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LETTER FROM THE CHAIR

As the outgoing Chair of the American Heart Association's Advocacy Coordinating Committee (AdCC), it is my pleasure to present you with the final Policy Report of my term.

This edition includes the most recent policy publications of the department, including New and Emerging Tobacco Products and the Nicotine Endgame. This report reviews the scientific landscape on this urgent public health issue and offers implications and suggestions for practice, policy and future research.

Also included in this issue is an update to AHA's 2005 policy statement on Stroke Systems of Care. Recommendations for the Establishment of Stroke Systems of Care: a 2019 Update assesses the important scientific and clinical advances in the field over the last 13 years and provides recommendations based on improvements.

Next, you will find an update to AHA's policy statement on Food Package and Retail Shelf Icon Systems. Evolving research, public demand and changes in the marketplace have created a window of opportunity for the establishment of a unified, nationwide, science-based front of package food labeling program and icon system to highlight foods that are "good for you" and those that should be avoided.

Our statement on Remote Patient Monitoring (RPM) highlights the use of RPM technology as having the ability to reduce readmissions as well as health care costs while pointing out that there is still room to grow. As a result, we provide this new set of principles that should be used to guide our policy work on RPM technologies to best serve patient care.

New in this issue is the policy position on balance billing or surprise medical bills. AHA has developed principles to frame our advocacy work in support of patient-centered and consumer-focused protections from surprise balance billing.

As I become the association's 2019-20 President, it is my pleasure to hand over the AdCC reins to Dr. Keith Churchwell, executive director and senior vice president for Heart and Vascular Services at Yale New Haven Health. Keith has been a dedicated AHA volunteer, a member of the National Board of Directors, and recently led our health equity task force to examine priorities for the Association as we embed an equity focus and consideration of the social determinants of health in all of our work. I am excited to see the Committee flourish under his leadership.

Sincerely,

Robert Harrington, MD Chair, Advocacy Coordinating Committee

HOW TO USE THIS REPORT

- Use data from the policy report in your organization's internal communications to support statements regarding cardiovascular disease (CVD) and brain health.
- Send a copy to your professional contacts in support the Association's mission or have a stake in cardiovascular and brain health.
- markets by referencing how Association policy translates into improved health outcomes and can be tied to broader health policy issues.

RECOMMENDATIONS FOR THE ESTABLISHMENT OF STROKE SYSTEMS OF CARE



Someone in the US has a stroke every 40 seconds and someone dies of a stroke every four minutes.² About 7.2 million Americans aged ≥20 years have had a stroke.² Approximately 800,000 people in the US have a new or recurrent stroke each year.² Optimized stroke systems of care that span health care delivery from primordial prevention, to rehabilitation and recovery can improve communication across patient care domains, identify relevant performance measures as well as key patient-related and systemrelated outcomes, and provide patients, caregivers and providers with tools needed for prevention, treatment and recovery.

"With the rapid evolution of stroke systems of care in recent years, this policy statement and its recommendations reflect how far we have progressed in the previous decade and what still needs to be accomplished in acute stroke care." — Opeolu Adeoye, MD, FAHA and Lead Author

As an update to the AHA's 2005 policy statement on stroke systems of care, the aim of *Recommendations for the Establishment of Stroke Systems of Care* is to assess the important scientific and clinical advances in the field in the 13 years since and provide recommendations based on these improvements. The recommendations span primordial and primary prevention, acute stroke recognition and activation of emergency medical services (EMS), triage to appropriate facilities, designation of and treatment at stroke centers, secondary prevention at hospital discharge, and rehabilitation and recovery. New recommendations were included to show the field's advancements in community education programs, telestroke, and the inclusion of Thrombectomy-capable Stroke Center as a new certification for identifying hospitals that meet rigorous standards for performing endovascular thrombectomy.



3 THINGS TO KNOW

Programs geared toward further improving the knowledge of the public, encouraging primordial and primary prevention, advancing and facilitating acute therapy, improving secondary prevention and recovery from stroke, and reducing disparities in stroke care should be actively developed in a coordinated and collaborative fashion by providers and policymakers at the local, state and national levels.

The Comprehensive Stroke Center, Primary Stroke Center, Thrombectomy Capable Stroke Center, and Acute Stroke Ready Hospital framework provides an appropriate platform for the data-driven development of hospital-based processes of care and outcome metrics.

