⁵⁷ COR = class of recommendation; LOE = level of evidence; other abbreviations as in [Figure 1](#).

later in life than men, women have a 2× increased risk of CV death as compared with men with the same CAC burden.⁴⁷ Atherosclerotic imaging risk markers are similarly correlated with higher risk of CHD events in women than men.^{48,49} The CSANZ emphasizes that FRS frequently underestimates women's risk, even in the presence of CAC >100 or CAC >75th percentile.^{13,50} In fact, a MESA study of FRS-allocated low-risk women found 6% with CAC >100 and 4% with CAC >300.⁵¹ Citing that most women under 60 years of age are stratified as low risk by the FRS, the CSANZ guidelines therefore suggest CAC for those with 6% to 10% 10-year risk.¹³

Although studies indicate that CAC screening is equally accurate in allocating risk in women and men, data on gender-informed CAC parameters for predicting ASCVD risk are scarce.^{48,49} To this point, major international CPGs have yet to include detailed recommendations for gender-based CAC stratification. Additional data on long-term CV risk among women versus men based on CAC measures are imperative to focus preventive strategies of care.

CAC AMONG YOUNGER AND OLDER AGE GROUPS

Recommendations stratified by age are strongly consistent when evaluating a 40- to 75-year-old patient population classified with intermediate ASCVD

risk. The ACC/AHA, CSANZ, ESC/EAS, and CCS guidelines all promote CAC scoring to guide pharmacotherapy if patients are between 40 and 75 years of age, if patients are asymptomatic, or if risk is calculated to be intermediate or uncertain.⁴ CAC's immense benefit comes from its ability to reclassify this intermediate-risk patient population into either a lower- or higher-risk pool.⁴ The NICE guidelines are similar to those discussed for this age group but allow instead for CAC scoring among all asymptomatic patients with suggested electrocardiography changes for ischemia.¹²

YOUNGER PATIENT POPULATION. Guidelines differ, however, when discussing CAC scoring among a younger patient population. For low-risk individuals under 45 years of age, the ACC/AHA and CCS use CAC scoring more sparingly. They reserve this screening instead for younger patients with increased risk factors. For this subgroup, the ACC/AHA recommends that ASCVD risk factors be evaluated every 4 to 6 years and that CAC scoring be performed if there are risk factors including history of hyperglycemia, hyperlipidemia, hypertension, or smoking.⁹ CCS guidelines are similar for this age group. They too consider CAC scoring in individuals with a strong family history of premature CVD events, smoking history, diabetes, hypertension, or genetic dyslipidemias.¹⁰ These guidelines each follow results and recommendations from the CARDIA (Coronary Artery Risk Development in Young Adults) trial. The CARDIA trial indicated that CAC >0 is common among individuals 32 to 46 years of age with risk factors and warrants follow-up.⁵² Unlike American and Canadian recommendations, The CSANZ guidelines suggest initiating the assessment of CV risk via CAC score at 45 years of age.^{23,53}

The ESC/EAS guidelines also utilize age stratification for predicting ASCVD risk. In fact, ESC/EAS prefer the CV risk age, with accounts for individual risk factors.¹¹ Still, the ESC/EAS has not yet endorsed the use of CAC scoring in younger or lower-risk individuals due to lower prognostic yield, associated costs, and radiation hazards.¹¹ The NICE guidelines employ CAC scoring as a "gatekeeper" for younger patients presenting with angina and intermediate CVD risk.^{12,54} The NICE promotes further investigation and imaging for all symptomatic individuals, not limited to computed tomography angiography.^{12,54}

The NLA similarly advocates CAC scoring in adults <40 years of age selectively, only for patients with multiple major ASCVD risk factors or with a family history of premature ASCVD.¹⁶ For these selected adults, the NLA recommends that CAC >0 favors lifestyle therapy up-regulation and risk

stratifying to more intensive CVD-preventive therapies.¹⁶

OLDER PATIENT POPULATION. For individuals >75 years of age, guidelines worldwide acknowledge the utility of CAC in reclassifying CV risk and predicting CV mortality.⁴⁰ Yet, CPGs do employ slight variations in their overall approach to CAC screening within this population.

