Molina Clinical Policy
Measurement of Carotid Intima-Media Thickness for Prediction of Clinical Vascular Events: Policy No. 235

Last Approval: 10/12/2023
Next Review Due By: October 2024

OHIO MEDICAID: Molina Ohio Medicaid will not exclude code 93895 and request will be reviewed for medical necessity on an individual basis.

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Carotid intima-media thickness (CIMT) measurement is a noninvasive test that historically has used B-mode ultrasound to measure the lining of the carotid arteries. Data currently available has been validated using imaging obtained from B-mode ultrasound. As magnetic resonance imaging (MRI) has become increasingly available this technology now offers a novel application to obtain CIMT imaging (De Groot 2022). CIMT is utilized as a marker of subclinical atherosclerosis, and its measurement has been suggested as a cardiovascular risk screening approach. The intima is the innermost layer of an artery, while the media is its middle layer. Routinely, carotid ultrasonography has been utilized for the examination of ischemic cerebrovascular symptoms. In the context of risk stratification including carotid ultrasonography, the intima-media thickness is assessed to detect preclinical or subclinical cardiovascular disease. The results are evaluated for any thickening or indications of anatomical alterations resulting from early atherosclerosis. Detection and monitoring of intima-medial thickening may allow for earlier intervention and/or monitoring of disease progression.

The CIMT is thought to be a surrogate marker with clinical correlation to risk of development of coronary atherosclerosis when increased thickness is identified. This has led to the theory that it may be a separate marker from the traditional risk factors for cardiovascular disease and stroke. It is unclear whether measuring CIMT provides an advantage over traditional risk factors or whether treatment guided by this test influences clinical outcomes.

The evidence includes large cohort studies and systematic reviews for individuals undergoing cardiac risk assessment determined by ultrasonic measurement of CIMT. Accuracy and morbidity are relevant outcomes. Numerous commonly used markers for coronary heart disease and the risk of future cardiovascular events have been linked by some studies to elevated CIMT. The lack of consistent scan protocols and application to clinical practice impact the ability to assess CIMT as a predictor of cardiovascular disease (CVD).

Lorenz et al. (2010) in a meta-analysis of individual participant data that CIMT was related with an increased risk of cardiovascular events, but that CIMT progression through time was not associated with an increased risk of cardiovascular events. The added predictive value of CIMT was modest in a 2012 systematic review by Peters et al., and the ability to reclassify patients into clinically relevant categories was not demonstrated (Peters et al. 2012). The findings of these reviews and other studies show that the predictive value of CIMT is uncertain, and that the predictive ability for any level of population risk cannot be determined with precision. Furthermore, no studies have been conducted to determine how the use of CIMT in clinical practice improves outcomes. No scientific literature directly evaluates the premise that CIMT measurement improves patient outcomes, nor is there guidance on how to incorporate CIMT data into risk assessment and risk management. The evidence is insufficient to assess the technology's impact on health outcomes.

Regulatory

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Measurement of CIMT is a procedure, and not subject to FDA regulation. The FDA regulates B-mode ultrasound devices used to assess CIMT, however there are numerous products.

COVERAGE POLICY

Ultrasonographic measurement of CIMT for prediction of clinical vascular events **is considered experimental, investigational, and unproven**. There is insufficient evidence in the peer reviewed medical literature to establish safety, efficacy, and effect on net health outcomes.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

While research dates to the early 1990's, there is insufficient published evidence to assess the role of CIMT measurement for the prediction of clinical vascular events and/or the impact on health outcomes or patient management. The clinical evidence to establish that CIMT testing has a benefit beyond traditional risk assessment is lacking. Prospective studies provide inadequate clinical evidence that the use of this technology alters patient management and improves clinical outcomes. There are no RCTs assessing the clinical utility of measuring CIMT for cardiac risk stratification, and no specific guidance on how measurements of CIMT should be incorporated into risk assessment and risk management. There is also a lack of standardization of measurement and imaging protocols and a lack of consensus regarding what constitutes expected normal limits. The literature does not show that CIMT can improve risk prediction beyond what traditional risk factors can provide, nor does it show the effect of these measurements on patient outcomes. The current published literature consists of several systematic reviews, meta-analyses, case series, and large longitudinal cohort studies. Additional studies involving larger, well-designed studies is required to establish the role of arterial compliance in the early detection, prevention, and management of CVD.

