



# BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

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

**Policy #** 00251

**Original Effective Date:** 02/17/2010

**Current Effective Date:** 02/19/2014

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*Note: Electron Beam/Spiral Computed Tomography to Detect Coronary Calcification is addressed in medical policy 00031.*

### **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 artery intima-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**

Ultrasonographic measurement of CIMT refers to the use of B-mode ultrasound to determine the thickness of the two innermost layers of the carotid artery wall, the intima and the media. Detection and monitoring of intima-medial thickening (atherosclerosis) may provide an opportunity to intervene earlier in atherogenic disease and/or monitor disease progression.

Coronary heart disease (CHD) accounts for 27% of all deaths in the U.S. Established major risk factors for CHD have been identified by the National Cholesterol Education Program (NCEP) Expert Panel. These risk factors include elevated serum levels of low-density lipoprotein (LDL) cholesterol, total cholesterol, and reduced levels of high-density lipoprotein (HDL) cholesterol. Other risk factors include a history of cigarette smoking, hypertension, family history of premature CHD, and age.

The third report of the NCEP Adult Treatment Panel (ATP III) establishes various treatment strategies to modify the risk of CHD, with emphasis on target goals of LDL cholesterol. Pathology studies have demonstrated that levels of traditional risk factors are associated with the extent and severity of atherosclerosis. 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. Therefore, there has been interest in identifying a technique that can improve the ability to diagnose those at risk of developing CHD, as well as measure disease progression, particularly for those at intermediate risk. Adult Treatment Panel III recommends use of the Framingham criteria to further stratify those patients with two or more risk factors for more intensive lipid management.

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. The intima-medial 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



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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 February 2003, SonoCalc<sup>®</sup> (SonoMetric Health, LLC, Bountiful, UT) was cleared for marketing by the 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 intima media thickness of the carotid artery from images obtained from ultrasound systems. Subsequently, several other devices have been approved through the 510(k) process.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination.

## **Rationale/Source**

A summary of the key literature follows.

Evaluation of a diagnostic technology typically focuses on the following 3 parameters: 1) technical performance; 2) diagnostic parameters (sensitivity, specificity, positive and negative predictive value); and 3) demonstration of clinical utility; the diagnostic information can be used to improve patient outcomes.

## **Literature Review**

The literature on the use of CIMT for cardiac risk stratification consists of numerous cohort studies and systematic reviews of these cohort studies. The following review includes the largest prospective cohort studies and the most important systematic reviews of these studies.

### *Diagnostic Utility*

#### **Systematic Reviews**

In a 2012 meta-analysis, the USE Intima-Media Thickness (USE-IMT) collaboration, investigators sought to determine whether common CIMT measurements could assist in estimating the 10-year risk of first-time myocardial infarction (MI) or first-time stroke when added to the Framingham Risk Score. Using individual data for 45,828 patients from 14 population-based cohort studies, Den Ruijter et al. found risk of first-time MI or stroke was related positively to both the Framingham Risk Score and the adjusted common CIMT. The mean common CIMT was 0.73 mm and increased in every cohort with patient age during a median follow-up of 11 years. For every 0.1 mm difference in common CIMT, the hazard ratio (HR) for risk of MI or stroke, which occurred in 4,007 patients, was 1.12 (95% confidence interval [CI]: 1.09-1.14) for women and 1.08 (95% CI: 1.05-1.11) for men. However, adding common CIMT measurements to the Framingham Risk Score did not improve risk prediction and resulted in reclassification of risk in only 6.6% of patients. The added value of mean common CIMT in reclassifying risk was only 0.8% (95% CI: 0.1-1.6%) and did not differ between men and women. The c-statistic of the Framingham Risk Score model with and without CIMT was similar (0.759; 95% CI: 0.752-0.766 and 0.757; 95% CI: 0.749-0.764), suggesting the addition of CIMT in risk assessment offered limited benefit.