The ACC/AHA utilize CAC scores to assist risk reclassification among this older patient demographic. Identifying atherosclerotic plaque subsequently allows for the downgrading or upgrading of risk and the deferral or initiation of pharmacotherapy, respectively. More specifically, the ACC/AHA guidelines state that for adults 76 to 80 years of age with an LDL-C level of 70 to 189 mg/dL, CAC of 0 warrants the deferral of statin therapy.⁹ The NLA similarly specifies an age range of 76 or 80 years, in which CAC scoring may be selectively used to reclassify ASCVD risk and facilitate statin treatment decisions.¹⁶

The CCS guidelines, in contrast, use 40 years of age as a point of reference. The Canadian recommendations suggest that individuals ≥ 40 years of age who are asymptomatic and at intermediate risk should receive CAC scoring.¹⁰ However, individuals ≥ 40 years of age who are high risk, asymptomatic and low risk, or on statin therapy do not necessarily require CAC screening. Of course, a genetic cause or family history of premature ASCVD is an exception.¹⁰

The CSANZ guidelines recommend that, before CAC screening is performed for those older than 75 years of age, CVD risk should first be calculated via the National Vascular Disease Prevention Alliance risk assessment. However, if personal risk factors are present, CSANZ acknowledges that immediate CAC screening is beneficial to reclassify individual risk.⁵⁵ ESC and NICE guidelines, in contrast, have not put forth any recommendations for CAC scoring in individuals over 75 years of age.^{11,12} As Chinese and Japanese guidelines do not specifically discuss CAC score with age stratification, these CPGs do not include CAC guidelines for younger or older populations.^{19,26}

CAC IN GUIDING STATIN THERAPY

CAC as a mean to guide statin therapy is a vital proponent among the international CPGs reviewed in this paper, as indicated in [Table 2](#). CAC screening is an effective reclassification tool to categorize asymptomatic patients into low-, intermediate-, and high-risk groups. CAC is an essential platform for

individualized CV care, providing clinicians the tools to alter statin therapy via personalized CAC scores. According to CAC score and associated risk group, patients can be subsequently up- or down-risked and statin therapy deferred or initiated.⁴

Most CPGs agree that a reported CAC score of 0 (with all other ASCVD risk factors remaining low) is reason to downgrade risk and withhold statin therapy. The CCS makes an exception and adds that statin therapy should be considered in patients with zero CAC, if positive for the following risk factors: history of cigarette smoking, diabetes, poorly controlled hypertension, genetic dyslipidemias such as familial hypercholesterolemia or elevated lipoprotein(a), or strong family history of premature ASCVD events.¹⁰ Only the ESC/EAS guidelines differ slightly; European agencies do not outline a recommendation for downgrading risk and deferring statin therapy within a zero CAC demographic.⁵⁶

For the CAC 1 to 99 subgroup, the ACC/AHA justify initiating statin therapy in patients ≥ 55 years of age.⁹ Canadian guidelines recommend that this CAC range allows for personalized decision making, as CV risk remains intermediate. If therapy is withheld, the CCS advises close follow-up.¹⁰ The CSANZ advocates against aspirin and statins for this CAC = 1 to 99 subgroup.^{13,55} Of note, the ESC/EAS do not explicitly describe this CAC score range.⁵⁶

The CAC >100 cohort is generally consistent among CPGs for adjudicating statin use. The ACC/AHA, CCS, and NICE all justify statin therapy with CAC above 100. The CSANZ, in contrast, considers 101 to 400 and <75th percentile as only intermediate risk.¹³ However, for CAC scores between 101 and 400 and >75th percentile, the CSANZ advocates statin therapy.¹³ The ESC guidelines promote reclassification of patients with CAC >100 and LDL-C levels <70 mg/dL into a high-risk category. Though it is implied, the ESC does not explicitly discuss guidance on statin therapy after up-risking patients.¹¹

The Japanese guidelines acknowledge the benefit for CAC score in adjudicating statin use. However, the agency notes a need for further studies to understand the prognostic value of CAC in predicting CVD morbidity and mortality among their unique Japanese population.¹⁵ The correlation of CAC with nuclear magnetic resonance measurements was comparable but not significant when compared with standard lipids.²⁶ Thus, Japanese CPGs provide no further information on CAC score and statin therapy. Instead, they utilize cholesterol levels and Suita scores to guide recommendations for pharmacotherapy.¹⁵

CAC IN GUIDING ASPIRIN THERAPY

Next, this review transitions to discuss aspects of downstream care after CAC testing, including aspirin and blood pressure management. It is important to note that specialty guidelines (ie, the NLA) have, of course, covered these topics at great length. However, the main international guidelines largely do not comment. In this regard, it is also important to recognize that many papers reviewed here were released after the original guideline documents were published. Thus, many specialized recommendations for aspirin and antihypertensive therapy in context of CAC testing, for instance, could not have been included within the less recently updated CPGs.

