



BlueCross BlueShield
of Alabama

Name of Policy:

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

Policy #: 245
Category: Medicine

Latest Review Date: May 2018
Policy Grade: C

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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 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.

Coronary Heart Disease

Coronary heart disease (CHD) accounts for 30.8% of all deaths in the United States. 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.

Diagnosis

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. ATP III recommends the 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. 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.

The carotid arteries can be well visualized by ultrasonography, and ultrasonographic measurements of the thickness of the carotid intimal-medial wall (CIMT) have been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used, and the intimal-medial thickness 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.

Policy:

Ultrasonographic measurement of carotid artery intimal-medial thickness (CIMT) as a technique for identifying subclinical atherosclerosis for use in the screening, diagnosis, or management of atherosclerosis **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administer benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was performed through April 5, 2018.

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 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.

Individuals who Receive Ultrasonographic Measurement of CIMT

Clinical Context and Test Purpose

The purpose of CIMT testing in patients who are undergoing cardiac risk assessment is to inform a decision whether the testing increases or decreasing the cardiac risk.

The question addressed in this evidence review is: Does CIMT improve risk categorization in individuals who are undergoing a cardiac risk assessment?

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

Patients

The relevant population(s) of interest is individuals undergoing cardiac risk assessment.

Interventions

The test being considered is ultrasonographic measurement of CIMT.

Comparators

Calculations for an individual of risk for a cardiac event may be determined from multivariate risk models, such as the Framingham Risk Score. It may also be determined by individual discussion of known risk factors for cardiac events.

Outcomes

The general outcomes of interest in CIMT testing are to characterize the disease activity accurately and predict major adverse cardiac events, including stroke, myocardial infarction, and heart failure.

Timing

Five- to 10-year studies are of particular interest due to the prolonged natural history of cardiovascular disease.

Setting

The primary setting is an outpatient clinic.

Simplifying Test Terms

There are 3 core characteristics for assessing a medical test. Whether imaging, laboratory, or other, all medical tests must be:

- Technically reliable
- Clinically valid
- Clinically useful

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.

Diagnostic tests detect presence or absence of a condition. Surveillance and treatment monitoring are essentially diagnostic tests over a time frame. Surveillance to see whether a condition develops or progresses is a type of detection. Treatment monitoring is also a type of detection because the purpose is to see if treatment is associated with the disappearance, regression, or progression of the condition.

Prognostic tests predict the risk of developing a condition in the future. Tests to predict response to therapy are also prognostic. Response to therapy is a type of condition and can be either a beneficial response or adverse response. The term predictive test is often used to refer to response to therapy. To simplify terms, we use prognostic to refer both to predicting a future condition or to predicting a response to therapy

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

In 2010, Mookadam et al conducted a systematic review of the role of CIMT in predicting individual cardiovascular event risk and as a tool in assessing therapeutic interventions. The authors 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 studies to identify the best approaches to screening and interventions to prevent progression of atherosclerosis.

In a 2012 meta-analysis, the USE Intima-Media Thickness (USE-IMT) collaboration, investigators sought to determine whether common carotid intima-media thickness (CIMT) measurements could assist in estimating the ten 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 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 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 (0.759; 95% CI, 0.752 to 0.766; and 0.757; 95% CI, 0.749 to 0.764), suggesting the addition of CIMT in risk assessment offered limited benefit.

In a 2012 meta-analysis of individual participant data pooled from 16 studies with a total of 36,984 patients, Lorenz et al examined CIMT progression from two ultrasound screenings taken two to seven years apart (median, four years). Patients were followed for a mean of seven years, during which time 1339 strokes, 1519 MI, and 2028 combined end points (MI, stroke, vascular death) occurred. The mean CIMT of the two ultrasound results was predictive of cardiovascular risk using the combined end point (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, end point, and adjustments. As an example, for the combined end points, an increase of 1 SD 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, and HR was 0.98 (95% CI, 0.95 to 1.01) when adjusted for vascular risk factors.

These data confirm that CIMT is a predictor of cardiovascular risk, but do not demonstrate that changes in CIMT over time are predictive of future events.

A 2013 meta-analysis of 15 articles by van den Oord et al 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 risk factors. While a CIMT increase of 0.1mm was predictive for MI (HR=1.15; 95% CI, 1.12 to 1.18) and for stroke (HR=1.17; 95% CI, 1.15 to 1.21), the addition of CIMT did not statistically significantly increase risk prediction over traditional cardiovascular risk factors (p=0.8).

Studies have found including carotid plaques in CIMT increases the predictive value of cardiovascular 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 2012 systematic review by Peters found adding carotid plaque to the traditional CIMT model increased the c-statistic from 0.01 to 0.06.

Prospective cohort studies

Numerous prospective cohort studies have evaluated the association of CIMT with future cardiovascular events. Some of the larger trials are discussed below.

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, low-density lipoprotein (LDL) cholesterol, and triglycerides. CIMT was then also correlated with the incidence of CHD in a subgroup of patients enrolled in the trial after four to seven years of follow-up. Among the 12,841 subjects studied, there were 290 incident events. The HR rate for men and women, adjusted for age and gender, comparing extreme CIMT (i.e., ≥ 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 coronary heart disease (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 7983 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 cardiovascular disease, in elderly people. 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 increasing risks of stroke and MI.