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A 2013 meta-analysis of 15 articles by van den Oord and colleagues found similar results on the added value of CIMT. Six cohort studies totaling 32,299 patients were evaluated to examine the value of CIMT added to traditional cardiovascular (CV) risk factors. While a CIMT increase of 0.1mm was predictive for MI (HR: 1.15, 95% CI: 1.12-1.18) and for stroke (HR 1.17, 95% CI: 1.15-1.21), the addition of CIMT did not statistically significantly increase risk prediction over traditional CV risk factors ( $p = 0.8$ ).

In a 2012 meta-analysis of individual participant data pooled from 16 studies with a total of 36,984 patients, Lorenz and colleagues examined CIMT progression from 2 ultrasound screenings taken 2-7 years apart (median 4 years). Patients were followed for a mean of 7 years during which time 1,339 strokes, 1,519 MIs and 2,028 combined endpoints (MI, stroke, vascular death) occurred. The mean CIMT of the 2 ultrasounds results was predictive of CV risk using the combined endpoint (adjusted HR: 1.16, 95% CI: 1.10-1.22). In sensitivity analyses, no associations were found between CV risk and individual CIMT progression regardless of CIMT definition, endpoint, and adjustments. As an example, for the combined endpoints, an increase of one standard deviation (SD) in mean common CIMT progression resulted in an overall estimated HR of 0.97 (95% CI: 0.94-1.00) when adjusted for age, sex, and mean common CIMT, and HR was 0.98 (0.95-1.01) when adjusted for vascular risk factors. These data confirm that CIMT is a predictor of CV risk, but do not demonstrate that changes in CIMT over time are predictive of future events.

In a 2012 systematic review of subclinical atherosclerosis imaging techniques, Peters et al. reviewed 12 studies on CIMT that examined reclassification of risk. For the impact on the primary outcome of CV events, when CIMT was added to the prediction model, the range of increase in the c-statistic was 0.00 to 0.03 on a scale of 0-1.0. Net reclassification improvement with CIMT was reported in 5 of the studies included in the review and ranged from -1.4% to 12%.

Recent studies have found including carotid plaques in CIMT increases the predictive value of CV risk over CIMT assessed only in plaque-free sites. However, the meta-analysis by Lorenz found no difference in the main results between studies that included CIMT with carotid plaque and plaque-free CIMT. The systematic review by Peters found adding carotid plaque to the traditional CIMT model increased the c-statistic from 0.01 to 0.06.

In 2010, Mookadam and colleagues conducted a systematic review of the role of CIMT in predicting individual CV event risk and as a tool in assessing therapeutic interventions. The authors concluded that CIMT is an independent risk factor for CV events and may be useful in determining treatment when there is uncertainty regarding the approach or patient reluctance. However, further studies are needed to identify the best approaches to screening and interventions to prevent progression of atherosclerosis.

### Prospective Cohort Studies

In the Atherosclerosis Risk in Communities (ARIC) study, the authors evaluated risk factors associated with increased CIMT in 15,800 subjects. CIMT had a graded relationship with increasing quartiles of plasma total cholesterol, LDL cholesterol, and triglycerides. Carotid intima-medial thickness was then also correlated with the incidence of CHD in a subgroup of patients enrolled in the trial after 4 to 7 years of follow-up. Among the 12,841 subjects studied, there were 290 incident events. The HR rate for men and women,



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adjusted for age and gender, comparing extreme CIMT (i.e.,  $\geq 1$  mm) to non-extreme CIMT (i.e.,  $< 1$  mm) was 5.07 for women and 1.85 for men. The strength of the relationship was reduced by including major CHD risk factors but remained elevated for higher measurements of CIMT. The authors concluded that mean CIMT is a noninvasive predictor of future CHD incidence.

The Rotterdam study was a prospective cohort study that started in 1989 and recruited 7,983 men and women aged 55 years and older. The main objective of the Rotterdam study was to investigate the prevalence and incidence of risk factors for chronic diseases, including CV disease, in elderly individuals. One aspect of the study sought to determine whether progression of atherosclerosis in asymptomatic elderly subjects is a prelude to CV events. Measurements of CIMT were used to assess the progression of atherosclerosis. Increasing CIMT was associated with increasing risks of stroke and MI. O'Leary and colleagues performed CIMT in 4,476 asymptomatic subjects aged 65 years or older without clinical CV disease. The incidence of CV events correlated with measurements of CIMT; this association remained significant after adjustment for traditional risk factors. The authors concluded that increases in CIMT are directly associated with an increased risk of MI and stroke in older adults without a history of CV disease.

