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

Policy #   00251
Original Effective Date:  02/17/2010
Current Effective Date:  04/10 /2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers ultrasonographic measurement of carotid intimal-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis for use in the screening, diagnosis or management of atherosclerotic disease to be investigational.*

Background/Overview
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. In a 2022 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 20.1 million Americans ≥20 years of age have CHD. The prevalence of CHD was higher for males than females ≥60 years of age. Total CHD prevalence is 7.2% in US adults ≥20 years of age; CHD prevalence is 8.3% for males and 6.2% 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 and total cholesterol, and reduced levels of high-density lipoprotein cholesterol. Other
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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 patients with 2 or more risk factors for more intensive lipid management. 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 an 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 CIMT has been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used to measure CIMT. Carotid intima-media thickness 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 2 lines constitutes the CIMT.

**FDA or Other Governmental Regulatory Approval**
**U.S. Food and Drug Administration (FDA)**
In 2003, SonoCalc® (SonoSite) was cleared for marketing by the U.S. 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.
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FDA product code: LLZ.

**Rationale/Source**
This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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

**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 (CV) events. Lorenz et al (2012) found in their meta-analysis that CIMT was associated with increased CV events, although CIMT progression overtime was not associated with increased CV event risk. Peters et al (2012) found that the added predictive value of CIMT was modest, and the ability to reclassify patients 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 1 study, however, was to define “normal” CIMT progression in low to moderate CV risk patients. Study results showed definite patterns related to various factors that could be used as a tool to earlier identify patients at
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increased CV 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.

Supplemental Information
Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US 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 CV risk did not recommend CIMT measurement in routine risk assessment of a first atherosclerotic cardiovascular disease (CVD) event (class III: no benefit; level of evidence: B). This differs from their 2010 joint guidelines for the assessment of CV risk, which indicated that CIMT might be reasonable for assessing CV risk in intermediate-risk asymptomatic adults.

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 CVD (grade B; best evidence level 2), but not routinely.

American Society of Echocardiography
In 2008, the American Society of Echocardiography (ASE) consensus statement, 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 risk assessment in patients at intermediate CVD risk (Framingham Risk Score 6% to 20%) without established CHD, 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. 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. Preventive 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 CHD risk assessment. 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 recommendations 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 the risk of CVD; CIMT was not mentioned in this recommendation.

**Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in Table 1.
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Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
<td><strong>Ongoing</strong></td>
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<td></td>
<td></td>
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<tr>
<td>NCT01849575</td>
<td>Direct Visualization of Asymptomatic Atherosclerotic Disease for Optimum Cardiovascular Prevention. A Population Based Pragmatic Randomized Controlled Trial Within Västerbotten Intervention Programme (VIP) and Ordinary Care (VIPVIZA)</td>
<td>3,532</td>
<td>Dec 2027</td>
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</table>

NCT: national clinical trial.

References

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**Policy History**

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02/04/2010 Medical Policy Committee approval
02/17/2010 Medical Policy Implementation Committee approval. New policy.
02/03/2011 Medical Policy Committee review
02/16/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/02/2012 Medical Policy Committee review
02/15/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/07/2013 Medical Policy Committee review
02/20/2013 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014 Medical Policy Committee review
02/19/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2015 Coding Update
02/05/2015 Medical Policy Committee approval
02/18/2015 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
02/04/2016 Medical Policy Committee approval
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02/17/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017 Coding update: Removing ICD-9 diagnosis codes
03/02/2017 Medical Policy Committee approval
03/15/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018 Medical Policy Committee review
03/21/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/16/2018 Coding update
03/07/2019 Medical Policy Committee review
03/20/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2020 Medical Policy Committee review
03/11/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/11/2020 Coding update
03/04/2021 Medical Policy Committee review
03/10/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2022 Medical Policy Committee review
03/09/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2024

Coding
The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®), copyright 2022 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of

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descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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<tr>
<th>Code Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>CPT</td>
<td>93895</td>
</tr>
<tr>
<td>HCPCS</td>
<td>No codes</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and...
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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.