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Medical Policy

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

Professional
Original Effective Date: February 27, 2007
Revision Date(s): August 24, 2009; September 6, 2011, September 18, 2012; January 1, 2015; October 13, 2015; February 15, 2017; August 1, 2018; August 14, 2019; July 6, 2021
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Populations	Interventions	Comparators	Outcomes
Individuals: • Who are undergoing cardiac risk assessment	Interventions of interest are: • Ultrasonic measurement of carotid intima-medial thickness	Comparators of interest are: • Standard of care • Alternative cardiovascular risk predictors	Relevant outcomes include: • Test accuracy • Morbid events

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DESCRIPTION

Ultrasonographic measurement of carotid intima-medial (or intimal-media) 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.

Objective

The objective of this evidence review is to evaluate whether results of ultrasonographic measurement of carotid intima-medial thickness improve risk categorization in individuals who are undergoing cardiac risk assessment.

Background

Coronary Heart Disease

Coronary heart disease (CHD) accounts for 30.8% of all deaths in the United States.[1] 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 cholesterol (LDL-C), 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 NCEP Adult Treatment Panel (ATP III) established various treatment strategies to modify the risk of CHD, with emphasis on target goals of LDL-C. Pathology studies have demonstrated that levels of traditional risk factors are associated with the extent and severity of atherosclerosis. ATP III recommended use of the Framingham criteria to further stratify those patients 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 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-medial thickness (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 lines are produced, representing the lumen-intima interface and the media-adventitia interface. The distance between these 2 lines constitutes the IMT.

Regulatory Status
In 2003, SonoCalc® (SonoSite) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. 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 FDA through the 510(k) process. Product code: LLZ.

POLICY

Ultrasonographic measurement of carotid intima-medial thickness as a technique for identifying subclinical atherosclerosis is considered **experimental / investigational** for use in the screening, diagnosis, or management of atherosclerotic disease.

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through March 4, 2019.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

The literature on the use of carotid intima-media thickness (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.

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Ultrasonographic Measurement of CIMT
Because different specialties may use different terms for the same concept, we are highlighting the core characteristics. The core characteristics also apply to different uses of tests, such as diagnosis, prognosis, and monitoring treatment.

The approach and metrics for assessing each of the core characteristics are described below.

Clinical Context and Test Purpose
The purpose of ultrasonic measurement of CIMT is to provide a diagnostic option that is an alternative to or an improvement on existing tests, such as standard of care and alternative cardiovascular risk predictors, in patients who are undergoing cardiac risk assessment.
The question addressed in this evidence review is: Does the results of ultrasonographic measurement of CIMT improve risk categorization in individuals who are undergoing cardiac risk assessment?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals who are undergoing cardiac risk assessment. This population may have other risk factors for coronary heart disease (CHD), including a history of cigarette smoking, hypertension, family history of premature CHD, and age.

Interventions
The test being considered is ultrasonic measurement of CIMT. 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, which is a surrogate marker for atherosclerosis, may provide an opportunity to intervene earlier in atherogenic disease and/or monitor disease progression.

Patients who are undergoing cardiac risk assessment are actively managed by cardiologists and primary care providers in an outpatient clinical setting.

Comparators
Comparators of interest include standard of care and alternative cardiovascular risk predictors.

Standard of care includes hypertension/blood pressure control and regular screenings. Alternative cardiovascular risk predictors commonly refer to the Framingham Risk Score,a gender-specific algorithm used to estimate the ten-year cardiovascular risk of an individual. The Framingham Risk Score was first developed based on data obtained from the Framingham Heart Study, to estimate the ten-year risk of developing CHD. In order to assess the 10-year cardiovascular disease risk, cerebrovascular events, peripheral artery disease and heart failure were subsequently added as disease outcomes for the 2008 Framingham Risk Score, on top of CHD.

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Outcomes

The general outcomes of interest are test accuracy and morbid events. Possible negative outcomes include stroke, myocardial infarction (MI) and heart failure.