The Carotid Atherosclerosis Progression Study (CAPS) was a longitudinal study of 4,904 subjects. All subjects received a baseline CIMT measurement, as well as traditional risk factor analysis, and were followed over a 10-year period (mean follow-up 8.5 years, range 7.1-10.0 years). Adverse outcome events were MI in 73 patients (1.5%), angina or MI in 271 patients (5.5%), and death in 72 subjects (1.5%). Lorenz et al. have recently published a retrospective review of the data from CAPS. The authors modeled the predictive value of CIMT on the CV adverse events within that decade. Because the thresholds of CIMT measurements that would lead to reclassification of risk are unknown, the authors used 24 different models of reclassification and 5 statistical tests. Each model compares the predictive value of traditional risk factors alone with those risk factors with the addition of CIMT. The authors were unable to find significance in the reclassification models with the addition of CIMT measurements. They concluded that this retrospective analysis does not support the use of CIMT as a clinically useful risk classification tool when used in conjunction with traditional risk factor analysis.

Several other studies have, in fact, used CIMT measurements as outcome measures. In this setting, serial measurements of CIMT are performed, as opposed to a single measure. For example, the Asymptomatic Carotid Artery Progression Study (ACAPS) was designed to evaluate the role of lovastatin (an HMG-CoA reductase inhibitor, i.e., a statin drug) in patients asymptomatic for CV disease and with LDL cholesterol levels at or below the limits established by the NCEP. A total of 919 asymptomatic men and women were randomly assigned to receive various combinations of lovastatin, warfarin, and placebo over a 3-year period. The principal outcome measurement was the progression of CIMT, tested at 6 sites in both carotid arteries. Lovastatin treatment was associated with a reduction in the progression of mean maximum CIMT. The Monitored Atherosclerosis Regression Study also included measurements of CIMT every 6 months for 4 years in a subset of enrolled subjects. The authors concluded that lipid-lowering therapy resulted in a regression of CIMT.



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Carotid intima-medial thickness is frequently being used in the research setting but application or widespread use is uncertain. In the Multi-Ethnic Study of Atherosclerosis (MESA) trial, an ongoing cohort study of atherosclerosis, CIMT was found to be a modestly better predictor of stroke but a worse predictor of CHD than coronary artery calcium score at a median follow-up of 3.9 years among 6,698 adults asymptomatic at baseline. In a 2010 article from MESA, CIMT results in 4,792 healthy, nondiabetic adults who were not on lipid-lowering medications were compared in 6 different lipid groups, including normolipemia and several types of common dyslipidemias. The mean CIMT values were increased only for the combined hyperlipidemia (defined as any HDL-C level, LDL-cholesterol [C]  $\geq 160$  and triglyceride  $\geq 150$ ) and simple hypercholesterolemia (defined as any HDL-C level, LDL-C  $\geq 160$  and triglyceride  $< 150$ ) groups. In another MESA report, in 2011, on 6,760 patients with elevated high-sensitivity C-reactive protein (hsCRP) as defined by the JUPITER study, CIMT increases correlated with obesity but only mildly with hsCRP. In the Bogalusa Heart Study of 991 subjects, obesity along with overweight and elevated metabolic risk were also associated with increased CIMT. In this study population, 41% of patients were found to have increased CHD risk. In the CARDIA study, clotting factor VII was associated with increases in CIMT in 1,254 subjects. Carotid intima-medial thickness is also used as a surrogate outcome measure in atherosclerosis treatment research studies.

In 2010, Raiko et al. compared CV disease risk-scoring tools for identification of CHD risk to CIMT results in 2,204 healthy adults, aged 24-39 years, from the Cardiovascular Risk in Young Finns study. The CV disease risk scoring tools evaluated included the Framingham, Reynolds Risk Score, Systematic Coronary Risk Evaluation (SCORE), PROCAM, and Finrisk CV risk scores. In this population-based follow-up study, the authors found all of the CV disease risk scores performed equally in being able to predict subclinical atherosclerosis as measured by high CIMT 6 years later.

