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

Policy # 00251
Original Effective Date: 02/17/2010
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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

CHD accounts for 30.8% of all deaths in the U. S. 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 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 two 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 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 has been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used to measure the carotid intima-media thickness. The intima-media thickness (IMT) is measured and averaged over several sites in each carotid artery. Imaging of the far wall of each common carotid artery yields more accurate and reproducible IMT measurements than imaging of 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 IMT.

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. 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.

Rationale/Source

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.

For individuals who are undergoing cardiac risk assessment who receive ultrasonic measurement of CIMT, the evidence includes a randomized controlled study, 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 coronary

heart disease 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 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 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 patients at increased cardiovascular risk, but patient outcomes were not assessed. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

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). This differs from their 2010 joint guidelines for assessment of cardiovascular risk, which indicated CIMT might be reasonable for assessing cardiovascular risk in intermediate-risk asymptomatic adults.

American Association of Clinical Endocrinologists et al

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.

American Society of Echocardiography
In 2008, the American Society of Echocardiography consensus statement,32, 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 patients 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, 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."

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. 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.

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 unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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)	3200	Sep 2022

NCT: national clinical trial.

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02/04/2010	Medical Policy Committee approval
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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
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

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03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
05/16/2018	Coding update
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03/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2022

Coding

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contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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

Code Type	Code
CPT	93895 Code deleted eff 1/1/2021: 0126T
HCPCS	No codes
ICD-10 Diagnosis	Z13.6

*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 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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.

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