Table 1. Outcomes of Interest for Individuals Who are undergoing cardiac risk assessment

Outcomes	Details	Timing
Test accuracy	Evaluating the efficacy of CIMT in assisting in estimation the risk of cardiovascular disease using tools such as the Framingham Risk Score or the European systematic coronary risk evaluation	1-10 years
Morbid events	Cardiovascular events may include myocardial infarction, stroke, angina, vascular death, etc.	5-10 years

CIMT: carotid intima-media thickness.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

a. The study population represents the population of interest. Eligibility and selection are described.
b. The test is compared with a credible reference standard.
c. If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
d. Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false-positive results are ideal. Studies reporting other measures (eg, receiver operating characteristic, area under receiver operating characteristic, c-statistic, likelihood ratios) may be included but are less informative.
e. Studies should also report reclassification of diagnostic or risk category.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review, and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Systematic Reviews

Mookadam et al (2010) conducted a systematic review of the role of CIMT in predicting individual cardiovascular event risk, and as a tool for assessing therapeutic interventions.[3] Reviewers concluded that CIMT is an independent risk factor for cardiovascular events and may be useful in determining treatment when there is uncertainty regarding the approach or patient

reluctance. However, they recommended further study to identify the best approaches to screening and interventions to prevent progression of atherosclerosis.

In meta-analysis, the USE Intima-Media Thickness collaboration investigators sought to determine whether common CIMT measurements can assist in estimating the ten-year risk of first-time MI or first-time stroke when added to the Framingham Risk Score.[4] Using individual data for 45828 patients from 14 population-based cohort studies, Den Ruijter et al (2012) 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 it 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 4007 patients, was 1.12 (95% confidence interval [CI], 1.09 to 1.14) for women and 1.08 (95% CI, 1.05 to 1.11) for men. However, adding common CIMT measurements to the Framingham Risk Score did not improve risk prediction and resulted in the 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% to 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 for men (0.759; 95% CI, 0.752 to 0.766) and women (0.757; 95% CI, 0.749 to 0.764), suggesting the addition of CIMT in risk assessment offered limited benefit.

In another meta-analysis of individual participant data pooled from 16 studies (total n=36984 patients), Lorenz et al (2012) examined CIMT progression from 2 ultrasound screenings taken 2 to 7 years apart (median, 4 years).[5]Patients were followed for a mean of 7 years, during which time 1339 strokes, 1519 MI, and 2028 combined endpoints (MI, stroke, vascular death) occurred. Mean CIMT of the 2 ultrasound results was predictive of cardiovascular risk using the combined endpoint (adjusted HR=1.16; 95% CI 1.10 to 1.22). In sensitivity analyses, no associations were found between cardiovascular risk and individual CIMT progression regardless of CIMT definition, endpoint, and adjustments. As an example, for the combined endpoints, an increase of 1 standard deviation in mean common CIMT progression resulted in an overall estimated HR of 0.97 (95% CI, 0.94 to 1.00) when adjusted for age, sex, and mean common CIMT; the HR was 0.98 (95% CI, 0.95 to 1.01) when adjusted for vascular risk factors. These data confirmed that CIMT is a predictor of cardiovascular risk but did not demonstrate that changes in CIMT over time are predictive of future events.

A meta-analysis of 15 articles by van den Oord et al (2013) found similar results on the added value of CIMT.[2,] Six cohort studies (total n=32299 patients) were evaluated to examine the predictive value of CIMT when added to traditional cardiovascular risk factors. While a CIMT increase of 0.1 mm was predictive for MI (HR=1.15; 95% CI, 1.12 to 1.18) and stroke (HR=1.17; 95% CI, 1.15 to 1.21), the addition of CIMT did not statistically improve risk prediction over traditional cardiovascular risk factors (p=0.8).

Studies have found that including carotid plaques in CIMT measurements improved the predictive value of cardiovascular risk over CIMT assessed only in plaque-free sites.[3,4,5,6,] However, the

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meta-analysis by Lorenz et al (2012) found no difference in the main results between studies that included CIMT with carotid plaque and plaque-free CIMT.[7,] The systematic review by Peters et al (2012) found adding carotid plaque to the traditional CIMT model increased the C statistic from 0.01 to 0.06.[8,]

Table 2. Systematic Reviews & Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Lorenz (2012)[7,]	NR	16	Patients who were assessed with CIMT > twice and followed up for myocardial infarction, stroke or death	36,984 (297-12,221)	Prospective, Longitudinal, Observational	NR
van den Oord (2013)[2,]	1997-2011	15	Patients at risk for CV events	76,201 (1,734–14,214)	Observational studies	NR

NR: not reported; CV: cardiovascular; CIMT: carotid intima-media thickness.