Like with statin treatment, CAC is an important risk adjudicator in guiding aspirin pharmacotherapy among major CPGs worldwide. The ACC/AHA Primary Prevention Guidelines recommend low-dose aspirin only among adults 40 to 70 years of age (**Figure 8, Central Illustration**), who have increased ASCVD risk but no heightened bleeding risk.^{9,57} ESC CPGs similarly support a daily dose of 75 mg aspirin for prevention of ischemic events in CAD patients with or without a history of myocardial infarction.¹¹ Both agencies only recommend aspirin for high-risk patients, although most CHD events occur in low- to intermediate-risk individuals.^{9,58} Moreover, neither American nor European guidelines suggest an explicit means for identifying these patient subgroups. To this end, numerous studies have since proposed CAC as a well-established means for guiding aspirin allocation in primary prevention.⁵⁷⁻⁵⁹ Utilizing aspirin meta-analysis data on CVD relative risk reduction and bleeding risk, Cainzos-Achirica et al,⁵⁷ Miedema et al,⁵⁸ and Greenland et al³ each conclude that CAC score can identify subcohorts of individuals (in both overall and within estimated risk strata) who may benefit from aspirin therapy. For subgroups with CAC ≥ 100 (especially those with CAC > 400), aspirin yields a net benefit regardless of risk factors. For CAC = 0, however, the risk of bleeding remains larger than aspirin's potential benefit.^{3,57,58} Ajufo et al⁵⁹ similarly determine that aspirin is beneficial for CAC = 0, only if patients have $> 20\%$ ASCVD risk. Regardless of CAC score, aspirin is net harmful in those with $< 5\%$ risk or with increased bleeding risk.⁵⁹ These data contributed to the American SCCT guidelines, which now recommend consideration of aspirin therapy for all individuals with CAC > 100 .¹⁷ To this end, patients who meet the

ACC/AHA's and ESC/EAS's criteria for low-dose aspirin therapy may benefit from CAC score quantification and subsequent individualized aspirin allocation. Applying the American and European recommendations alongside CAC empowers a personalized approach for aspirin therapy in primary ASCVD prevention.

The NICE, in contrast, considers aspirin therapy only if the patient's chest pain is likely stable angina.¹² The UK guidelines strongly assert that routine antiplatelet treatment is not appropriate for primary CVD prevention, except for those with high stroke or myocardial infarction risk.¹² In this regard, the NICE only specifies CAC as a tool for adjudicating statin allocation; CAC recommendations for aspirin use are not mentioned. Similarly, the Japanese guidelines do not discuss CAC in guiding aspirin therapy.²⁶

Unlike the aforementioned CPGs, the CSANZ definitively recommends CAC for guiding aspirin allocation.¹³ In tandem with statins, the CSANZ suggests that patients at moderately high or high risk based on CAC score (CAC 101-400 and CAC > 400 , respectively) should receive preventive aspirin therapy. The CSANZ does not recommend either aspirin or statins for CAC < 100 .¹³ Like the CSANZ, the Chinese guidelines definitively discuss CAC as an arbitrator for aspirin allocation.⁶⁰ Chinese CPGs advocate for primary prevention via aspirin for adults 40 to 69 years of age, who have high risk of ischemia and low risk of bleeding. Recommendations state that high-risk ASCVD groups, classified by CAC score ≥ 100 , may consider taking low-dose aspirin (75-100 mg/d) for primary prevention.⁶⁰

Like the Australian and Chinese CPGs, the NLA explicitly advocates CAC for guiding aspirin use, as indicated in **Figure 5** and the **Central Illustration**. In fact, the NLA statement is one of the few that includes detailed recommendations on both aspirin and antihypertensive therapy after CAC testing. At length, this guideline discusses the interaction of ASCVD risk and CAC score in predicting net benefit of aspirin therapy in primary prevention.¹⁶ The NLA cites Cainzos-Achirica et al⁵⁷ and numerous others, evidencing that aspirin therapy risks outweigh benefits when stratifying patients via ASCVD risk score.¹⁶ In contrast, CAC ≥ 100 appears to identify a subgroup of patients in which benefit of aspirin therapy exceeds bleeding risk.^{16,57} To this end, the NLA advocates that aspirin 81 mg daily is reasonable for patients with CAC ≥ 100 , who do not have bleeding-related contraindications.¹⁶