In order to standardize post-acute care after stroke discharge, stroke centers should comprehensively screen for postacute complications, provide individualized care plans for patients during the transition of care, provide referrals to community services, and reinforce secondary prevention and selfmanagement of stroke risk factors and lifestyle changes to decrease the risk of recurrent stroke.

NEW AND EMERGING TOBACCO PRODUCTS AND THE NICOTINE ENDGAME

3 THINGS TO KNOW

The 2011–2018 National Youth Tobacco Surveys showed a dramatic increase in adolescent e-cigarette initiation. During 2017–2018 alone, e-cigarette use rose by 78% in high school students and 48% in middle school students.

The Monitoring the Future Survey releases annual results, surveying over 40,000 8th, 10th, and 12th graders. Recent data for e-cigarettes show the largest one-year increases seen for any substance in the history of the survey.

Noting this unprecedented spike in e-cigarette use, in December 2018, the US Surgeon General issued an advisory for parents, teachers and health professionals about the negative health consequences of e-cigarettes.



"The tobacco endgame is within sight, but the recent surge in youth and adolescent e-cigarette use driven by the tobacco industry's ruthless marketing tactics poses a real threat to achieving this lifesaving goal."

— Dr. John Warner, AHA President

On March 13, 2019 the American Heart Association published a presidential advisory in the journal Circulation about new and emerging tobacco products, and the role of robust regulation and comprehensive tobacco control and prevention in achieving the "nicotine endgame." The paper reviews the scientific landscape on this urgent public health issue and offers implications and suggestions for practice, policy and future research. The ultimate goal is to end to all tobacco and nicotine addiction in the US while first minimizing the use of all combustible tobacco products, such as traditional cigarettes and cigars, and ensuring e-cigarettes and other newer products do not addict a new generation to nicotine. The American Heart Association believes the "tobacco endgame" is within sight. However, that goal is threatened with the recent surge in youth and adolescent e-cigarette use. To achieve the endgame, the American Heart Association advocates for the Food and Drug Administration to vigorously regulate all tobacco products, Federal, state and local governments to implement strong tobacco-control and prevention policies, and the need to educate health care providers, patients, and consumers about the dangers of nicotine addiction from all tobacco products. The paper also calls for global coordination of regulatory efforts to achieve the endgame.



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BALANCE BILLING STATEMENT



For many Americans, an unexpected or surprise medical bill is an expense they simply cannot afford. Often, surprise bills arise from medical care that was unknowingly provided to the patient by an out-ofnetwork physician or at an out-of-network facility. This is an example of "balance billing", which occurs when a provider or medical group, hospital, facility, laboratory or other supplier directly bills a patient for the balance of the amount above what their insurance plan agreed to pay for their medical care. The receipt of a surprise balance bill after a patient has already sought and received care can result in significant financial duress for many Americans.

Several states have passed laws and issued regulations to protect patients from balance bills, however none are comprehensive enough to protect every insured consumer within each state. Due to its preemption clause, even in states where consumer protections exist, ERISA supersedes state law and bars the application of balance billing protections to self-funded plans and the majority of individuals and families with employersponsored insurance.

AHA believes policymakers and other stakeholders must take a multi-faceted approach to comprehensively address balance billing. To that end, we have developed a set of principles to frame our advocacy in support of patient-centered and consumer-focused protections from surprise balance bills:

- Patients and consumers should be held harmless from balance bills in situations that arise from emergencies (including emergency ground or air transportation and transfers) and instances where an insured patient visits an in-network facility for a covered service, but unknowingly receives care from an out-of-network provider.
- Patients should be provided with timely, actionable, and easily understood information to help them avoid using out-of-network services for non-emergent care.
- In non-emergent situations, patients should receive prior notification at the point of care that they will be seen by a noncontracted health professional or are receiving care in an out-of-network setting.
- Policymakers should craft an equitable dispute resolution process that holds patients harmless and takes them out the middle.

Policymakers should ensure that federal remedies do not undermine existing state laws that provide comprehensive

consumer protections, but instead -ensure a minimum standard for patient protections from which states can build on.



