Subject: Measurement of Carotid Intima-Media Thickness for Prediction of Clinical Vascular Events		Original Effective Date: 2/2/15
Policy Number: MCP-235	**Revision Date(s):** 7/10/18	
Review Date: 12/16/15, 9/15/16, 6/22/17, 9/18/19, 9/16/20, 12/14/20		
MCPC Approval Date: 7/10/18, 9/18/19, 9/16/20		

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

Contents

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Ultrasonographic measurement of carotid intima-medial (also called intimal-medial or intima-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. Ultrasonographic measurement of CIMT has been examined as a screening test for progression of atherosclerosis and is proposed for use in identifying and monitoring coronary heart disease.

CIMT is performed on the common carotid artery on both sides of the neck and the measurements of the intima and the media thickness are recorded. This noninvasive test is performed by scanning with high-resolution B mode ultrasonography and using computer enhancement and analysis to determine the thickness of the intima and media of the carotid artery. The results evaluate for any thickening or signs of anatomical changes from early atherosclerotic disease.

RECOMMENDATION

Measurement of carotid intima-media thickness for prediction of clinical vascular events is considered investigational/experimental and unproven due to insufficient evidence in the peer reviewed medical literature that that have not established safety, efficacy and effect on net health outcomes.

SUMMARY OF MEDICAL EVIDENCE [2-17]

There is insufficient published evidence to assess the role of carotid intima-media thickness measurement for the prediction of clinical vascular events and/or the impact on health outcomes or patient management. There are no randomized clinical trials in the published literature that directly test the theory that carotid or femoral IMT measurements result in improved patient outcomes, and no specific guidance on how measurements of carotid IMT should be incorporated into risk assessment and risk management. The current published literature consists of several systematic reviews, meta-analyses, case series, and large longitudinal cohort studies. A summary of the most relevant studies is outlined below.

A very large cohort study called IMPROVE (2012) compared the performance of several measures of carotid intima-media thickness (C-IMT) as predictors of cardiovascular events (CVEs), and investigated whether they add to the predictive accuracy of Framingham risk factors (FRFs). The study was carried out in 5 European countries. A total of 3,703 subjects (median age 64.4 years; 48% men) were followed-up for a median of 36.2 months, and 215 suffered a first CVE (incidence: 19.9/1,000 person-years). All measures of C-IMT and the interadventitia common carotid artery diameter (ICCAD) were associated with the risk of CVEs, after adjustment for FRFs and therapies (all $p < 0.005$). The average of 8 maximal IMT measurements (IMT(mean-max)), alone or combined with ICCAD, classified events and non-events better than the common carotid mean IMT (net reclassification improvement [NRI]: +11.6% and +19.9%, respectively; both $p < 0.01$). Compared with classification based on FRFs alone, the NRI resulting from the combination of FRFs+ICCAD+IMT(mean-max) was +12.1% ($p < 0.01$). The presence of at least 1 plaque (maximum IMT >1.5 mm) performed significantly worse than composite IMTs that incorporated plaques ($p < 0.001$). Adjusted Kaplan-Meier curves showed that individuals with a FRS = 22.6% (cohort average), and both IMT(mean-max) and ICCAD above the median, had a 6.5% risk to develop a CVE over 3 years versus a 3.4% risk for those with the same FRS, and both IMT(mean-max) and ICCAD below the median. The authors concluded that a risk stratification strategy based on C-IMT and ICCAD as an adjunct to FRFs is a rational approach to prevention of cardiovascular disease. [3]

In a large randomized controlled trial of 984 participants data was analyzed from the Measuring Effects on Intima-Media Thickness: an Evaluation of Rosuvastatin (METEOR) study, which showed that rosuvastatin attenuated the rate of change of carotid intima-media thickness (CIMT). In this post hoc analysis, duplicate baseline ultrasound images from the far wall of the left and right common carotid arteries were used for the evaluation of the echolucency of the carotid intima-media, measured by grey-scale median (GSM) on a scale of

