

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria Carotid Intima Media Thickness (IMT or CIMT) for Coronary Artery Disease Screening and Monitoring

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. (Kaiser Permanente) provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Clinical Review Criteria, at Kaiser Permanente's sole discretion, at any time, with or without notice. **Member contracts differ in health plan benefits. Always consult the patient's Evidence of Coverage or call Kaiser Permanente Member Services at 1-888-901-4636 (TTY 711), Monday through Friday, 8 a.m. to 5 p.m. to determine coverage for a specific medical service.**

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, " <i>Carotid Intima Media Thickness</i> <i>(IMT or CIMT) for Coronary Artery Disease Screening and</i> <i>Monitoring</i> " for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Atherosclerosis is a progressive disease that usually starts early in life. It begins with thickening of the vessel wall due to proliferation of smooth muscle cells, and progresses with the accumulation of lipids carbohydrates, calcium deposits, fibrous tissue, and blood products within the lesions resulting in hard calcified plaques (Libby 2000). Acute manifestations of atherosclerosis such as acute myocardial infarction, stroke, or sudden cardiac death are due to thrombosis following rupture of an unstable plaque. It is thus valuable to detect coronary atherosclerosis early in its course and try to alter its progression by modifying certain identifiable risk factors. Several noninvasive imaging techniques to identify and quantify atherosclerosis have evolved in the last decades. These include echocardiography, stress echocardiography with perfusion, MRI, electron beam computed tomography, carotid artery imaging, and others.

B-mode ultrasound is a well-established method to evaluate atherosclerosis of peripheral arteries, and ultrasonographic assessment of 0easily accessible arteries has been advocated as surrogate markers for less accessible vessels. To consider a test as a surrogate marker, it should have the ability to predict the risk of a disease, and to improve with the improvement of the disease process (Feinstein 2002).

Atherosclerosis predominantly affects the intima of the vessel wall; however, ultrasound imaging cannot discriminate between the intima and media, and is thus applied to the intima-media complex. Carotid artery intima-media thickness (IMT or CIMT) involves a high-resolution ultrasound imaging of the distance between the lumen-intima interface and the media-adventitia interface, reflecting the arterial wall characteristics. It can be measured at several areas along the vessel wall; at the posterior aspect of the common carotid artery, the anterior wall of the internal carotid artery or at the common carotid artery bifurcation. Researchers differ on the choice of wall or segment of the carotid artery to image. It is believed however that imaging from different segments will most likely increase the likelihood of providing more relevant information, based on the fact that atherosclerosis tends to develop in an asymmetric manner. IMT thickness measurements can be calculated as the average of arterial wall thickness, the maximal measured value, or the average of maximal values of different segments. The inter-reader variability is fairly high, and there is no clear cut-off point above which atherosclerosis can be defined. The cut-off points to determine the presence of an atherosclerotic plaque were arbitrarily chosen. It was suggested that an average thickness of the combined intima and media ranging between 0.5 and 1.2 mm is considered to be normal, and that >1.2 mm is used to define the presence of a plague. It was also reported that the abnormal range of IMT is age dependent, and an IMT >1.00 mm is considered highly abnormal in younger patients and is sometimes used as the cutoff in clinical trials (Feinstein 2002).

The estimated progression of atherosclerosis per year is 0.02 to 0.05 mm (Feinstein 2002). IMT may be a potential useful marker for coronary atherosclerosis, as well as an indicator for its progression or regression, on the condition that the carotid atherosclerosis reflects coronary atherosclerosis. Still the occurrence of an acute event does not only depend on the condition of the coronaries, and carotid IMT does not visualize coronary arteries, and does not provide detailed insight into plaque composition or stability.

Medical Technology Assessment Committee (MTAC)

Carotid IMT in the Evaluation of Risk for CVD or to Monitor the Treatment Effect on CAD 04/04/2005: MTAC REVIEW