¹Kaiser Family Foundation. "2017 Employer Health Benefits Survey." Available at: https://www.kff.org/reportsection/ehbs-2017-section-10-plan-funding/

$\mathbf{3}$ things to know

More than half (57%) of insured Americans have been caught off guard by a medical bill for care they thought would be paid by their insurance plan.

Out-of-network doctors can submit bills up to nearly 100 times higher than the fees paid by Medicare for the same service.

AHA believes patients should have comprehensive protection from surprise balance bills regardless of the type of health insurance plan they are enrolled in or the funding mechanism under which that plan was established.

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NALOXONE IN CPR TRAINING AND AED PLACEMENT

3 THINGS TO KNOW

The opioid crisis calls for comprehensive measures to combat the rising pace of misuse, addiction and overdose related deaths. Even though initial positive results of naloxone access expansion efforts are encouraging, policy makers need more on-going evaluations of such initiatives to guide crucial decisions.

Naloxone is a prescription drug that normally requires a medical professional's prescription for procurement from a pharmacist. It is a safe medication and has not been reported to have produced adverse effects when administered in normal doses.

In emergencies, trained healthcare professionals (or first responders) are permitted to administer naloxone without a prescription. Naloxone access expansion efforts focus on relaxing some or all of these restrictions to ensure the lifesaving agent is more readily available in times of need.



The opioid epidemic, one of the nation's dire public health crises, has had overwhelmingly grave consequences on public health as well as on social and economic well-being. Drug overdose has surpassed motor vehicle and firearms related deaths, suicides and homicides to become the leading cause of injury-related death.¹ Opioid overdoses have been reported to claim over 115 lives each day and their incidence has increased 30 percent during the period between July 2016 and September 2017 in 52 areas in 45 states.² Naloxone is a drug used to counter the effects of an opioid overdose. The American Heart Association (AHA) takes the following position on naloxone availability with CPR/AED equipment:

- The AHA supports integrating guidance on using naloxone within CPR/AED training; the AHA has already done this within Basic Life Support courses and is creating two new opioid education modules for laypeople and for healthcare providers.
- We are not in favor of making naloxone mandatory for those who place AEDs in public facilities (may be a barrier in AED availability if someone doesn't want to store Naloxone).
- But for those who choose to do so, we support integrating naloxone guidance into training and maintenance protocol, which must make mention of naloxone expiration, and could be coupled with periodic AED checks if that is possible.
- It is likely that those who use naloxone in emergency situations are already covered under Good Samaritan Laws.
- We would not proactively open up Good Samaritan Laws to include naloxone, but are supportive of efforts to reaffirm Good Samaritan coverage.



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ISSUE 5, VOLUME 1 · SUMMER 2019

REMOTE PATIENT MONITORING



Remote patient monitoring (RPM) has the potential to reduce initial and secondary readmissions, incidence and mortality rates, and direct and indirect healthcare costs, particularly for such cardiovascular diseases as hypertension, heart failure, atrial fibrillation and stroke. And with the proliferation of wireless medical technology and the movement toward outpatientbased healthcare, the use of RPM technologies has become more attractive to providers and patients alike.

"When used by clinicians, remote patient monitoring can provide a more holistic view of a patient's health over time, increase visibility into a patient's adherence to a treatment, and enable timely intervention before a costly care episode."

However, there are potential pitfalls with the use of RPM that, if not negotiated and understood properly, could lead to deleterious consequences for the patient. As such, this guidance document outlines a set of principles that should be used to guide the manufacture and use of RPM technologies to ensure they produce the best possible outcomes.



3 THINGS TO KNOW

The design and manufacture of RPM technologies should reflect an evidence-based, user-centered model that includes patient-focused behavioral theories and eases the burden on the end-user.

RPM technologies should be fully interoperable. Standards governing interoperability should allow for a flexible definition of a care team and permit data to be shared amongst all relevant entities regardless of the application being used to share the data.

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RPM technologies must include strict standards to verify the accuracy, integrity, and privacy of the data being captured, stored, and transmitted.

