

MEDICAL POLICY – 2.02.16

Ultrasonographic Measurement of Carotid Intimal-Medial Thickness as an Assessment of Subclinical Atherosclerosis

BCBSA Ref. Policy: 2.02.16

Effective Date: Aug. 1, 2023

Last Revised: July 10, 2023

Replaces: N/A

RELATED MEDICAL POLICIES:

None

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[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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Introduction

Atherosclerosis is a condition in which plaque builds up on artery walls. Plaque is made up of fat, cholesterol, and other substances in the blood. Over time, the plaque hardens. This hardening causes the arteries to narrow. Narrowed arteries means less blood can flow to organs like the heart and brain. There are a number of well proven tests that doctors use to diagnose atherosclerosis. A newer test uses sound waves (ultrasound) to look at the two innermost layers of the carotid artery. (The carotid arteries are on both sides of the neck.) The goal of this ultrasound test is to try to see if plaque is building up in arteries before other tests are able to identify it. Medical studies have found that this type of ultrasound test is uncertain in trying to predict who will develop atherosclerosis. Also, there are no studies showing how this testing leads to better health results compared to standard testing. For these reasons, ultrasound testing to try to identify atherosclerosis is considered investigational.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Ultrasonographic measurement of carotid intima-medial thickness (CIMT)	Ultrasonographic measurement of carotid intima-media thickness (CIMT) as a technique for identifying subclinical atherosclerosis is considered investigational for use in the screening, diagnosis, or management of atherosclerotic disease.

Coding

Code	Description
CPT	
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral

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Related Information

N/A

Evidence Review

Description

Ultrasonographic measurement of carotid intima-media (or intimal-medial) thickness (CIMT) refers to the use of B-mode ultrasound to determine the thickness of the 2 innermost layers of the carotid artery wall, the intima and the media. Detection and monitoring of intima-medial



thickening, which is a surrogate marker for atherosclerosis, may provide an opportunity to intervene earlier in atherogenic disease and/or monitor disease progression.

Background

Coronary Heart Disease

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary heart disease (CHD), also known as coronary artery disease, is the most common cause of heart disease.¹ In a 2023 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 720,000 Americans have a new coronary attack (first hospitalized myocardial infarction or CHD death) and 335,000 have a recurrent attack annually. An estimated 20.5 million Americans ≥ 20 years of age have CHD. The prevalence of CHD was higher for males than females in all age groups. Total CHD prevalence is 7.1% in US adults ≥ 20 years of age; CHD prevalence is 8.7% for males and 5.8% for females. On the basis of data from the 2018 National Health Interview Survey, CHD prevalence estimates are 5.7% among White people, 5.4% among Black people, 8.6% among American Indian/Alaska Native people, and 4.4% among Asian people ≥ 18 years of age.

Established major risk factors for CHD have been identified by the National Cholesterol Education Program Expert Panel. These risk factors include elevated serum levels of low-density lipoprotein cholesterol, total cholesterol, and reduced levels of high-density lipoprotein cholesterol. Other risk factors include a history of cigarette smoking, hypertension, family history of premature CHD, and age.

Diagnosis

The third report of the National Cholesterol Education Program Adult Treatment Panel established various treatment strategies to modify the risk of CHD, with emphasis on target goals of low-density lipoprotein cholesterol. Pathology studies have demonstrated that levels of traditional risk factors are associated with the extent and severity of atherosclerosis. The third report of the National Cholesterol Education Program Adult Treatment Panel recommended use of the Framingham criteria to further stratify those individuals with 2 or more risk factors for more intensive lipid management.² However, at every level of risk factor exposure, there is substantial variation in the amount of atherosclerosis, presumably related to genetic susceptibility and the influence of other risk factors. Thus, there has been interest in identifying a



technique that can improve the ability to diagnose those at risk of developing CHD, as well as to measure disease progression, particularly for those at intermediate risk.

The carotid arteries can be well-visualized by ultrasonography, and ultrasonographic measurement of the carotid intima-media thickness (CIMT) has been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used to measure the CIMT. CIMT is measured and averaged over several sites in each carotid artery. Imaging the far wall of each common carotid artery yields more accurate and reproducible CIMT measurements than imaging the near wall. Two echogenic lines are produced, representing the lumen-intima interface and the media-adventitia interface. The distance between these two lines constitutes the CIMT.