### Conclusions

Evidence from large, prospective cohort studies has established that CIMT is an independent risk factor for CV disease. However, systematic reviews have concluded that the ability of CIMT to reclassify patients into clinically relevant categories is modest and may not be clinically important. The uncertainty around the ability to reclassify patients into clinically relevant categories limits the potential for CIMT to improve health outcomes.

### Clinical Utility

In a 2011 study by Johnson and colleagues, 355 patients, aged 40 years with one or more CV disease risk factor, received carotid ultrasound screenings to prospectively determine whether abnormal results would change physician and patient behaviors. Results were considered abnormal (when CIMT was greater than the 75<sup>th</sup> percentile or the presence of carotid plaque) in 266 patients. Self-reported questionnaires were completed before the carotid ultrasound, immediately after the ultrasound, and 30 days later to determine behavioral changes. Physician behavior in prescribing aspirin and cholesterol medication changed significantly ( $p < 0.001$  and  $p < 0.001$ , respectively) after identification of abnormal carotid ultrasound results. Abnormal ultrasound results predicted reduced dietary sodium (odds ratio [OR]: 1.45;  $P = 0.002$ ) and increased fiber intake (OR: 1.55;  $P = 0.022$ ) in patients but no other significant changes. Health outcomes were not evaluated in this study, and the short-term follow-up limits interpretation of results.

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The evidence on reclassification of CV risk offers a potential indirect chain of evidence to improve outcomes. If a measure is able to reclassify patients into risk categories that have different treatment approaches, then clinical management changes may occur that lead to improved outcomes. Since the ability to reclassify patients into clinically relevant categories with CIMT is modest at best, the clinical utility of this measure for reclassification is uncertain.

### Conclusions

There is no direct evidence on the clinical utility of measuring CIMT for cardiac risk stratification. The available evidence on reclassification into clinically relevant categories does not support that the use of CIMT will improve health outcomes.

### **Ongoing Trials**

A search of the online site [ClinicalTrials.gov](http://ClinicalTrials.gov) database in June 2013 identified two open, randomized, controlled trials (RCT). In the VIP-VIZA (visualization of asymptomatic atherosclerotic disease for optimum CV prevention) RCT, the benefits of incorporating carotid ultrasound results into a CV disease prevention program will be studied (NCT01849575). Estimated study enrollment is 3,200 subjects. After 1 and 3 years, CV risk factors, medication usage and lifestyle will be evaluated. After 5 years, CV morbidity and mortality will be evaluated until the year 2020. The IMPRESS Study (NCT01330602) will randomly stratify 1,310 subjects with an intermediate risk of CV events and a family history of premature atherosclerosis to either a disease management program with intensive pharmacologic and behavioral interventions for primary prevention or usual health care management. The study will evaluate whether the disease management program is effective and whether changes in CIMT over 3 years can determine atherosclerotic status and future CV events.

### **Summary**

Ultrasonographic measurement of CIMT or IMT 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.

Some studies correlate increased CIMT with many other commonly used markers for risk of CHD and with risk for future CV events. While a 2012 meta-analysis of individual participant data by Lorenz et al. found that CIMT was associated with increased CV events, CIMT progression over time was not associated with increased CV event risk. In a systematic review by Peters and colleagues, 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 studies and others demonstrate the predictive value of CIMT is uncertain, and the predictive ability for any level of population risk cannot be determined with precision.

In addition, available studies do not define how the use of CIMT in clinical practice improves outcomes. There appears to be no scientific literature that directly and experimentally 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 existing



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data are insufficient to determine the impact of this technology on net health outcome. Therefore, CIMT is considered investigational for use in the screening, diagnosis, or management of atherosclerotic disease.

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CPT	0126T, 93880, 93882
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ICD-9 Diagnosis	V81.0
ICD-9 Procedure	No codes





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- 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:
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  3. reference to federal regulations.

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