

POLICY TITLE	ULTRASONOGRAPIC MEASUREMENT OF CAROTID INTIMAL MEDIAL THICKNESS AS AN ASSESSMENT OF SUBCLINICAL ATHEROSCLEROSIS
POLICY NUMBER	MP 5.036

Effective Date:	10/1/2023
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POLICY RATIONALE DISCLAIMER POLICY HISTORY PRODUCT VARIATIONS DEFINITIONS CODING INFORMATION DESCRIPTION/BACKGROUND BENEFIT VARIATIONS REFERENCES

### I. POLICY

Ultrasonographic measurement of carotid artery intimal-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis is considered **investigational** for use in the screening, diagnosis, or management of atherosclerotic disease. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

#### II. PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: <u>https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies</u>

### III. DESCRIPTION/BACKGROUND

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

### CORONARY HEART DISEASE

Heart disease is the leading cause of mortality in the United States, accounting for more than half of all deaths. Coronary heart disease (CHD), also known as coronary artery disease, is the most common cause of heart disease. In a 2023 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 720,000 Americans have a new coronary attack (first hospitalized myocardial infarction or CHD death) and 335,000 have a recurrent attack annually. An estimated 20.5 million Americans ≥20 years of age have CHD. The prevalence of CHD was higher for males than females in all age groups. Total CHD prevalence is 7.1% in US adults ≥20 years of age; CHD prevalence is 8.7% for males and 5.8% for females. On the basis of data from the 2018 National Health Interview Survey, CHD prevalence estimates are 5.7% among White people, 5.4% among Black people, 8.6% among American Indian/Alaska Native people, and 4.4% among Asian people ≥18 years of age.

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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 lowdensity 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 NCEP Adult Treatment Panel (ATP III) establishes various treatment strategies to modify the risk of CHD, based in part 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 use of the Framingham criteria to further stratify those patients with 2 or more risk factors for more intensive lipid management. However, at every level of risk factor exposure, there is substantial variation in the amount of atherosclerosis, presumably related to genetic susceptibility and the influence of other risk factors. Therefore, there has been interest in identifying a technique that can improve the ability to diagnose those at risk for developing CHD, as well as measure disease progression, particularly for those at intermediate risk.

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

### **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. FDA product code: LLZ.

### IV. RATIONALE

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### SUMMARY OF EVIDENCE

For individuals who are undergoing cardiac risk assessment who receive ultrasonic measurement of carotid intima-media thickness (CIMT), the evidence includes large cohort studies and systematic reviews. Relevant outcomes are test accuracy and morbid events. Some studies correlate increased 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 although CIMT progression over time was not associated with increased



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cardiovascular event risk. In a 2012 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 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. In addition, available studies do not define how 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 CV risk patients. Study results showed definite patterns related to various factors that could be used as a tool to earlier identify patients at increased CV risk, but patient outcomes were not assessed. The evidence is insufficient to determine the effects of the technology on health outcomes.

#### V. DEFINITIONS

N/A

### VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

#### VII. DISCLAIMER

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

#### **VIII. CODING INFORMATION**

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Investigational when used for ultrasonographic measurement of carotid artery intimalmedial thickness (IMT) as a technique of identifying subclinical atherosclerosis for use in the screening, diagnosis, or management of atherosclerotic disease; therefore, the following are not covered:

Procedur	e Codes				
93895					

#### IX. REFERENCES

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### X. POLICY HISTORY

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MP 5.036	CAC 01/27/2004
	CAC 05/31/2005
	CAC 06/27/2006
	CAC 07/31/2007
	CAC 07/29/2008
	CAC 07/28/2009
	CAC 05/25/2010 Adopted BCBSA Criteria
	CAC 04/26/2011 Consensus
	CAC 06/26/2012 Consensus. No change to policy statement.
	07/30/2013 Admin coding review completed
	CAC 09/24/2013 Consensus. No change to policy statement. Added rationale
	section. Updated references. Changed FEP variation to reference the policy
	manual.
	07/24/2014 Administrative update. Added LCD L34711 Non-invasive
	Cerebrovascular Arterial Studies to reference list.
	CAC 09/30/2014. Consensus. No change to policy statements. Reference and
	rationale sections updated.
	01/2015 New 2015 CPT codes added to policy.
	11/02/2015 Administrative change. LCD number changed from L32641 and
	L31686 to L35084 and L35094 due to Novitas update to ICD-10.
	CAC 09/29/2015 Consensus review. No change to the policy statement.
	Reference and rationale update. Coding Reviewed
	CAC 09/27/2016 Consensus review. No change to the policy statement.
	Reference and rationale update. Coding Reviewed. Variation reformatting.
	CAC 11/28/2017 Consensus. No change to policy statements. References and
	rationale updated. Coding reviewed.
	<b>10/16/2018 Consensus review</b> . No change to policy statements. References
	updated. Rationale condensed.



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<b>07/15/2019 Consensus review</b> . No change to policy statements. References updated.
06/26/2020 Consensus Review. No change to policy statements.
<b>11/24/2020 Administrative update.</b> CPT 0126T removed from policy as a deleted code.
<b>06/23/2021 Consensus review.</b> No change to policy statement. No coding changes. Description/Background updated. Product Variation statement updated. References reviewed and updated.
<b>07/08/2022 Consensus review.</b> No change to policy statement. FEP language updated. Coding table format updated. References reviewed.
6/22/2023 Consensus review. No change in policy statement. Background, rationale, references updated. No coding changes.

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