Summary of Evidence

For individuals who are undergoing cardiac risk assessment who receive ultrasonic measurement of CIMT, the evidence includes large cohort studies, case-control studies, and systematic reviews. Relevant outcomes are test accuracy and morbid events. Some studies have correlated increased CIMT with other commonly used markers for risk of CHD and with risk for future cardiovascular events. Lorenz et al (2012) found in their meta-analysis that CIMT was associated with increased cardiovascular events, although CIMT progression over time was not associated with increased cardiovascular event risk. Peters et al (2012) found that the added predictive value of CIMT was modest, and the ability to reclassify individuals into clinically relevant categories was not demonstrated. The results from these reviews and other studies have demonstrated the predictive value of CIMT is uncertain and that the predictive ability for any level of population risk cannot be determined with precision. Also, available studies do not define how the use of CIMT in clinical practice improves outcomes. There is no scientific literature that directly tests the hypothesis that measurement of CIMT results in improved patient outcomes and no specific guidance on how measurements of CIMT should be incorporated into risk assessment and risk management. The objective of one study, however, was to define "normal" CIMT progression in low to moderate cardiovascular risk patients. Study results showed definite patterns related to various factors that could be used as a tool to earlier identify individuals at increased cardiovascular risk, but patient outcomes were not assessed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in [Table 1](#).

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03314818 ^a	BiImage 2: Long-Term Follow-up of BiImage Study Cohort to Investigate Natural History of Carotid Plaque as Determined by 3D Ultrasound	1000	Oct 2023
NCT02508454 ^a	The Miami Heart Study at Baptist Health South Florida: A Prospective Study of Sub-Clinical Cardiovascular Disease and Emerging Cardiovascular Risk Factors in Asymptomatic Young and Middle-Aged Adults	4000	Sep 2024
NCT01849575	Direct VisualiZation of Asymptomatic Atherosclerotic Disease for Optimum Cardiovascular Prevention. A Population Based Pragmatic Randomised Controlled Trial Within Västerbotten Intervention Programme (VIP) and Ordinary Care (VIPVIZA)	3532	Dec 2027

NCT: national clinical trial ^aDenotes industry-sponsored or cosponsored trial.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.



American College of Cardiology and American Heart Association

In 2013, the guidelines from the American College of Cardiology and the American Heart Association on the assessment of cardiovascular risk did not recommend carotid intima-media thickness (CIMT) measurement in routine risk assessment of a first atherosclerotic cardiovascular disease event (class III: no benefit; level of evidence: B).³⁰ This differs from their 2010 joint guidelines for the assessment of cardiovascular risk, which indicated CIMT might be reasonable for assessing cardiovascular risk in intermediate-risk asymptomatic adults.³¹

American Association of Clinical Endocrinologists

In 2017, the American Association of Clinical Endocrinologists and American College of Endocrinology published guidelines stating that CIMT could be applied as a risk stratification tool in determining the need for more aggressive preventive strategies against cardiovascular disease (grade B; best evidence level 2) but not routinely.³²

American Society of Echocardiography

In 2008, the American Society of Echocardiography (ASE) consensus statement,³³ endorsed by the Society for Vascular Medicine, stated that CIMT is a feature of arterial wall aging "that is not synonymous with atherosclerosis, particularly in the absence of plaque." The statement recommended measurement of both CIMT and carotid plaque by ultrasound "for refining CVD [cardiovascular disease] risk assessment in individuals at intermediate cardiovascular disease risk (Framingham Risk Score 6%-20%) without established CHD [coronary heart disease], peripheral arterial disease, cerebrovascular disease, diabetes mellitus, or abdominal aortic aneurysm." However, the Society acknowledged that "More research is needed to determine whether improved risk prediction observed with CIMT or carotid plaque imaging translates into improved patient outcomes." The recommendations made in the 2008 consensus statement were endorsed in ASE's 2020 guideline entitled Recommendations for the Assessment of Carotid Arterial Plaque by Ultrasound for the Characterization of Atherosclerosis and Evaluation of Cardiovascular Risk.³⁴ Authors of the 2020 guideline also note the following: "Since the largest portion of CIMT (approximately 99% in healthy individuals and approximately 80% when diseased) consists of the medial layer, CIMT has not been shown to consistently add to CVD risk prediction."