Table 3. Systematic Reviews & Meta-Analysis Results

Study	CIMT Progression HR (CI)	Association of CIMT with CV Risk HR (CI)
Lorenz (2012)[7,]		
	0.97[1](0.94-1.00)	1.16 (1.10-1.22)
		Association of 1 SD (0.1 mm) Increase in CIMT with Future MI
van den Oord (2013)[2,]		
	NR	1.26 (1.15)

CIMT: carotid intima-media thickness; CV: cardiovascular; MI: myocardial infarction; HR: hazard raio; CI: 95% confidence interval; SD: standard deviation.
[1]When adjusted for age, sex, and mean common CIMT.

Prospective Cohort Studies

Numerous prospective cohort studies have evaluated the association between CIMT and future cardiovascular events. Some of the larger trials are discussed below. For example, in the Atherosclerosis Risk in Communities study, trialists evaluated risk factors associated with increased CIMT in 15800 subjects.[9,] CIMT had a graded relation with increasing quartiles of plasma total cholesterol, low-density lipoprotein cholesterol, and triglycerides. CIMT also correlated with the incidence of CHD in a subgroup of patients enrolled in the trial after four to seven years of follow-up.[10,] Among the 12841 subjects studied, there were 290 incident events. The HR rates for women and men, adjusted for age and sex, comparing extreme CIMT (ie, ≥1 mm) with nonextreme CIMT (ie, <1 mm), were 5.07 for women and 1.85 for men. The strength of the relation was reduced by including major CHD risk factors but remained elevated for higher measurements of CIMT. Authors concluded that mean CIMT was a noninvasive predictor of future CHD incidence.

The Rotterdam cohort study started in 1989 and recruited 7983 men and women ages 55 years and older. Its main objective was to investigate the prevalence and incidence of risk factors for chronic diseases, including cardiovascular disease (CVD), in older adults. One aspect of the study

sought to determine whether progression of atherosclerosis in asymptomatic elderly subjects is a prelude to cardiovascular events. Measurements of CIMT were used to assess the progression of atherosclerosis. Increasing CIMT was associated with increased risks of stroke and MI.[11,]

OLeary et al (1999) performed CIMT measurement on 4476 asymptomatic subjects ages 65 years or older without clinical CVD in the Cardiovascular Health Study.[12,] The incidence of cardiovascular events correlated with measurements of CIMT; this association remained significant after adjusting for traditional risk factors. Authors concluded that increases in CIMT were directly associated with an increased risk of MI and stroke in older adults without a history of CVD.

The longitudinal Carotid Atherosclerosis Progression Study included 4904 subjects. All subjects received a baseline CIMT measurement as well as traditional risk factor analysis and were followed for ten years (mean follow-up, 8.5 years; range, 7.1-10.0 years). Adverse events were MI in 73 (1.5%) patients, angina or MI in 271 (5.5%) patients, and death in 72 (1.5%) subjects. Lorenz et al (2010) retrospectively reviewed Carotid Atherosclerosis Progression Study data.[13,] They modeled the predictive value of CIMT on the cardiovascular adverse events within that decade. Because the thresholds of CIMT measurements that would lead to reclassification of risk are unknown, the authors used 24 models of reclassification and 5 statistical tests. Each model compared the predictive value of traditional risk factors alone with those risk factors plus CIMT. None of the reclassification models improved with the addition of CIMT measurements. Trialists concluded that their retrospective analysis did not support the use of CIMT as a clinically useful risk classification tool when used with traditional risk factor analysis.