PUBLIC CHARGE STATEMENT



The public charge test is a longstanding federal immigration policy that has been applied under numerous administrations for more than 100 years. The term "public charge" is used to define a person who the government deems "primarily dependent on the government for subsistence."³ Since the late 1990s, immigration officials have used two criteria for determining if an applicant will be deemed a public charge: the receipt of public cash assistance benefits such as Temporary Assistance for Needy Families (TANF) or Supplemental Security Income (SSI), or long-term care through Medicaid. If an applicant is found likely to become a "public charge" they are deemed inadmissible to the country or ineligible for lawful permanent residency. Obtaining lawful permanent residency is a key step for immigrants who may eventually seek citizenship through naturalization. Currently, only 3% of noncitizen immigrants use cash benefits,⁴ making admission or green card denials on the grounds of public charge relatively rare.

A proposed rule released in October of 2018 aimed to significantly expand the benefits criteria used by immigration officials to determine if an applicant is a public charge.² This paper discusses how the proposed inclusion of critical safety-net programs such as

3 THINGS TO KNOW

Research shows that programs that help families struggling to afford the basics effectively improve self- sufficiency and have long-term health and psychological benefits for families and children.²

Efforts to reform public charge policy should not impede access to healthcare, housing, nutrition, or any other social determinant of health.

Expanding the benefits criteria for public charge will almost certainly result in farreaching consequences for immigrants that will extend to the healthcare system, workforce, educational attainment, and the public health of our nation.

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(non-emergency and non-long-term care associated) Medicaid, the Supplemental Nutrition Assistance Program (SNAP), Section 8 housing assistance, and Medicare Part D subsidies for prescription drugs, would have broad consequences — not only for prospective immigrants, but also for lawful, working U.S. immigrants and their U.S. citizen children, spouses, and relatives who use public benefits for which they fully qualify. Health coverage losses could reduce access to care, contributing to worse overall health outcomes, particularly for the one in four U.S. citizen children with a noncitizen parent.⁵ Additionally, legal immigrants may be less willing to visit the doctor or seek preventive care, leading to health complications or the development of complex chronic diseases that otherwise could have been mitigated by a visit to a medical professional.

For decades, public charge has been applied in a way that allows immigrants with legal status to access these essential safety-net services and programs without fear of compromising their ability to stay in this country. Tethering an immigrant's usage of basic public benefits to which they are legally entitled, to the ability to obtain lawful permanent residency is not only a dramatic departure from the original intent of these programs, but it is fundamentally at odds with the association's support of policies that promote healthy behaviors, access to quality, affordable healthcare, and overall well-being. We oppose any change to public charge policy that would restrict access to critical support services, cause health coverage losses, lead to negative health outcomes, and force immigrant families to make an impossible choice between financial assistance to meet their basic needs and their ability to stay together or reunite in the United States.

- ² Hoynes, H, Schanzenbach DW, Almond, D. Long-run impacts of childhood access to the safety net. American Economic Review. 2016; 106(4): 903934. https://gspp. berkeley.edu/assets/uploads/research/pdf/Hoynes-Schanzenbach-Almond-AER-2016.pdf
- ³ U.S. Citizenship and Immigration Services. Public Charge Fact Sheet. April 2011. https://www.uscis.gov/news/fact-sheets/public-charge-fact-sheet ⁴ Batalova J, Fix M, Greenberg M. Chilling effects: the expected public charge rule and its impact on legal immigrant families' public benefits use. Washington, DC: Migration Policy Institute; June 2018 https://www.migrationpolicy.org/research/chilling-effects-
- expected-public-charge-ruleimpact-legal-immigrant-families ⁵ Artiga, S, Damico, A, Garfield, R. Potential Effects of Public Charge Changes on Health Coverage for Citizen Children. Kaiser Family Foundation; May 2018. https://www.kff.org/ report-section/potential-effects-of-public-charge changes-on-health-coverage-for-citizen-childrenissuebrief/#endnote_link_257512-5



UPDATE TO THE POLICY POSITION STATEMENT ON FOOD PACKAGE AND RETAIL SHELF ICON SYSTEMS



Consumers, manufacturers, third party organizations, such as the American Heart Association, and retailers realize the benefit of informing consumers how to facilitate healthy purchasing by providing symbols and other messaging on food packaging or retail shelves. Consequently, health-related icons have proliferated in the marketplace across the U.S. and internationally from third-party organizations, retail outlets, and manufacturers. Some publicize the criteria used by their systems and others are proprietary and do not release

their algorithms or criteria to the public. Even if the criteria are transparent, they may vary dramatically across each system.