0-256. Low GSM values reflect echolucent, whereas high values reflect echogenic structures. The relationship between baseline GSM and cardiovascular risk factors was evaluated using linear regression models. RESULTS: Mean baseline GSM (± SD) was 84 ± 29. Lower GSM of the carotid intima-media was associated with older age, high body mass index (BMI) and low levels of high-density lipoprotein cholesterol (HDL-C) [beta -4.49, 95% confidence interval (CI) -6.50 to -2.49; beta -4.51, 95% CI -6.43 to -2.60; beta 2.45, 95% CI 0.47 to 4.42, respectively]. Common CIMT was inversely related to GSM of the carotid intima-media (beta -3.94, 95% CI -1.98 to -5.89). Older age, high BMI and low levels of HDL-C are related to echolucency of the carotid intima-media. The authors concluded that echolucency of the carotid intima-media may be used as a marker of cardiovascular risk profile to provide more information than thickness alone. [11]

In the Tromsø Study (2012) subjects were 1307 men and 1436 women who participated in a longitudinal population-based study with ultrasound examination of the right carotid artery at baseline and after 13 years of follow-up. Total cholesterol, high-density lipoprotein cholesterol, blood pressure, body mass index, and information about smoking habits, prevalent diabetes, and cardiovascular disease were obtained at baseline. Carotid atherosclerosis was assessed as TPA and mean IMT of plaque-free segments of the common carotid artery. Associations between z-scores of risk factors and carotid atherosclerosis were assessed in multiple linear regression models. RESULTS: In multivariable models, total cholesterol, systolic blood pressure, and smoking were stronger predictors of follow-up TPA than of IMT, whereas sex and age were stronger predictors of IMT. Total cholesterol (standardized β=0.081), systolic blood pressure (standardized β=0.062), and smoking (standardized β=0.107) were significant predictors of ΔTPA, whereas only total cholesterol (standardized β=0.084) was an independent predictor of ΔIMT. The variance explained by traditional cardiovascular risk factors was somewhat greater for TPA than for IMT. The authors concluded that the cardiovascular risk factors total cholesterol, smoking, and systolic blood pressure were stronger long-term predictors of TPA and TPA progression than for IMT and IMT progression. [5]

The systematic reviews and meta-analyses investigated the ability of CIMT measurement to identify coronary artery disease in asymptomatic patients and predict first-time myocardial infarction (MI) or first-time stroke. The inclusion criteria varied for the studies included in these reviews. The results consistently reported that CIMT is a predictor of cardiovascular risk but the addition of CIMT measurement did not significantly improve risk prediction over conventional cardiovascular risk factors. In addition, most of the reviewed studies were conducted in the research setting and therefore cannot be used to describe conclusions on the applicability of CIMT measurement in the clinical setting for asymptomatic patients. [2 4 7 8 12 14]

Professional Society Guidelines [18-24]

The 2013 American College of Cardiology Foundation/American Heart Association guideline for the assessment of CVD risk does not recommend the routine use of CIMT in clinical practice for CVD risk assessment. The U.S. Preventative Services Task Force (USPSTF) 2009 Guidelines conclude that the current evidence is insufficient to assess the balance of benefits and harms of using the nontraditional risk factors such as CIMT to screen asymptomatic men and women with no history of CAD to prevent CHD events. The 2010 American College of Cardiology Foundation/American Heart Association guidelines for the assessment of CVD risk in asymptomatic adults give CIMT a level IIa recommendation for cardiovascular risk evaluation in intermediate risk patients. No recommendations were made regarding the use of CIMT in low-risk patients, high-risk patients, or patients with established CVD.

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral
0126T	Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
I70.0-I70.92	Atherosclerosis code range

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Peer Reviewed Publications

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Review/Revision History:

2/2/15: New Policy
12/16/15, 9/15/16, 6/22/17: No changes.
7/10/18: This policy was reviewed and this testing remains controversial and experimental. The following sections were updated: professional society guidelines and references.
9/18/19 & 9/16/20: Policy reviewed, no changes.