# **Medical Coverage Policy** | Ultrasonographic Measurement of Carotid Intima-Medial Thickness as an Assessment of Subclinical Artherosclerosis



**EFFECTIVE DATE:**10|01|2015 **POLICY LAST UPDATED:** 05|19|2021

#### **OVERVIEW**

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.

#### **MEDICAL CRITERIA**

Not applicable.

### **PRIOR AUTHORIZATION**

Not applicable.

#### **POLICY STATEMENT**

### Medicare Advantage Plans

Ultrasonographic measurement of carotid artery intima-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis is not covered for use in the screening, diagnosis, or management of atherosclerotic disease as the evidence is insufficient to determine the effects of the technology on health outcomes.

#### Commercial

Ultrasonographic measurement of carotid artery intima-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis is not medically necessary for use in the screening, diagnosis, or management of atherosclerotic disease as the evidence is insufficient to determine the effects of the technology on health outcomes.

#### COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

#### BACKGROUND

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.1, In a 2020 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 605,000 Americans have a new coronary attack (first hospitalized myocardial infarction or CHD death) and 200,000 have a recurrent attack annually.

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 low-density 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.

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 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 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 CIMT has been investigated as a technique to identify and monitor subclinical atherosclerosis. B mode ultrasound is most commonly used to measure CIMT. CIMT is measured and averaged over several sites in each carotid artery. Imaging the far wall of each common carotid artery yields more accurate and reproducible CIMT measurements than imaging 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 CIMT.

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 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.

### **Regulatory Status**

In February 2003, SonoCalc® (SonoMetric Health, LLC, Bountiful, UT) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this softwarewas 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, several other devices have been approved through the 510(k) process. Product code: LLZ.

### CODING

### The following code(s) are not medically necessary:

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

### **RELATED POLICIES**

None

### PUBLISHED

Provider Update, July 2021 Provider Update, August 2020 Provider Update, September 2019 Provider Update January 2019 Provider Update January 2018

#### **REFERENCES:**

 Virani SS, Alonso A, Benjamin EJ, et al. Heart Disease and Stroke Statistics-2020 Update: A Report From the American Heart Association. Circulation. Mar 03 2020; 141(9): e139-e596. PMID 31992061
 Pasternak RC. Report of the Adult Treatment Panel III: the 2001 National Cholesterol Education Program guidelines on the detection, evaluation and treatment of elevated cholesterol in adults. Cardiol Clin. Aug 2003; 21(3): 393-8. PMID 14621453

3. Mookadam F, Moustafa SE, Lester SJ, et al. Subclinical atherosclerosis: evolving role of carotid intimamedia thickness. Prev Cardiol. 2010; 13(4): 186-97. PMID 20860643

4. Den Ruijter HM, Peters SA, Anderson TJ, et al. Common carotid intima-media thickness measurements in cardiovascular risk prediction: a meta-analysis. JAMA. Aug 22 2012; 308(8): 796-803. PMID 22910757

5. Lorenz MW, Polak JF, Kavousi M, et al. Carotid intima-media thickness progression to predict cardiovascular events in the general population (the PROG-IMT collaborative project): a meta-analysis of individual participant data. Lancet. Jun 02 2012; 379(9831): 2053-62. PMID 22541275

6. van den Oord SC, Sijbrands EJ, ten Kate GL, et al. Carotid intima-media thickness for cardiovascular risk assessment: systematic review and meta-analysis. Atherosclerosis. May 2013; 228(1): 1-11. PMID 23395523 7. Bytyci I, Shenouda R, Wester P, et al. Carotid Atherosclerosis in Predicting Coronary Artery Disease: A Systematic Review and Meta-Analysis. Arterioscler Thromb Vasc Biol. Apr 2021; 41(4): e224-e237. PMID 33626907

8. Tschiderer L, Klingenschmid G, Seekircher L, et al. Carotid intima-media thickness predicts carotid plaque development: Metaanalysis of seven studies involving 9341 participants. Eur J Clin Invest. Apr 2020; 50(4): e13217. PMID 32112400

9. Plichart M, Celermajer DS, Zureik M, et al. Carotid intima-media thickness in plaque-free site, carotid plaques and coronary heart disease risk prediction in older adults. The Three-City Study. Atherosclerosis. Dec 2011; 219(2): 917-24. PMID 22005196