Villines et al. (2017) reported on the Jackson Heart Study (JHS), a community-based cohort study evaluating the etiology of cardiovascular, renal, and respiratory diseases among African Americans (AA) residing in the three counties (Hinds, Madison, and Rankin) that make up the Jackson, Mississippi metropolitan area. At the time it was conducted, JHS is the largest single-site, community-based epidemiologic study of environmental and genetic factors associated with cardiovascular disease in AA. The study enrolled 5301 adults ages 21 to 94 [681 (12.8%) of the 5,301 participants were excluded from the current analyses due to preexisting CVD (410 with CAD, 161 with stroke, and 110 with both), 226 (4.3%) missing CIMT measures, 428 (8.1%) missing other risk factor data, and 165 (3.1%) younger than 30 or older than 80 years]. The study included 2,463 women and 1,338 men who had no clinical CVD at the start. At the baseline assessment of the study, participants were measured bilaterally for far-wall CIMT. The incidence of CVD events was then evaluated over a 7 to 11-year period of follow-up. Incident CVD events were evaluated from samples of 2,463 women (107 CVD events) and 1,334 men (64 CVD events) who were free of clinical CVD at baseline. Each 0.2 mm increase in CIMT was linked with age-adjusted incident CVD hazard ratios of 1.4 for women and 1.3 for men. Similarly, the addition of CIMT had a little effect on risk-reclassification: Net Reclassification Index (NRI) 0.13 and 0.05 for women and men, respectively; Integrated Discrimination Improvement (IDI) 0.02 and 0.01 for women and men, respectively. The study concluded that CIMT was related with incident CVD but provided modest incremental improvement in risk reclassification beyond standard risk factors in an AA population group. There were several limitations to the study: 1) The study was limited to a single geographical region, which may limit generalizability; 2) While the follow-up period was relatively long in comparison to many prognostic studies, 9.0 years is shorter than the 10-year period used to calculate the Framingham risk score, which may reduce the overall power of the observations; 3) Carotid plaque was not evaluated on a systemic level. Previous research has shown that including carotid plaque in CVD risk prediction models improves accuracy significantly more than measuring CIMT alone; and 4) It is unknown

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what effect statins, antihypertensive, and antiplatelet medications had during the study period. [Funded by the National Heart, Lung and Blood Institute and the National Institute on Minority Health and Health Disparities.0

Systematic Reviews

Azcui Aparicio et al. (2021) conducted a systematic review to examine the predictive usefulness of CIMT, carotid plaque identification, and CAC score in diagnosing sub-clinical atherosclerosis and estimating future risk of CVD in asymptomatic, low-to-moderate risk patients. The review included 30 studies with 92,498 participants (23 prospective cohort studies, 1 retrospective cohort study, 1 case-control study, and 5 cross-sectional studies). In 11 studies, the average duration of follow-up was 10.3±4.8 years and the median duration was 6.0 years. Inclusion of CAC scores resulted in the greatest HR, ranging from 1.45 (95% CI, 1.11–1.88, p = 0.006) to 3.95 (95% CI, 2.97–5.27, p 0.001), followed by maximal CIMT (HR 1.08; 95% CI, 1.06–1.11, p 0.001 to 2.58; 95% CI, 1.83–3.62, p 0.001) and carotid plaque presence CAC had the highest net reclassification index (11.2%), followed by carotid plaque (2%) and CIMT (3%). The authors concluded that CAC scoring is superior to carotid plaque and CIMT assessments in asymptomatic, low-to-moderate risk people. This systematic review noted the variety of ultrasound indicators employed in different articles, particularly those for CIMT, as a drawback. Furthermore, this study did not address how CIMT affects patient management and improves clinical outcomes.

Willeit et al. (2020) conducted a meta-analysis of randomized clinical trials to evaluate CIMT progression as a surrogate marker for multiple types of CVD endpoints, including myocardial infarction, stroke, revascularization procedures, and fatal CVD. The analysis included 119 RCTs involving 100,667 patients who were followed for an average of 3.7 years. A total of 12,038 patients developed the combined CVD end point. Each 10 μm/y reduction in CIMT progression across all interventions led to a relative risk for CVD of 0.91 (0.87-0.94), and an additional relative risk for CVD of 0.92 (0.87-0.97) was reached independently of cIMT progression. The total estimated relative risks for interventions slowing CIMT progression by 10, 20, 30, or 40 μm/y are 0.84 (0.75-0.93), 0.76 (0.67-0.85), 0.69 (0.59-0.79), or 0.63 (0.52-0.74), respectively. Results were comparable when trials were categorized by intervention type, conduct date, time to ultrasonography follow-up, availability of participant-specific data, primary versus secondary preventive trials, type of CIMT measurement, and percentage of female patients. The analysis demonstrated a statistically significant association between treatment effects on progression of CIMT and treatment effects on CVD. Results were comparable when trials were grouped by intervention type, time of conduct, time to ultrasonography follow-up, availability of participant-specific data, primary vs. secondary preventive trials, type of CIMT measurement, and proportion of female patients. The authors found that the effects of therapies on cIMT progression and on CVD risk are related, hence validating the utility of cIMT progression as a surrogate marker in clinical trials. The study had limitations, which should be noted. The type of therapeutic intervention varied across the trials included, which may influence the CIMT surrogate value, and the individuals had varying comorbidities. Further, the study did not investigate how incorporating CIMT measurement into clinical care affects patient management and clinical outcomes.