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 (CAC) score at a median follow-up of 3.9 years among 6698 adults asymptomatic at baseline.[14,] In a report from the MESA trial by Paramsothy et al (2010), CIMT results in 4792 healthy, nondiabetic adults who were not on lipid-lowering medications were compared across 6 different lipid groups, including normolipemia and several types of common dyslipidemias.[15,]Mean CIMT values were increased only for the combined hyperlipidemia (defined as any high-density lipoprotein cholesterol level, low-density lipoprotein cholesterol ≥160 mg/dL, and triglyceride ≥150 mg/dL) and simple hypercholesterolemia (defined as any high-density lipoprotein cholesterol level, low-density lipoprotein cholesterol ≥160 mg/dL, and triglyceride <150 mg/dL) groups. In another MESA report, assessing 6760 patients with elevated high-sensitivity C-reactive protein as defined by the Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin study, Blaha et al (2011) found CIMT increases correlated with obesity but only mildly with high-sensitivity C-reactive protein.[16,] A report from MESA trial by Patel et al (2015), which evaluated 6125 individuals with a family history of premature CHD, identified 382 atherosclerotic CVD events at a mean follow-up of 10.2 years.[17,] The study found that CAC data improved the risk estimation of atherosclerotic CVD events, but CIMT did not.

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In the Bogalusa Heart Study (n=991 subjects), obesity along with overweight and elevated metabolic risk were associated with increased CIMT.[18,] In this study population, Camhi et al (2011) found that 41% of patients had increased CHD risk. In an association between clotting factor VII and the carotid intima-media thickness study, clotting factor VII was associated with increases in CIMT in 1254 subjects.[19,] CIMT has also been used as a surrogate outcome measure in atherosclerosis treatment research studies.[20,]

The BioImage study, reported by Baber et al (2015), enrolled 5808 asymptomatic individuals from the U. S.[21,] All patients were evaluated by 3-dimensional carotid ultrasound and by CAC score and followed for a median of 2.7 years. The primary endpoint was major cardiovascular events, defined as cardiovascular death, MI, and ischemic stroke. Carotid plaque burden was an independent predictor of outcomes, with an HR of 2.36 (95% CI, 1.13 to 4.92) for individuals in the highest tertile. The CAC score was also an independent predictor of outcomes, with HRs similar to carotid plaque. Both carotid plaque and CAC score led to significant net reclassification, with a net reclassification index of 0.23.

Geisel et al (2017) conducted a prospective cohort study of 3108 patients without CVD on entrance to the study.[22,] All patients were evaluated for traditional risk factors of CVD; they were also assessed to calculate the CIMT, CAC score, and Ankle-Brachial Index score. During a mean follow-up of 10 years, 223 individuals suffered a major cardiovascular event (coronary event, stroke, CV death). All three methods helped predict adverse cardiovascular events. While CIMT was found to be higher in those who experienced an adverse cardiovascular event (0.76) than those who did not (0.69), CIMT did not significantly improve the prediction of cardiac risk for patients with an intermediate Framingham Risk Score.

Villines et al (2017) prospectively assessed a cohort of 3801 African American patients free of CVD at baseline.[23,] Over a median follow-up of 9 years, there were 171 new cases of CVD and 339 deaths. The incidence of cardiovascular events correlated with changes in CIMT and participants in the highest CIMT quartile had the largest unadjusted incident rates of CVD for both men and women. However, risk reclassification improved only slightly when adding CIMT to a model that included only traditional risk factors for CVD.

Table 4. Summary of Key Prospective Cohort Clinical Validity Study Characteristics

Study	Study Population	Study Type	Country	Dates	Follow-Up
Chambless (1997)[10,]	Asymptomatic for CHD	Prospective	US	1987-1993	Median 5.2 y
O'Leary (1999)[12,]	Asymptomatic for CHD; ≥65 y	Prospective	US	1989-1993	Median 6.2 y
van der Meer (2004)[11,]	Asymptomatic for CHD;≥55 y	Cohort	EU	1990-1993	NR
Folsom (2008)[14,]	Initially free of CVD	Cohort	US	2000-2007	Median 3.9 y
Baber (2015)[21,]	Asymptomatic for CVD	Cohort	US, EU	2008-2009	Median 2.7 y
Lorenz (2010)[13,]	Initially free of CVD	Retrospective	EU	NR	10 y
Geisel (2017)[22,]	Initially free of CVD	Prospective	EU	2000-2003	Mean 10.3±2.8 y

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Study	Study Population	Study Type	Country	Dates	Follow-Up
Villines (2017)[23,]	African Americans without CVD	Prospective	US	2000-2011	Median 9 y

CHD: coronary heart disease; CVD: cardiovascular disease; N: number; NR: not reported.