10. Keo HH, Baumgartner I, Hirsch AT, et al. Carotid plaque and intima-media thickness and the incidence of ischemic events in patients with atherosclerotic vascular disease. Vasc Med. Oct 2011; 16(5): 323-30. PMID 21908682

11. Nambi V, Chambless L, He M, et al. Common carotid artery intima-media thickness is as good as carotid intima-media thickness of all carotid artery segments in improving prediction of coronary heart disease risk in the Atherosclerosis Risk in Communities (ARIC) study. Eur Heart J. Jan 2012; 33(2): 183-90. PMID 21666250

 Xie W, Liang L, Zhao L, et al. Combination of carotid intima-media thickness and plaque for better predicting risk of ischaemic cardiovascular events. Heart. Aug 2011; 97(16): 1326-31. PMID 21653216
 Peters SA, den Ruijter HM, Bots ML, et al. Improvements in risk stratification for the occurrence of cardiovascular disease by imaging subclinical atherosclerosis: a systematic review. Heart. Feb 2012; 98(3): 177-84. PMID 22095617

14. Dobs AS, Nieto FJ, Szklo M, et al. Risk factors for popliteal and carotid wall thicknesses in the Atherosclerosis Risk in Communities (ARIC) Study. Am J Epidemiol. Nov 15 1999; 150(10): 1055-67. PMID 10568620

15. Chambless LE, Heiss G, Folsom AR, et al. Association of coronary heart disease incidence with carotid arterial wall thickness and major risk factors: the Atherosclerosis Risk in Communities (ARIC) Study, 1987-1993. Am J Epidemiol. Sep 15 1997; 146(6): 483-94. PMID 9290509

16. van der Meer IM, Bots ML, Hofman A, et al. Predictive value of noninvasive measures of atherosclerosis for incident myocardial infarction: the Rotterdam Study. Circulation. Mar 09 2004; 109(9): 1089-94. PMID 14993130

17. O'Leary DH, Polak JF, Kronmal RA, et al. Carotid-artery intima and media thickness as a risk factor for myocardial infarction and stroke in older adults. Cardiovascular Health Study Collaborative Research Group. N Engl J Med. Jan 07 1999; 340(1): 14-22. PMID 9878640

18. Lorenz MW, Schaefer C, Steinmetz H, et al. Is carotid intima media thickness useful for individual prediction of cardiovascular risk? Ten-year results from the Carotid Atherosclerosis Progression Study (CAPS). Eur Heart J. Aug 2010; 31(16): 2041-8. PMID 20530503

19. Folsom AR, Kronmal RA, Detrano RC, et al. Coronary artery calcification compared with carotid intimamedia thickness in the prediction of cardiovascular disease incidence: the Multi-Ethnic Study of

Atherosclerosis (MESA). Arch Intern Med. Jun 23 2008; 168(12): 1333-9. PMID 18574091

20. Paramsothy P, Knopp RH, Bertoni AG, et al. Association of combinations of lipid parameters with carotid intima-media thickness and coronary artery calcium in the MESA (Multi-Ethnic Study of Atherosclerosis). J Am Coll Cardiol. Sep 21 2010; 56(13): 1034-41. PMID 20846602

21. Blaha MJ, Rivera JJ, Budoff MJ, et al. Association between obesity, high-sensitivity C-reactive protein 2 mg/L, and subclinical atherosclerosis: implications of JUPITER from the Multi-Ethnic Study of Atherosclerosis. Arterioscler Thromb Vasc Biol. Jun 2011; 31(6): 1430-8. PMID 21474823

22. Patel J, Al Rifai M, Blaha MJ, et al. Coronary Artery Calcium Improves Risk Assessment in Adults With a Family History of Premature Coronary Heart Disease: Results From Multiethnic Study of Atherosclerosis. Circ Cardiovasc Imaging. Jun 2015; 8(6): e003186. PMID 26047825