Evolving research, public demand, and changes in the marketplace have created a window of opportunity for the establishment of a unified, nationwide, sciencebased system. Consumers are increasingly receptive to this type of information to inform and guide their dietary purchasing and choices. The AHA ultimately favors the

UPDATE TO THE POLICY POSITION STATEMENT ON FOOD PACKAGE AND RETAIL SHELF ICON SYSTEMS (CONTINUED)

3 THINGS TO KNOW

According to one consumer survey, "health and nutrition" is now only second to "taste" as the most important attribute when selecting foods and beverages. However, the data also show that consumers are confused about what is healthy a major barrier to making healthier choices.

Recent research indicates that Front-of-Pack (FOP) labeling can influence consumers' understanding of the healthfulness of foods.

Some research indicates that FOP labeling can also influence purchasing patterns. establishment by the U.S. Food and Drug Administration of a directed, standardized, comprehensive front-of-package food labeling program and icon system with unified criteria based upon the best available science and consumer research, featuring consumer education as a primary goal along with healthier food selection and consumption. In the meantime, systems currently in the marketplace and additional research will determine which type of guidance works best for educating the consumer and facilitating healthier food choices.

"The AHA favors the establishment by the U.S. Food and Drug Administration of a directed, standardized, comprehensive front-of-package food labeling program and icon system with unified criteria based upon the best available science and consumer research."

If a single, unified system is created, sufficient resources must be committed to the management and enforcement of the program, criteria, and rules. The system should be generalized to the entire U.S. population (it should not be disease-specific), highlighting foods and nutrients that are "good for you" and those that should be avoided. All foods and beverages should be considered for display of the icon with manufacturers responsible for producing current lab analyses for their products. Government or third-party oversight would confirm this testing with regular spot-checks. The process should be objective and specific, transparent, adaptable to accommodate a wide range of foods and beverages, easily understandable to the general public, and financed without the appearance of conflict of interest. The process for implementing such a system, monitoring, and updating needs to be streamlined, timely, and efficient. The AHA is concerned that until such a comprehensive program is established, competing health-related icons will continue to proliferate in the marketplace. The AHA will evaluate the environment carefully to determine its role in the evolution of a unified system.



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EXPANDING ACCESS TO HEALTHY FOOD FOR MEDICAID BENEFICIARIES



While there's little debate over the fact that having access to and consuming nutritious foods are good for people's health and well-being, efforts to expand programs that provide healthy, nutrient-dense meals and foods to Medicaid beneficiaries have been stymied by cost-related concerns and opposition to providing free or discounted food under a program that was designed and authorized primarily to provide access to health insurance coverage and medical care for low-income Americans. With that said, however, having access to insurance and a core set of mandated benefits are necessary when examining the factors that affect Medicaid beneficiaries' physical and mental health.

The American Heart Association (AHA) recognizes the importance of "food as medicine" programs and supports activities that aim to increase access to healthy food across the care continuum. Further, as it pertains to the Medicaid population, the AHA supports efforts by public and private stakeholders to increase access to balanced or medically-tailored meals and healthy foods, including fresh fruits and vegetables, that might be cost-prohibitive or otherwise unattainable.

As an organization, the AHA strongly believes that targeted nutritional interventions play an important role in both well- and sick-care, spanning the prevention and treatment strati and complementing the standard medical services and care provided to millions of Medicaid beneficiaries across the United States. Given the direct correlation between dietary habits and health, as well as the abundance of evidence supporting how even small dietary changes can help prevent and treat disease, making access to healthy food a formal part of the benefits and services available to Medicaid beneficiaries could increase quality and satisfaction, improve outcomes and lower costs. Therefore, the AHA will advocate for the development of data-centric demonstration and pilot projects that test the feasibility, scalability, and viability of innovative programs in the Medicaid arena that explore the

link between access to and consumption of healthy foods with positive health outcomes and reduced morbidity and mortality risks.



3 THINGS TO KNOW

Medicaid is the nation's public health insurance program for low-income individuals and families and is projected to cover approximately 76 million people in fiscal year 2019

Medicaid beneficiaries report the highest incidence of chronic health conditions compared to individuals receiving insurance coverage from other sources.

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Leading experts agree that increasing access to healthy, nutrient-dense foods could help prevent, manage, and/or mitigate the negative effects of chronic diseases in the Medicaid population.