UTILIZING CAC TO GUIDE PHARMACOLOGICAL TREATMENT OF EARLY HYPERTENSION AND SELECTION OF BLOOD PRESSURE GOALS

CPGs tend to agree that ASCVD risk assessment in guiding the decision to pharmacologically treat early hypertension is of vital importance. However, like many recommendations for aspirin therapy, the international guidelines do not designate coronary visualization for risk stratification. The ACC/AHA suggests ASCVD risk assessment for informing hypertension therapy in adults with elevated blood pressure or low-risk stage 1 hypertension, and suggests that a high CAC may warrant more aggressive blood pressure control.⁶¹ European guidelines similarly concur that CV risk assessment systems are vital but still recommend PCE for management of arterial hypertension.⁶² Instead of suggesting coronary visualization via CAC, the ESC designates the SCORE system to adjudicate risk level and inform antihypertensive therapy.⁶² Similarly, none of the Canadian, Australian, UK, Chinese, or Japanese CPGs specify CAC to help allocate hypertension treatment. Especially for an intermediate-risk cohort, stratification of risk and subsequent therapy remains unclear among these international agencies.

A multitude of literature, however, has since analyzed CAC as a tool to help inform the selection of blood pressure goals and decide the pharmacological treatment of early hypertension. The current controversy over optimal SBP threshold for initiating or intensifying treatment spurs questions about whom to treat, particularly among intermediate-risk patients with prehypertension or mild hypertension.³⁰ In this regard, there is heightened interest in global ASCVD risk estimates alongside SBP to guide personalized therapy. McEvoy *et al*,³⁰ for instance, compared multivariable-adjusted HRs for ASCVD or heart failure, after stratifying by CAC. The project found that coronary calcium stratifies event risk in patients with SBP <160 mm Hg.³⁰ Increasing HRs were found for events with CAC 1 to 100 (HR: 1.7 [95% CI: 1.0-2.6] or HR: 2.0 [95% CI: 1.1-3.8]) and CAC >100 (HR: 3.0 [95% CI: 1.8-5.0] or HR: 5.7 [95% CI: 2.9-11.0]), all relative to CAC = 0.³⁰ In this regard, combining CAC score with assessment of ASCVD risk offers a tool to guide personalized SBP goals in intermediate-risk subgroups.^{30,61} For statins, aspirin, and antihypertensive therapies, CAC offers a potentially crucial model to identify candidates who may benefit from initiation or intensification of medical management.

As noted previously with aspirin management, the main international guidelines largely do not comment

on CAC with regard to reclassifying blood pressure management. Seeing as the papers reviewed previously were released after most CPGs were published, they could not have been included in major guideline recommendations. Uniquely, the NLA discusses the role of CAC score in deciding pharmacological treatment of early-stage hypertension at great length. The NLA notes that CAC appears to reclassify risk in patients with stage 1 hypertension and thus may prove useful for guiding decisions about pharmacotherapy.¹⁶ Specifically, CAC = 220 identifies patients with annual ASCVD risk similar to those enrolled in the SPRINT (Systolic Blood Pressure Intervention Trial) trial. To this point, the NLA advocates that CAC may be useful in guiding blood pressure targets.¹⁶

IMPORTANT ASPECTS AND QUALITY IMPROVEMENT OF CURRENT CLINICAL CAC APPLICATIONS

CAC COST AND INSURANCE COVERAGE. The CAC test averages 10 minutes total for the patient, including about 1 minute of actual scan time. Calcium score screenings are now covered more widely, as the 2018 guidelines included this test within their algorithm of care. Anthem, UnitedHealthcare, and Aetna all have favorable coverage decisions, and Medicare pays in certain states. Texas covers CAC scanning by state law. However, most HMOs and some insurance carriers still do not cover this test, and for those patients, it may be available only on a self-pay basis. This cash price ranges from approximately \$75 to \$250.

BARRIERS TO ADOPTION OF GUIDELINES. The main barrier of utilizing CAC score is lack of coverage by many health insurance plans and its designation by these companies as experimental. Radiation exposure (although minimal at <1 mSv) is another concern, but this is largely due to citing of earlier doses, which are higher and no longer relevant.