U.S. Preventive Services Task Force Recommendations

In 2009, the U.S. Prevention Services Task Force (USPSTF) published a systematic review of CIMT within the scope of a larger recommendation on the use of nontraditional risk factors in coronary heart disease risk assessment.³⁵ The USPSTF could not draw conclusions on the applicability of CIMT to the intermediate-risk population at large outside the research setting. The USPSTF summary of recommendation specific to CIMT stated that:

“...the current evidence is insufficient to assess the balance of benefits and harms of using... [CIMT]...to screen asymptomatic men and women with no history of CHD to prevent CHD events.”

The USPSTF identified the following research need:

“The predictive value...of carotid IMT...should be examined in conjunction with traditional Framingham risk factors for predicting CHD events and death.”

In 2018, the USPSTF published a recommendation statement on using nontraditional risk factors to assess risk of cardiovascular disease; CIMT was not mentioned in this recommendation.³⁶

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

In 2003, SonoCalc® (SonoSite) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this software was substantially equivalent to existing image display products for use in the automatic measurement of the IMT of the carotid artery from images obtained from ultrasound systems. Subsequently, other devices have been cleared for marketing by the FDA through the 510(k) process.

FDA Product code: LLZ.

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History

Date	Comments
10/16/03	Add to Medicine Section - New Policy
01/11/05	Replace Policy - Policy updated with literature review; no change in policy statement; references added.
11/11/05	Replace Policy - Policy updated with literature review; no change in policy statement; reference added.
05/26/06	Update Scope and Disclaimer - No other changes.
11/14/06	Replace Policy - Policy updated with literature review; policy statement unchanged. References added.
01/08/08	Replace Policy - Policy updated with literature review; no change to policy statement. References added.
08/11/09	Replace Policy - Policy updated with literature search. Minor edits made to the policy statement, intent unchanged. References added.
09/14/10	Replace Policy - Policy updated with literature review; references 1, 3 and 8 have been added. The policy statement remains unchanged.
09/15/11	Replace Policy - Policy updated with literature review, policy statement unchanged. References added. Code 93882 added to the policy.
09/11/12	Replace policy. Policy updated with literature review, policy statement unchanged. References 3-8 and 25 added.
09/27/13	Replace policy. Policy updated with literature review through May 2013, policy statement unchanged. References 3-4 added.
10/18/13	Update Related Policies. Add 2.04.509.
09/23/14	Annual Review. Policy updated with literature review through June 16, 2014, policy statement unchanged. Reference 28 added.
12/22/14	Update Related Policies. Remove 6.01.03 as it was archived.
01/14/15	Coding update. New CPT code 93895, effective 1/1/15, added to policy.



Date	Comments
09/08/15	Annual Review. Policy updated with literature review through May 31, 2015; references 17-19 removed; reference 24 added. No change to policy statement. CPT codes 93880 & 93882 removed; these are not reviewed.
08/01/16	Annual Review, approved July 12, 2016. Policy updated with literature review through June 20, 2016. USPSTF recommendation updated. Reference added.
04/01/17	Annual Review, approved March 14, 2017. Policy updated with literature review through December 15, 2016; reference 20 added. Policy statement unchanged.
10/24/17	Policy moved to new format, no changes to policy statement.
08/01/18	Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 26-27, and 31 added. Policy statement unchanged.
08/01/19	Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019; references added. Policy statement unchanged.
08/01/20	Annual Review, approved July 2, 2020. Policy updated with literature review through March, 2020; references added. Policy statement unchanged.
12/01/20	Coding update, added note that CPT code 0126T terminated 1/1/21.
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through March 16, 2021; references added. Policy statement unchanged.
08/01/22	Annual Review, approved July 11, 2022. Policy updated with literature review through March 19, 2022; reference added. Policy statement unchanged. Removed CPT code 0126T.
08/01/23	Annual Review, approved July 10, 2023. Policy updated with literature review through March 14, 2023; reference added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/online-services/cc/pub/complaintinformation.aspx>.

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ໂປດອຸລາ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ຄມມຸນມິພ້ອມໃຫ້ທ່ານ. ໂທ 800-722-1471 (TTY: 711).

注意事項: 日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 (TTY:711) まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyan. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតលុយ គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም አርዳታ ድርጅቶች: በነጻ ሊያግኙዎት ተዘጋጅተዋል: ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው: 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajjila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

ထိပ်စီး: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS: 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجہ: اگر بہ زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.