AMERICAN HEART ASSOCIATION POLICY STATEMENT ON DRUG FORMULARIES

3 THINGS TO KNOW

The AHA supports a formulary system that assures access to the range of pharmaceuticals that patients with cardiovascular disease may need.

The AHA supports the prescriber's ability to override, without undue administrative burden, the substitution of a restricted, non-formulary, or more expensive drug when necessary for an individual patient.

AHA believes that decisions about medications for use by a patient should be made by the patient and provider.



In recognizing the various factors to be considered when developing a formulary, the AHA has outlined a set of priorities and standards that frame our advocacy in support of a formulary system that facilitates patient access to quality drugs, treatments and therapies. The Association supports a formulary system that: assures access to the range of pharmaceuticals that patients with cardiovascular disease may need; is under the supervision of qualified physicians, pharmacists, and other appropriate health professionals; provides protocols for the procurement, storage, distribution, and safe use of formulary and non-formulary drug products; has policies for the development, maintenance, approval and dissemination of the drug formulary, and for periodic - at least yearly - comprehensive review of formulary drugs; and provides active surveillance mechanisms to regularly monitor both compliance with these standards and outcomes where substitution has occurred, and to intercede where indicated. Additionally, the AHA supports the use of methods and criteria that are open and transparent and objectively evaluate all available pharmaceuticals, taking several factors into account, including level and strength of evidence, potential differences in patients' medical conditions, and economic factors.

The paper goes on to outline our support for open formularies, transparency of pharmacy benefit information, and a responsive, streamlined prior authorization process. We discuss the appropriateness of therapeutic interchange and how interchange processes should be applied to the substitution of biosimilars for biologics. Importantly, we highlight that decisions about medications and therapies should be ultimately made by the patient and provider. Methods such as "fail first," or "step therapy" should include such a process for prescribers to bypass when

medically appropriate.

Cite #AHAPolicy

CORONARY ARTERY CALCIUM SCORING



Cardiac computed tomography, commonly known as a cardiac CT scan, is utilized to take images of a patient's beating heart to visualize their cardiac anatomy, coronary circulation and great vessels. Cardiac CT scans are commonly used by clinicians to evaluate the state of a patient's heart muscle, coronary arteries, pulmonary veins, pericardium, and thoracic and abdominal aorta. Given the existing body of evidence on the procedure's cost- and clinical-effectiveness in certain situations, the AHA supports efforts to expand coverage of and appropriate payment for coronary artery calcium (CAC) tests across the payor continuum, especially for patients who might benefit from knowing their score and having it considered in care decisions made by their physician or team of healthcare providers, including:

- Men and women of all ages with high cholesterol who are reluctant to begin statin therapy and who want to understand their risks and potential benefits of medication therapy more precisely;
- Men and women of all ages with high cholesterol who are concerned about re-starting statin therapy after stopping treatment because of side effects;
- Men ages 55 to 80 or women ages 60 to 80 with high cholesterol, but few or no other risk factors for having or developing ASCVD, who question whether they would benefit from statin therapy; and
- Men and women ages 40 to 55 with a calculated 10-year risk estimate for ASCVD between 5 percent and 7.5 percent, as calculated using the ASCVD Risk Calculator, and added risk factors (e.g., smoking, hypertension, diabetes, being overweight, lack of physical activity) that increase their chances of having or developing coronary artery disease.

The ACC/AHA do not generally recommend CAC testing of asymptomatic patients who are classified as "low risk" or "high risk"

as the score is unlikely to provide any new or additive information that would be useful in defining a patient's risk or directing a personalized treatment plan.



3 THINGS TO KNOW

In November 2018, the joint American College of Cardiology (ACC)/American Heart Association (AHA) Task Force on Clinical Practice Guidelines issued new cholesterol-related recommendations supporting the use of cardiac CT scans to produce CAC scores for certain at-risk patients.

The newly-released guidelines lead clinicians through a process, using a calculated formula and taking into account known risk factors, to place a patient in one of four classifications of risk: low, borderline, intermediate or high.

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For patients classified as an "intermediate risk" for having or developing atherosclerotic cardiovascular disease (ASCVD), the guidelines suggest that patients and clinicians consider CAC scoring as a tool for providing a greater degree of certainty as to whether statin use is medically necessary and clinically appropriate to prevent or decrease the risk of an adverse event.