# MEDICAL POLICY

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

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| **Original Issue Date (Created):** | **5/3/2004** |
| **Most Recent Review Date (Revised):** | **6/25/2020** |
| **Effective Date:** | **1/1/2021** |


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## I. POLICY

Ultrasonographic measurement of carotid artery intimal-medial thickness (IMT) 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 conclusion concerning the health outcomes or benefits associated with this procedure.

## II. PRODUCT VARIATIONS Top

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

## III. DESCRIPTION/BACKGROUND Top

Ultrasonographic measurement of carotid intimal-medial thickness (IMT) 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 intimal-medial thickening (atherosclerosis) may provide an opportunity to intervene earlier in the atherogenic disease and/or monitor disease progression.

### CORONARY HEART DISEASE

Coronary heart disease (CHD) accounts for 30.8% of all deaths in the U.S.[1] Established major risk factors for coronary heart disease (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, 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.[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. 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 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. 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 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 evidence is insufficient to determine the effects of the technology on health outcomes.

## V. DEFINITIONS Top

N/A

## VI. BENEFIT VARIATIONS Top

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 BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

## VII. DISCLAIMER Top

*Capital BlueCross'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 BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

## VIII. CODING INFORMATION Top

**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 intimal-medial 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:**

| CPT Codes® | | | | | | | | |
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| 93895 | | | | | | | | |



## IX. REFERENCES

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35. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.02.16, Ultrasonographic Measurement of Carotid Intima-Medial Thickness as an Assessment of Subclinical Atherosclerosis. June 25, 2020.*

## X. POLICY HISTORY

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| **MP 5.036** | **CAC 1/27/04** |
| | **CAC 5/31/05** |
| | **CAC 6/27/06** |
| | **CAC 7/31/07** |
| | **CAC 7/29/08** |
| | **CAC 7/28/09** |
| | **CAC 5/25/10 Adopted BCBSA Criteria** |
| | **CAC 4/26/11 Consensus** |
| | **CAC 6/26/12 Consensus**. No change to policy statement. |
| | **7/30/13 Admin coding review** completed |
| | **CAC 9/24/13 Consensus.** No change to policy statement. Added rationale section. Updated references. Changed FEP variation to reference the policy manual. |
| | **7/24/14 Administrative update**. Added LCD L34711 Non-invasive Cerebrovascular Arterial Studies to reference list. |
| | **CAC 9/30/14. Consensus.** No change to policy statements. Reference and rationale sections updated. |
| | **01/2015** New 2015 CPT codes added to policy. |

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| | **11/2/15 Administrative change.** LCD number changed from L32641 and L31686 to L35084 and L35094 due to Novitas update to ICD-10. |
| | **CAC 9/29/15 Consensus review**. No change to the policy statement. Reference and rationale update. Coding Reviewed |
| | **CAC 9/27/2016 Consensus review**. No change to the policy statement. Reference and rationale update. Coding Reviewed. Variation reformatting. |
| | **CAC 11/28/17 Consensus**. No change to policy statements. References and rationale updated. Coding reviewed. |
| | **10/16/18 Consensus review**. No change to policy statements. References updated. Rationale condensed. |
| | **07/15/19 Consensus review**. No change to policy statements. References updated. |
| | **06/26/20 Consensus Review.** No change to policy statements. |
| | **11/24/20 Administrative update.** CPT 0126T removed from policy as a deleted code. |

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