O'Leary et al (1999) performed CIMT in 4476 asymptomatic subjects aged 65 years or older without clinical cardiovascular disease in the Cardiovascular Health Study. The incidence of cardiovascular 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 cardiovascular disease.

The Carotid Atherosclerosis Progression Study (CAPS) was a longitudinal study of 4904 subjects. All subjects received a baseline CIMT measurement, as well as traditional risk factor analysis, and were followed over a ten 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 (2010) retrospectively reviewed the data from CAPS. The authors 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 different models of reclassification and five 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.

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 6698 adults asymptomatic at baseline. In a 2010 article from MESA, CIMT results in 4792 healthy, nondiabetic adults who were not on lipid-lowering medications were compared in six different lipid groups, including normolipemic and several types of common dyslipidemias. The mean CIMT values were increased only for the combined hyperlipidemia (defined as any high-density lipoprotein [HDL]-C level, LDL-cholesterol [C] ≥ 160 and triglyceride ≥ 150) and simple hypercholesterolemia (defined as any HDL-C level, LDL-C ≥ 160 and triglyceride < 150) groups. In another MESA report, in 2011, on 6760 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. A 2015 report from MESA of 6125 individuals with a family history of premature coronary heart disease identified 382 atherosclerotic cardiovascular disease events at a mean follow-up of 10.2 years. The study found that coronary artery calcium improved the risk estimation atherosclerotic cardiovascular disease events but CIMT did not.

In the Bogalusa Heart Study of 991 subjects, obesity along with overweight and elevated metabolic risk was 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 1254 subjects. CIMT is also used as a surrogate outcome measure in atherosclerosis treatment research studies.

In 2010, Raiko et al compared cardiovascular disease risk-scoring tools for identification of CHD risk to CIMT results in 2204 healthy adults, aged 24 to 39 years, from the Cardiovascular Risk in Young Finns study. The cardiovascular disease risk scoring tools evaluated included the Framingham, Reynolds Risk Score, Systematic Coronary Risk Evaluation (SCORE), PROCAM, and Finrisk cardiovascular risk scores. In this population-based follow-up study, the authors found all of the cardiovascular disease risk scores performed equally in being able to predict subclinical atherosclerosis, as measured by high CIMT six years later.

The BioImage study enrolled 5808 asymptomatic individuals from the United States. All patients were evaluated by 3-dimensional carotid ultrasound and by coronary artery calcification score, and followed for a mean of 2.7 years. The primary endpoint was major cardiovascular events, defined as cardiovascular death, MI, and ischemic stroke. The carotid plaque burden was an independent predictor of outcomes, with a hazard ratio of 2.36 (95% CI, 1.13 to 4.92) for individuals in the highest tertile. The coronary calcium score was also an independent predictor of outcomes, with similar hazard ratios to carotid plaque. Both carotid plaque and coronary calcium score led to significant net reclassification, with a net reclassification index of 0.23.

Geisel et al (2017) is a prospective cohort study of 3108 patients without cardiovascular disease on entrance to the study. All patients were evaluated by CIMT, coronary artery calcification, and ankle brachial index. During a mean follow-up time of 10 years, 223 individuals suffered a major cardiovascular event (coronary event, stroke, CV death). All three methods served to help predict adverse cardiovascular event. While CIMT was found to be higher in those who experienced an adverse cardiovascular event than those who did not (0.76 ± 0.17 vs 0.69 ± 0.15), it did not lead to a significant improvement in predicting cardiac risk for patients with an intermediate Framingham Risk Score.

Villines et al (2017) is a prospective cohort study of 3801 African American patients who were free of cardiovascular disease at baseline. Over a median follow-up time of 9 years, there were 171 new cases of cardiovascular disease and 339 deaths. The incidence of cardiovascular events was related to changes in CIMT, and participants in the highest CIMT quartile had the largest crude incident rates of cardiovascular disease for both men and women. However, risk reclassification improved only slightly when adding CIMT to a model which required only traditional risk factors for cardiovascular disease.

Section Summary: Prognostic Value

Evidence from large, prospective cohort studies has established that CIMT is an independent risk factor for cardiovascular 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.

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 2011 study by Johnson et al, 355 patients, aged 40 years with one or more cardiovascular disease risk factors, 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 75th 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.

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 reclassification of cardiovascular 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. 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.

Section Summary: Clinical Utility

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.

Summary of Evidence

For individuals who are undergoing cardiac risk assessment who receive ultrasonic measurement of carotid intima-media thickness, the evidence includes large cohort studies, case control studies, and systematic reviews. Relevant outcomes are test accuracy and morbid events. Some studies correlate increased carotid intima-medial thickness (CIMT) with many other commonly used markers for risk of coronary heart disease (CHD) and with risk for future cardiovascular events. A 2012 meta-analysis of individual participant data by Lorenz et al found that CIMT was associated with increased cardiovascular events, CIMT progression over time was not associated with increased cardiovascular event risk. In a systematic review by Peters et al, 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 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 existing evidence is therefore insufficient to determine the impact of this technology on net health outcome.

