Payment Policy | Ultrasonographic Measurement of Carotid Intima-Medial Thickness as an Assessment of Subclinical Artherosclerosis

EFFECTIVE DATE:10|01|2015
POLICY LAST UPDATED: 12|05|17

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
BlueCHiP for Medicare and Commercial
Ultrasonographic measurement of carotid artery intima-medial thickness (CIMT) as a technique of identifying subclinical atherosclerosis is considered not medically necessary for use in the screening, diagnosis, or management of atherosclerotic disease. The existing data are insufficient to determine the impact of this technology on net health outcome.

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

BACKGROUND
Coronary heart disease (CHD) accounts for 27% of all deaths in the U.S.(1) Established major risk factors for CHD have been identified by the National Cholesterol Education Program Expert Panel (NCEP). 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.

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.(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 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. The intima-medial thickness (IMT) 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 2 lines constitutes the IMT.

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 codes are not medically necessary:
93895 Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral
0126T Common carotid intima-medial thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment

RELATED POLICIES

None

PUBLISHED

Provider Update January 2018
Provider Update January 2017
Provider Update August 2015

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