STRATEGIES TO INCREASE UTILIZATION. CPGs from the United States and Europe have universally recommended risk factor equations that use office-based measurements of age, smoking history, presence or absence of diabetes, blood lipids, and blood pressure as mainstays of clinical risk assessment. Moreover, all American and European CPGs now include CAC in their risk assessment. To this end, CAC will undoubtedly increase in utilization as physicians begin to adapt to the new clinical pathways.

IS THERE A NEED FOR FURTHER TRIALS? Based on single-center and multicenter clinical and population-based studies with short-term and long-term outcomes data (up to 15 years' follow-up), CAC

scoring has emerged as a widely available, consistent, and reproducible means of assessing risk of major CV outcomes. CAC has proven especially useful in asymptomatic people for planning primary prevention interventions such as statins and aspirin. Additional research and rigorous data are vital for younger age groups and the female population.

Ongoing randomized trials in Europe, United States, and Australia studying CAC versus no CAC to evaluate for outcomes will answer any lingering questions about the utility of the test, and these are due out in the next few years. One such ongoing European trial is the DANCAVAS (Danish Cardiovascular Screening) trial, investigating whether multifaceted advanced CV screening will prevent CV events and whether possible health benefits are cost-effective.⁶³ The ROBINSICA (Risk or Benefit IN Screening for CArdiovascular Disease) trial is awaiting final outcome results, after comparing traditional risk scores versus CAC.⁶⁴ American trials are also extensive, including the CorCal (Effectiveness of a Proactive Cardiovascular Primary Prevention Strategy, With or Without the Use of Coronary Calcium Screening, in Preventing Future Major Adverse Cardiac Events) trial.⁶⁵ The ongoing CorCal trial tests effectiveness of a proactive CV primary prevention strategy with or without CAC, compared with current standard care in preventing major adverse cardiac events.⁶⁵ Also ongoing is the ACCURATE (Assessment of Patients With suspecTed Coronary Artery Disease by Coronary calciUm fIRst strATegy vErsus Usual Care Approach) trial, examining whether a CAC-first strategy may be used as a gatekeeper for progression to the cardiac positron emission tomography stress test. Australian CAUGHT-CAD (Coronary Artery calcium score: Use to Guide management of Hereditary Coronary Artery Disease) trial examines coronary calcium for risk evaluation and prevention in patients with a family history of CAD.⁶⁶

Last, there is also an interest in studying role of CAC in predicting non-CVD outcomes. CAC has been shown to predict CKD, chronic obstructive pulmonary disease, hip fracture, cancer, and dementia independent of age, sex, and risk factors.³

CONCLUSIONS AND CLINICAL IMPLICATIONS

In summary, the CPGs compared in this review hold more similarities than differences from both a clinical and practical perspective (**Central Illustration, Figure 3, Table 1**). All CPGs recommend statins for primary prevention and CAC as a reasonable risk adjudicator. Importantly, clinical practice recommendations worldwide emphasize shared decision

HIGHLIGHTS

- Guidelines worldwide emphasize the importance of CAC in up- or down-risking of patients for ASCVD risk and for initiating or prolonging preventive pharmacotherapies.
- International guidelines empower a dynamic clinician-patient relationship and advocate for individualized discussions regarding disease management and pharmacotherapy treatment.
- Understanding the parallels among international CAC guidelines is essential for clinicians to individualize further medical management.

making between clinician and patient. With these commonalities in mind, international medical practice should be rooted on early detection of individuals with increased CVD risk via CAC score.

This review does find some differences in precise CAC score intervals, risk cut points, treatment thresholds, and stratifiers of specific patient subgroups among international guidelines (**Central Illustration, Figure 3, Table 1**). Understanding both similarities and differences among international CPGs is therefore vital for physicians to correctly determine personalized statin therapy and subsequent management. It is imperative to unify universal ASCVD risk assessment and establish global solutions for CPGs on CAC scoring. Notably, this review underscores that additional research and rigorous data are vital for younger age groups and the female population. By summarizing the framework behind global guidelines of CAC in ASCVD risk assessment, this analysis allows for applications in both the clinical setting and preventive therapy. Helping physicians understand universal differences and similarities is key to refine risk detection, focus preventive strategies of care, and empower the most fitting choices in CVD prevention and management.