Section Summary: Clinically Valid

Evidence from a randomized controlled trial and large, prospective cohort studies has established that CIMT is an independent risk factor for CAD. However, systematic reviews have shown that use of CIMT data to reclassify patients into clinically relevant categories is modest and may not be clinically important. The uncertainty concerning the ability to reclassify patients into clinically relevant categories limits the potential for CIMT to improve health outcomes.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

In a study by Johnson et al (2011), 355 patients, ages 40 years with 1 or more CAD risk factors, received carotid ultrasound screenings to determine prospectively whether abnormal results would change physician and patient behaviors.[24,] Results were considered abnormal (when CIMT was >75th percentile or with 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 assess behavioral changes. Physician behavior in prescribing aspirin ($p<0.001$) and cholesterol medication ($p<0.001$) changed significantly after identification of abnormal carotid ultrasound results. Abnormal ultrasound results predicted reduced dietary sodium (odds ratio, 1.45; $p=0.002$) and increased fiber intake (odds ratio, 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.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

The evidence on the reclassification of cardiovascular risk offers a potential chain of evidence to improve outcomes. If a measure helps reclassify patients into risk categories that have different treatment approaches, then clinical management changes may occur that lead to improved outcomes. Because 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.

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Section Summary: Clinically Useful
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 indicate that use of CIMT will improve health outcomes.

Summary of Evidence
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. The 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. A meta-analysis of individual patient data by Lorenz et al (2012) found that CIMT was associated with increased cardiovascular events although CIMT progression over time was not associated with increased cardiovascular event risk. In a systematic review by Peters et al (2012), 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 evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American College of Cardiology and American Heart Association
The guidelines on the assessment of cardiovascular risk from the American College of Cardiology and the American Heart Association (2013) did not recommend carotid intimal-medial thickness (CIMT) measurement in routine risk assessment of a first atherosclerotic cardiovascular disease event (class III: no benefit; level of evidence: B).[29] 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.[25,]

American Association of Clinical Endocrinologists et al
The American Association of Clinical Endocrinologists and American College of Endocrinology (2017) 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)¾but not routinely.[26,]

American Society of Echocardiography
The American Society of Echocardiography (2008) consensus statement,[27,] 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

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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

The USPSTF (2009) 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.[28,]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."

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 5.

Table 5. 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	3200	Jun 2021

NCT: national clinical trial.

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CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

93895 Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral

DIAGNOSIS

Experimental / investigational for all diagnoses related to this policy.

REVISIONS	
08-24-2009	Policy added to the bcbsks.com web site.
09-06-2011	Description section updated
	Rationale section updated
	In Coding section ▪ Added the instructional phrase "It is possible that providers might incorrectly use CPT code 93880, which describes bilateral duplex scan of extracranial arteries."
	References updated
09-18-2012	Description section updated
	Rationale section updated
	References updated
01-01-2015	Policy posted 01-16-2015
	In Coding section: ▪ Added CPT Code: 93895 (Effective January 1, 2015)
10-13-2015	Description section updated
	Rationale section updated
	References updated
02-15-2017	Description section updated
	In Policy section: ▪ Removed "CIMT" abbreviation.
	Rationale section updated
	In Coding section: ▪ Coding notations updated
	References updated
08-01-2018	Description section updated
	Rationale section updated
	References updated
08-14-2019	Rationale section updated
	References updated

No review or update is scheduled on this Medical Policy as it is unlikely that further published literature would change the policy position. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, your professional or institutional relations representative, or submit a predetermination request.

REVISIONS	
08-14-2019	**Policy Archived**
07-06-2021	In Coding section: • Removed CPT Codes: 0126T (Code Termed 01-01-2021)

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