23. Camhi SM, Katzmarzyk PT, Broyles ST, et al. Subclinical atherosclerosis and metabolic risk: role of body mass index and waist circumference. Metab Syndr Relat Disord. Apr 2011; 9(2): 119-25. PMID 21133775
24. Green D, Foiles N, Chan C, et al. An association between clotting factor VII and carotid intima-media thickness: the CARDIA study. Stroke. Jul 2010; 41(7): 1417-22. PMID 20466994

25. Bots ML, Palmer MK, Dogan S, et al. Intensive lipid lowering may reduce progression of carotid atherosclerosis within 12 months of treatment: the METEOR study. J Intern Med. Jun 2009; 265(6): 698-707. PMID 19298496

26. Baber U, Mehran R, Sartori S, et al. Prevalence, impact, and predictive value of detecting subclinical coronary and carotid atherosclerosis in asymptomatic adults: the BioImage study. J Am Coll Cardiol. Mar 24 2015; 65(11): 1065-74. PMID 25790876

27. Geisel MH, Bauer M, Hennig F, et al. Comparison of coronary artery calcification, carotid intima-media thickness and anklebrachial index for predicting 10-year incident cardiovascular events in the general population. Eur Heart J. Jun 14 2017; 38(23): 1815-1822. PMID 28379333

28. Villines TC, Hsu LL, Blackshear C, et al. Relation of Carotid Intima-Media Thickness to Cardiovascular Events in Black Americans (From the Jackson Heart Study). Am J Cardiol. Nov 01 2017; 120(9): 1528-1532. PMID 28844515

29. Johnson HM, Turke TL, Grossklaus M, et al. Effects of an office-based carotid ultrasound screening intervention. J Am Soc Echocardiogr. Jul 2011; 24(7): 738-47. PMID 21477989

30. Olmastroni E, Baragetti A, Casula M, et al. Multilevel Models to Estimate Carotid Intima-Media Thickness Curves for Individual Cardiovascular Risk Evaluation. Stroke. Jul 2019; 50(7): 1758-1765. PMID 31164073

31. Goff DC, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. Jun 24 2014; 129(25 Suppl 2): S49-73. PMID 24222018

32. Greenland P, Alpert JS, Beller GA, et al. 2010 ACCF/AHA guideline for assessment of cardiovascular risk in asymptomatic adults: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Dec 14 2010; 56(25): e50-103. PMID 21144964

33. Jellinger PS, Handelsman Y, Rosenblit PD, et al. AMERICAN ASSOCIATION OF CLINICAL ENDOCRINOLOGISTS AND AMERICAN COLLEGE OF ENDOCRINOLOGY GUIDELINES FOR MANAGEMENT OF DYSLIPIDEMIA AND PREVENTION OF CARDIOVASCULAR DISEASE -EXECUTIVE SUMMARY Complete Appendix to Guidelines available at http://journals.aace.com. Endocr Pract. Apr 02 2017; 23(4): 479-497. PMID 28156151

34. Stein JH, Korcarz CE, Hurst RT, et al. Use of carotid ultrasound to identify subclinical vascular disease and evaluate cardiovascular disease risk: a consensus statement from the American Society of Echocardiography Carotid Intima-Media Thickness Task Force. Endorsed by the Society for Vascular Medicine. J Am Soc Echocardiogr. Feb 2008; 21(2): 93-111; quiz 189-90. PMID 18261694

35. Johri AM, Nambi V, Naqvi TZ, et al. Recommendations for the Assessment of Carotid Arterial Plaque by Ultrasound for the Characterization of Atherosclerosis and Evaluation of Cardiovascular Risk: From the American Society of Echocardiography. J Am Soc Echocardiogr. Aug 2020; 33(8): 917-933. PMID 32600741 36. Calonge N, Petitti DB, DeWitt TG, et al. Using nontraditional risk factors in coronary heart disease risk assessment: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. Oct 06 2009; 151(7): 474-82. PMID 19805770

37. Curry SJ, Krist AH, Owens DK, et al. Risk Assessment for Cardiovascular Disease With Nontraditional Risk Factors: US Preventive Services Task Force Recommendation Statement. JAMA. Jul 17 2018; 320(3): 272-280. PMID 29998297

## CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.



500 EXCHANGE STREET, PROVIDENCE, RI 02903-2699 (401) 274-4848 WWW.BCBSRI.COM