Evidence Conclusion: In conclusion, there is evidence for an association between carotid artery IMT and risk of coronary heart disease events, but there is no evidence that measuring carotid IMT, or treating patients based on this measurement would reduce their risk of CVD. There is also insufficient evidence to support the additive value of carotid IMT markers over the global risk assessment strategies using Framingham risk stratification. Use of carotid ITM to monitor effect of treatment on CAD: Several studies evaluated the effect of statins on the progression of atherosclerosis using imaging of carotid ITM thickness as an outcome measure. In these studies, carotid IMT was used a surrogate marker for coronary atherosclerosis. The LIPID trial randomized 522 subjects to receive pravastatin 40 mg/day or placebo in addition to a low-fat diet. Total cholesterol, triglycerides, HDL, and LDL cholesterol were measured at randomization repeatedly during follow-up. Ultrasound scans of the common carotid artery were performed before randomization, and after 2- and 4-years using B-mode ultrasonography. The study showed a regression of the common carotid artery IMT following pravastatin therapy. Carotid IMT was only an intermediate marker, and the relation between the IMT and cardiovascular events was not studied. A change in carotid intima-media thickness does not necessarily indicate a change in cardiovascular risk. Articles: The search revealed 214 articles. The majority were review articles, opinion pieces, or dealt with specific subgroups of patients. As a screening tool/ risk predictor for coronary artery disease: The search did not reveal any randomized controlled trial that evaluated the use of carotid IMT as a screening test for coronary artery disease. There were several prospective studies that investigated carotid IMT as a risk predictor for CHD including two large population based-studies conducted in the USA (ARIC study and CHS). The search also revealed few other studies conducted in Europe (e.g. Rotterdam study in the Netherlands, and KIHD study in Finland). ARIC study and CHS were selected for critical appraisal, as well as Rotterdam study that evaluated the benefit of adding carotid IMT measurement to traditional risk factors used to predict risk of CHD. Chambless LE, Heiss G, Folsom AR, et al. Association of coronary heart disease incidence with carotid artery wall thickness and major risk factors: The Atherosclerosis Risk in Communities (ARIC) Study, 1987-1993. Am J Epidemiol. 1997; 146:483-494. See Evidence Table. O'Leary DH, Polak JF, Kronmal RA, et al, for the Cardiovascular Health Study Collaborative Research Group. Carotid-artery intima and media thickness as a risk factor for myocardial infarction and stroke in older adults. N Engl J Med. 1999; 340:14-22. See Evidence Table. Iglesias del Sol A, Moons KGM, Hollander M. et al. Is Carotid Intima-media thickness useful in cardiovascular diseases risk assessment. The Rotterdam Study. Stroke 2001; 32:1532-1538. See Evidence Table As a monitoring tool measure efficacy of a therapeutic intervention: The search revealed several earlier studies conducted in the 1990s to examine the effect of statins and lipid modifying therapy on the progression of atherosclerosis, using changes in the carotid IMT. measured by B-mode Ultrasonography, as their surrogate outcome. Among these studies were ACAPS, BCAPS, KAPS, LIPID, REGRESS, PLAC II as well as others. These studies did not have clinical outcomes, only the intermediate endpoint of carotid IMT. The LIPID trial with a large population size and long follow-up period of 4 years was selected for critical appraisal. MacMahon S, Sharpe N, Gamble G, et al. Effects of lowering average or

below-average cholesterol levels on the progression of carotid atherosclerosis. Results of the LIPID atherosclerosis substudy. Circulation. 1998; 97:1784-1790. See <u>Evidence Table</u>. As a diagnostic tool for coronary <u>artery disease</u>: The search revealed at least six studies that investigated the potential use of carotid intima media thickness in the diagnosis of coronary artery disease. In these studies, results of carotid ultrasonography were compared to those of coronary angiography, and/ or exercise tests, or SPECT among symptomatic patients with a suspected CAD. None of these studies was critically appraised as it not the purpose of this review to evaluate the technology as a diagnostic test.

The use of carotid IMT in the evaluation of risk for CVD or to monitor the treatment effect on CAD does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

Applicable Codes

Considered Not Medically Necessary:

CPT [®] Codes	Description	
93895	Quantitative carotid intima med	a thickness and carotid atheroma evaluation, bilateral

*Note: Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the Pre-authorization Code Check.

CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Date Created	Date Reviewed	Date Last Revised
04/04/2005	04/04/2005, 04/12/2005 ^{MDCRPC} , Initiated annual review because of Medicare criteria on 05/03/2011 ^{MDCRPC} , 09/06/2011 ^{MDCRPC} , 07/03/2012 ^{MDCRPC} , 05/07/2013 ^{MDCRPC} , 03/04/2014 ^{MPC} , 01/06/2015 ^{MPC} , 11/03/2015 ^{MPC} , 09/06/2016 ^{MPC} , 07/11/2017 ^{MPC} , 05/01/2018 ^{MPC} , 05/07/2019 ^{MPC} , 05/05/2020 ^{MPC} , 05/04/2021 ^{MPC} , 05/03/2022 ^{MPC} , 05/02/2023 ^{MPC} , 05/07/2024 ^{MPC} , 05/06/2025 ^{MPC}	05/04/2021

^{MDCRPC} Medical Director Clinical Review and Policy Committee ^{MPC} Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.
05/04/2021	Updated applicable codes – removed deleted code 0126T