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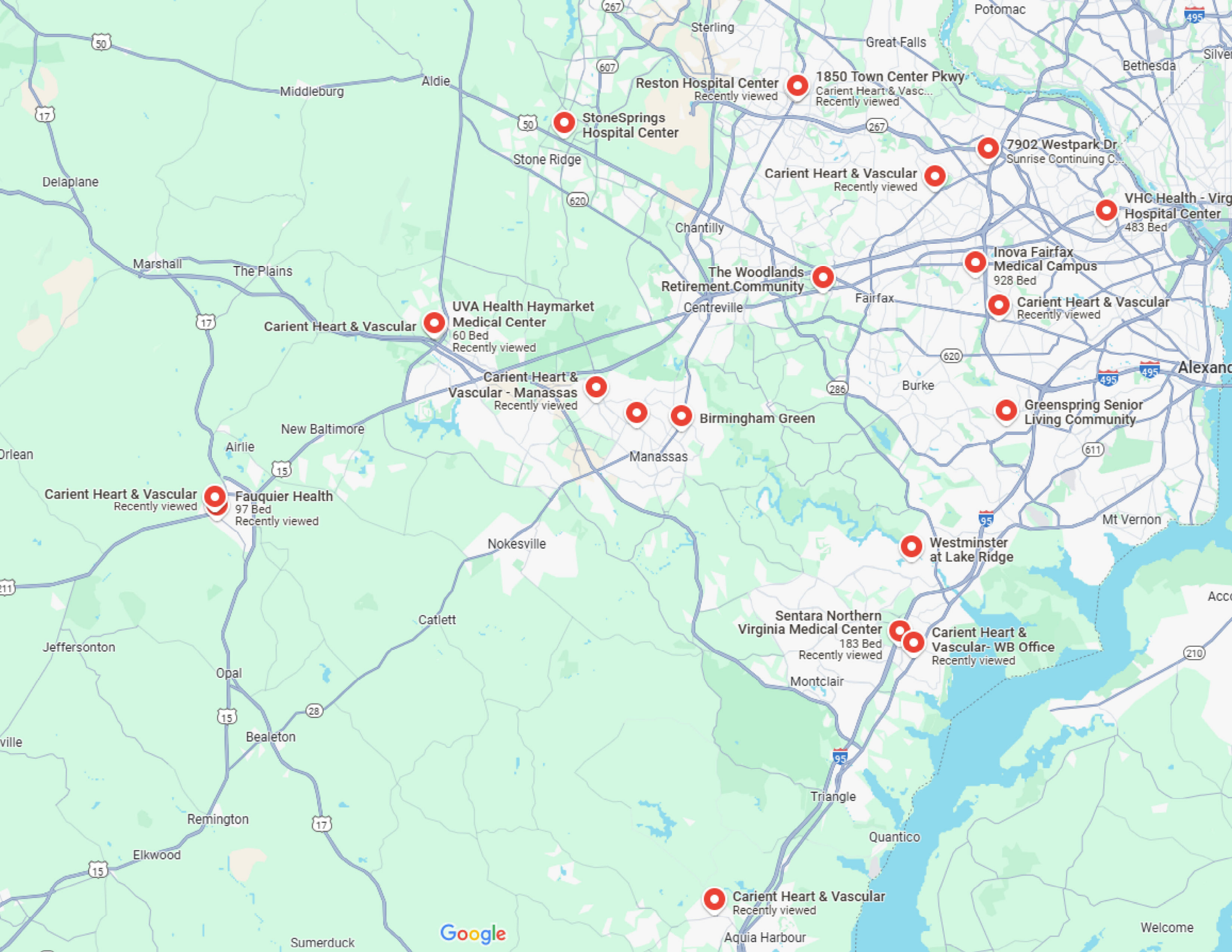
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KEY WORDS American College of Cardiology/American Heart Association (ACC/AHA), atherosclerotic cardiovascular disease, Canadian Cardiovascular Society

(CCS), cardiovascular disease, Cardiac Society of Australia and New Zealand (CSANZ), Clinical Practice Guidelines, computed tomography angiography, coronary artery calcium, European Society for Cardiology/European Atherosclerosis Society (ESC/EAS), Japanese Atherosclerosis Society (JAS), National Institute for Health and Care Excellence (NICE)



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Responses to Completeness Questions

COPN Request No. VA-8813

Carient Heart & Vascular, LLC Planning District 8

Introduce CT imaging for calcium scoring using the CT portion of the PET/CT

Supplemental Questions / Discussion Points

Consolidated List of Questions with Health Systems Agency of Northern Virginia (HSANV)

*The following questions are keyed to the **Roman numeral sections** and **letter and number-designated subsections** of the Certificate of Public Need (COPN) application form. Questions are further identified by a **number in parentheses** when there is more than one question for a particular subsection of the application form.*

SECTION I: FACILITY ORGANIZATION AND IDENTIFICATION

I.G.c. Please identify US Health Virginia (Rockville, MD) and the relationship between Carient and US Health.