Practice Guidelines and Position Statements

American College of Cardiology and American Heart Association

A 2013 guideline on the assessment of cardiovascular risk from the American College of Cardiology and the American Heart Association (ACC/AHA) does not recommend CIMT for routine risk assessment of a first atherosclerotic cardiovascular disease event. ACC/AHA Class III: no benefit, LOE: B. This differs from the previous 2010 version of the ACC/AHA 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

The American Association of Clinical Endocrinologists and American College of Endocrinology published 2017 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; BEL 2)—but that it should not be performed routinely.

American Society of Echocardiography

The 2008 American Society of Echocardiography Consensus Statement endorsed by the Society for Vascular Medicine, states that CIMT is a feature of arterial wall aging “that is not synonymous with atherosclerosis, particularly in the absence of plaque.” The statement recommends measurement of both CIMT and carotid plaque by ultrasound “for refining CVD risk assessment in patients at intermediate cardiovascular disease risk (Framingham Risk Score 6–20%) without established CHD, peripheral arterial disease, cerebrovascular disease, diabetes mellitus, or abdominal aortic aneurysm.” However, the authors acknowledge that, “More research is needed to determine whether improved risk prediction observed with CIMT or carotid plaque imaging translates into improved patient outcomes.”

National Cholesterol Education Program Adult Treatment Panel (NCEP ATP)

The Third Report of NCEP ATP does not recommend using “emerging risk factors” in the assessment of persons for primary prevention. It does state that “emerging risk factors” may be useful in certain patient-centered circumstances.

U.S. Preventive Services Task Force Recommendations

In October 2009, the U.S. Preventive Services Task Force (USPSTF) published a systematic review of CIMT within the scope of a larger recommendation statement entitled “Using Nontraditional Risk Factors in Coronary Heart Disease Risk Assessment”. On the basis of one fair- and two good-quality studies, the USPSTF states that CIMT, independently of Framingham risk factors, predicts coronary heart disease (CHD) in asymptomatic patients. These studies were longitudinal, population-based studies conducted in the U.S. and the Netherlands. USPSTF reviewed the Atherosclerosis Risk in Communities (ARIC) study and concluded that CIMT measurement can result in risk prediction that is modestly improved, particularly in adult men. However, the review cautions that the studies that did show an association were all done in a research setting, and therefore one cannot draw conclusions on the applicability of CIMT to the intermediate-risk population at large. The studies which USPSTF referenced are further detailed within this policy.

The Summary of Recommendation specific to CIMT is stated as:

“The U.S. Preventive Services Task Force (USPSTF) concludes 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 identifies 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.”

Key Words:

Carotid intimal medial thickness (CIMT), B-mode ultrasound, intimal medial thickness, IMT, atherosclerosis, ultrasonographic measurement, SonoCalc®, Cardioscan

Approved by Governing Bodies:

In February 2003, SonoCalc® (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.

Benefit Application:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply

FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT code:

93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral (Effective 01/01/15)
0126T	Carotid intima media thickness

It is possible that providers may incorrectly use the following CPT code:

93880	Duplex scan of extracranial arteries; complete bilateral study
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Previous Coding:

93799	Unlisted cardiovascular service or procedure
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Policy History:

Medical Policy Group, August 2005 (3)

Medical Policy Administration Committee, August 2005

Available for comment August 27-October 10, 2005

Medical Policy Group, August 2006 (1)

Medical Policy Group, August 2007(1)

Medical Policy Group, March 2009 (4)

Medical Policy Group, July 2009 (3)

Medical Policy Group, July 2010 (1): Policy updated, no coverage change

Medical Policy Group, July 2011 (1): Update to Description, Key Points and References

Medical Policy Group, July 2012 (1): Update to Key Points and References related to MPP update; no change to policy statement

Medical Policy Group, July 2013 (4): 2013 Update to Key Points and References related to Diagnostic Utility

Medical Policy Panel, July 2014

Medical Policy Group, July 2014 (4): Updated Key Points, Practice Guidelines and References. No change to policy statement at this time.

Medical Policy Group, November 2014: 2015 Annual Coding update. Added code 93895 to current coding

Medical Policy Panel, July 2015

Medical Policy Group, July 2015 (4): Updates to Description, Key Points, Key Words, Coding, and References. No change to policy statement. Moved CPT 93799 to previous coding section

Medical Policy Group, January 2016 (4): Added CPT code 93880 to Coding section.

Medical Policy Group, April 2016 (4): Added the statement “It is possible that providers may incorrectly use the following CPT code”.

Medical Policy Panel, January 2017

Medical Policy Group, January 2017(4): Updates to Description, Key Points, and References. No change to policy statement.

Medical Policy Group, October 2017 (4): Added Key Word Cardioscan.

Medical Policy Panel, May 2018

Medical Policy Group, May 2018 (4): Updates to Description, Key Points, and References. No change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date

hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.