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



**EFFECTIVE DATE:**10|01|2015 **POLICY LAST UPDATED:** 06|15|2022

# **OVERVIEW**

Ultrasonographic measurement of carotid intima-media (or intimal-medial) 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-media 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 Products**

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

# **Coronary Heart Disease**

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 2022 update on heart disease and stroke statistics from the American Heart Association, it was estimated that 720,000 Americans have a new coronary attack (first hospitalized myocardial infarction or CHD death) and 335,000 have a recurrent attack annually. An estimated 20.1 million Americans  $\geq$ 20 years of age have CHD. The prevalence of CHD was higher for males than females  $\geq$ 60 years of age. Total CHD prevalence is 7.2% in US adults  $\geq$ 20 years of age; CHD prevalence is 8.3% for males and 6.2% for females. On the basis of data from the 2018 National Health Interview Survey, CHD prevalence estimates are 5.7% among White people, 5.4% among Black people, 8.6% among American Indian/Alaska Native people, and 4.4% among Asian people  $\geq$ 18 years of age.

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.

# Diagnosis

The third report of the National Cholesterol Education Program Adult Treatment Panel established various treatment strategies to modify the risk of CHD, with emphasis on target goals of low-density lipoprotein cholesterol. Pathology studies have demonstrated that levels of traditional risk factors are associated with the extent and severity of atherosclerosis. The third report of the National Cholesterol Education Program Adult Treatment Panel recommended 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. Thus, there has been an interest in identifying a technique that can improve the ability to diagnose those at risk of developing CHD, as well as to measure disease progression, particularly for those at intermediate risk. The carotid arteries can be well-visualized by ultrasonography, and ultrasonographic measurement of the carotid intima-media thickness (CIMT) has been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used to measure CIMT. Carotid intima-media thickness 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 thenear wall. Two echogenic lines are produced, representing the lumenintima interface and the media-adventitia interface. The distance between these 2 lines constitutes the CIMT.

# **Regulatory Status**

In 2003, SonoCalc® (SonoSite) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this software was 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, other devices have been cleared for marketing by the FDA through the 510(k) process. FDA product code: LLZ.

# CODING

# Medicare Advantage Plans and Commercial Products

The following code(s) are not medically necessary: 93895 Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral

# **RELATED POLICIES**

Not applicable.

# PUBLISHED

Provider Update, August 2022 Provider Update, July 2021 Provider Update, August 2020 Provider Update, September 2019 Provider Update January 2019

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