Answer: US Health Virginia, LLC is the sole owner of Carient Heart & Vascular, LLC. US Health Partners, LLC is the national holding company for operations.

SECTION II: ARCHITECTURE AND DESIGN

II. H. 3. Please confirm that the target date of opening is immediately on receipt of the certificate.

Answer: As soon as approval is received from DCOPN, our nuclear medicine techs will submit their applications for Limited Radiologic Technologist with Virginia Department of Health Board of Medicine. Their current education meets the requirements for Limited Radiologic Technologist, and once they have received authorization from the board, they will take the AART exam.

The FAQ section on the Board of Medicine Website (link below), states: "Question: May I take x-rays under the supervision of a licensed physician without a radiologic technologist-limited license? Answer: Only if you have submitted an application and received authorization for training from the board." While they are completing the licensure requirements, they will be able to perform the CACS testing.
<https://www.dhp.virginia.gov/Boards/Medicine/AbouttheBoard/RegulatedProfessions/RadiologicTechnology/>.

SECTION III: SERVICE DATA

III. A. Please provide the proposed charge for calcium scoring cases/procedures.

Answer: \$95 per patient.

Will charity care policies and practices apply to calcium scoring patients? Please explain.

Answer: Yes, Carient will follow the same Charity Care guidelines and expectations that were a condition of approval for the PET camera (COPN VA-04642). Carient currently has partnerships with Prince William

Free Clinic, Fauquier County Free Clinic, Greater Prince William Health Center, Sentara Mobile Charities, Mother of Mercy Free Medical Clinic, and Culmore Clinic to provide charity care.

III. F. 5. Should the 4:15 time listing in the calcium scoring schedule in the appointments be 4:45 p.m.?

Answer: Yes, the 4:15 time listed in the calcium scoring schedule was a typo and should be 4:45 p.m.

III. G. Volumes appear to include both the Vienna and Manassas sites. Please provide 2023 and 2024 service volumes separately for the Manassas site.

Answer: The chart below breaks out the SPECT Volume at all four locations and the PET volume at Manassas and Vienna.

SPECT per Location	2023	2024
Manassas	689	677
Vienna	245	314
Woodbridge	277	265
Warrenton	37	73
TOTAL	1248	1329
PET per Location		
Manassas	3759	3467
Vienna	543	1082
TOTAL	4302	4549

SECTION IV: PROJECT JUSTIFICATION AND IDENTIFICATION OF COMMUNITY NEED

No questions.

SECTION V: FINANCIAL DATA

V. H. 3. Please provide the facility's estimated income, expense and capital budget for the first two years of operation after the proposed project is completed.

Carient Calcium Score P&L

Revenue

Annual Volume

Y1	600	50 combined per month
Y2	600	50 combined per month

Annual Volume Location Mix

Manassas	70%
Vienna	30%

Revenue per Unit (CPT 75771 Medicare Allowable)

Manassas	\$97	Novitas 2025 Allowable (Global)
Vienna	\$115	Palmetto 2025 Allowable (Global)

Effective Revenue per Unit \$103

Patient Cash Pay Rate \$95.00

Total Annual

	Year	Year 2
Revenue	\$57,000 to \$61,800	\$57,000 to \$61,800
Charity Care	(\$3,300)	(\$3,300)
Operating Expenses	-	-
One Time Expense	(2,760)	
Profit (Loss)	\$50,940 to \$55,740	\$53,700 to \$58,500

Notes:

Revenue: We have provided a range based on patient cash pay and Medicare. \$57,000 based on 600 procedures at a patient cash pay rate of \$95 \$61,800 based on 600 procedures at an effective unit rate of \$103

Charity Care: 5% of Revenue

Operating Expenses: No incremental expenses to operate the existing PET/CT

One Time Expenses: Application and technologist certifications