Kumar et al. (2020) performed a meta-analysis to determine the relationship between CCA-IMT and stroke risk. The study included 19 studies; 16 studies involving 3475 ischemic stroke (IS) cases and 11,826 controls; 6 studies with 902 large vessel disease (LVD) and 548 small vessel diseases (SVD) of IS subtypes; 5 studies with 228 intracerebral hemorrhage (ICH) and 1032 IS cases. The authors reported that increased CCA-IMT was associated with a higher risk of IS when compared to control subjects. There was a higher risk of LVD compared to the SVD subtype of IS and a higher likelihood of IS occurrence rather than ICH. The authors found that CIMT are related to the risk of stroke and may be utilized as a diagnostic marker to predict the probability of stroke occurrences; however, to validate the findings, prospective research with larger sample sizes is required.

National and Specialty Organizations

The **American College of Cardiology (ACC)** and **American Heart Association (AHA)** (2019) issued an update to the 2017 guideline on the primary prevention of CVD. This guideline does not include or indicate the use of CIMT as a routine measurement in clinical practice for the prevention of CVD.

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The ACC / AHA (2013) guideline on the assessment of cardiovascular risk indicates that CIMT is not recommended for routine measurement in clinical practice for risk assessment for first atherosclerotic cardiovascular disease (ASCVD) event. [Grade N: No Recommendation for or against; Level of Evidence B: Limited populations evaluated; data derived from a single randomized trial or nonrandomized studies; ACC/AHA Class III (No benefit – procedure/test not helpful] (Goff et al. 2014).

The **American Society of Echocardiography (ASE)** 2020 guideline *Recommendations for the Assessment of Carotid Arterial Plaque by Ultrasound for the Characterization of Atherosclerosis and Evaluation of Cardiovascular Risk* endorsed the recommendations stated in the 2008 consensus statement. Authors of the 2020 guidelines informed that "Since the largest portion of CIMT (approximately 99% in healthy individuals and approximately 80% when diseased) consists of the medial layer, CIMT has not been shown to consistently add to CVD risk prediction." (Johri et al. 2020)

The **United States Preventive Services Task Force (USPSTF)** (2018) issued a recommendation statement on CVD risk assessment with nontraditional risk factors; CIMT was not mentioned in this recommendation. The USPSTF Summary of Recommendation "concludes that the current evidence is insufficient to assess the balance of benefits and harms of adding the ankle-brachial index (ABI), high-sensitivity C-reactive protein (hsCRP) level, or coronary artery calcium (CAC) score to traditional risk assessment for CVD in asymptomatic adults to prevent CVD events."

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/12/2023	Policy reviewed, no changes to criteria, updated references.
10/12/2022	Policy revised. Updated Overview, Summary of Evidence, and References section; inclusion and summary of relevant clinical studies and professional society guidelines. IRO Peer Review September 2022, by a practicing, board-certified physician in Interventional Cardiology.
10/13/2021	Policy reviewed, no changes to criteria, updated references.
09/16/2020	Policy reviewed, no changes to criteria.
09/18/2019	Policy reviewed, no changes.
07/10/2018	Policy reviewed, no changes to criteria, updated Summary of Medical Evidence section, and references. IRO Peer Review. March 27, 2018, by a practicing, board-certified physician in Interventional Cardiology.
06/22/2017	Policy reviewed, no changes.
09/15/2016	Policy reviewed, no changes.
02/02/2015	New policy.

REFERENCES

1. Azcui Aparicio RE, Ball J, Yiallourou S, et al. Imaging-guided evaluation of subclinical atherosclerosis to enhance cardiovascular risk prediction in asymptomatic low-to-intermediate risk individuals: A systematic review. Prev Med. 2021 Dec;153:106819. doi: 10.1016/j.ypmed.2021.106819. Epub 2021 Sep 29. PMID: 34599926.

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2. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database – no National Coverage Determination identified (search: "carotid intima media thickness" or "non-invasive cerebrovascular studies"). Accessed August 23, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
3. De Groot E, Duivenvoorden R. Carotid intima-media thickness. Updated February 28, 2022. Accessed August 24, 2023. www.uptodate.com.
4. Goff DC, Lloyd-Jones DM, Bennett G, Coady S, 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. 2014;129:S49–S73. published online November 12, 2013. PMID 24222018.
5. 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. 2020 Aug;33(8):917-933. doi: 10.1016/j.echo.2020.04.021. Epub 2020 Jun 27. PMID: 32600741.

APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

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