Ultrasonographic Measurement of Carotid Intima-Medial Thickness as an Assessment of Subclinical Atherosclerosis

Introduction

Atherosclerosis is a condition in which plaque builds up on artery walls. Plaque is made up of fat, cholesterol, and other substances in the blood. Over time, the plaque hardens. This hardening causes the arteries to narrow. Narrowed arteries means less blood can flow to organs like the heart and brain. There are a number of well proven tests that doctors use to diagnose atherosclerosis. A newer test uses sound waves (ultrasound) to look at the two innermost layers of the carotid artery. (The carotid arteries are on both sides of the neck.) The goal of this ultrasound test is to try to see if plaque is building up in arteries before other tests are able identify it. Medical studies have found that this type of ultrasound test is uncertain in trying to predict who will develop atherosclerosis. Also, there are no studies showing how this testing leads to better health results compared to standard testing. For these reasons, ultrasound testing to try to identify atherosclerosis is considered investigational.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
**Policy Coverage Criteria**

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
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<tbody>
<tr>
<td>Ultrasonographic measurement of carotid artery intima-medial thickness (CIMT)</td>
<td>Ultrasonographic measurement of carotid artery intima-medial thickness (CIMT) as a technique for identifying subclinical atherosclerosis is considered investigational for use in the screening, diagnosis, or management of atherosclerotic disease.</td>
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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>CPT</td>
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<tr>
<td>0126T</td>
<td>Common carotid intima-media thickness (IMT) study for evaluation of atherosclerotic burden or coronary heart disease risk factor assessment</td>
</tr>
<tr>
<td>93895</td>
<td>Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral</td>
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**Related Information**

N/A

**Evidence Review**

**Description**

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 two 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.

**Background**

**Coronary Heart Disease**

Coronary heart disease (CHD) accounts for 30.8% of all deaths in the United States.\(^1\) 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, 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 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 artery intima-medial thickness has been investigated as a technique to identify and monitor subclinical atherosclerosis. B-mode ultrasound is most commonly used to measure carotid intima-media thickness. 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 two lines constitutes the IMT.
Summary of Evidence

For individuals who are undergoing cardiac risk assessment who receive ultrasonic measurement of carotid intima-media thickness (CIMT), the evidence includes large cohort studies, case-control studies, and systematic reviews. Relevant outcomes are test accuracy and morbid events. Some studies have correlated increased CIMT with other commonly used markers for risk of coronary heart disease (CHD) and with risk for future cardiovascular events. A meta-analysis of individual patient data by Lorenz et al (2012) found that CIMT was associated with increased cardiovascular events although CIMT progression over time was not associated with increased cardiovascular event risk. In a systematic review by Peters et al (2012), the added predictive value of CIMT was modest, and the ability to reclassify patients into clinically relevant categories was not demonstrated. The results from these reviews and other studies have demonstrated the predictive value of CIMT is uncertain, and that the predictive ability for any level of population risk cannot be determined with precision. Also, available studies do not define how the use of CIMT in clinical practice improves outcomes. There is no scientific literature that directly 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 evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tbody>
<tr>
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<tr>
<td>NCT01849575</td>
<td>Direct VIsualiZAtion of Asymptomatic Atherosclerotic Disease for Optimum Cardiovascular Prevention. A Population Based Pragmatic Randomised Controlled Trial Within Västerbotten Intervention Programme (VIP) and Ordinary Care</td>
<td>3200</td>
<td>Jun 2021</td>
</tr>
</tbody>
</table>

NCT: national clinical trial
Practice Guidelines and Position Statements

**American College of Cardiology and American Heart Association**

The 2013 guidelines on the assessment of cardiovascular risk from the American College of Cardiology and the American Heart Association did not recommend carotid intimal-medial thickness (CIMT) measurement in routine risk assessment of a first atherosclerotic cardiovascular disease event (Class III: no benefit, level of evidence B). This differs from the previous 2010 joint guidelines for assessment of cardiovascular risk, which indicated CIMT might be reasonable for assessing cardiovascular risk in intermediate-risk asymptomatic adults.

**American Association of Clinical Endocrinologists et al**

The American Association of Clinical Endocrinologists and American College of Endocrinology published guidelines (2017) stating that CIMT could be applied as a risk stratification tool in determining the need for more aggressive preventive strategies against cardiovascular disease (grade B; best evidence level 2) - but not routinely.

**American Society of Echocardiography**

The American Society of Echocardiography (2008) consensus statement, endorsed by the Society for Vascular Medicine, stated that CIMT is a feature of arterial wall aging “that is not synonymous with atherosclerosis, particularly in the absence of plaque.” The statement recommends measurement of both CIMT and carotid plaque by ultrasound “for refining CVD risk assessment in patients at intermediate cardiovascular disease risk (Framingham Risk Score 6–20%) without established CHD [coronary heart disease], peripheral arterial disease, cerebrovascular disease, diabetes mellitus, or abdominal aortic aneurysm.” However, the Society acknowledged that “More research is needed to determine whether improved risk prediction observed with CIMT or carotid plaque imaging translates into improved patient outcomes.”
U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2009, USPSTF) published a systematic review of CIMT within the scope of a larger recommendation on the use of nontraditional risk factors in coronary heart disease risk assessment. USPSTF could not draw conclusions on the applicability of CIMT to the intermediate-risk population at large outside the research setting. The USPSTF summary of recommendation specific to CIMT stated that: “... the current evidence is insufficient to assess the balance of benefits and harms of using ... [CIMT] ... to screen asymptomatic men and women with no history of CHD to prevent CHD events.” USPSTF identified the following research need: “The predictive value ... of carotid IMT ... should be examined in conjunction with traditional Framingham risk factors for predicting CHD events and death.”

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Regulatory Status

In 2003, SonoCalc® (SonoSite) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. 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, several other devices have been approved through the 510(k) process.

Product code: LLZ.

References


<table>
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<tr>
<th>Date</th>
<th>Comments</th>
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<td>11/11/05</td>
<td>Replace Policy - Policy updated with literature review; no change in policy statement; reference added.</td>
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<tr>
<td>05/26/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>11/14/06</td>
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</tr>
<tr>
<td>01/08/08</td>
<td>Replace Policy - Policy updated with literature review; no change to policy statement. References added.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Replace Policy - Policy updated with literature search. Minor edits made to the policy statement, intent unchanged. References added.</td>
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<tr>
<td>09/14/10</td>
<td>Replace Policy - Policy updated with literature review; references 1, 3 and 8 have been added. The policy statement remains unchanged.</td>
</tr>
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<td>09/11/12</td>
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<tr>
<td>09/27/13</td>
<td>Replace policy. Policy updated with literature review through May 2013, policy statement unchanged. References 3-4 added.</td>
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<td>10/18/13</td>
<td>Update Related Policies. Add 2.04.509.</td>
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<tr>
<td>12/22/14</td>
<td>Update Related Policies. Remove 6.01.03 as it was archived.</td>
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<td>01/14/15</td>
<td>Coding update. New CPT code 93895, effective 1/1/15, added to policy.</td>
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<tr>
<td>09/08/15</td>
<td>Annual Review. Policy updated with literature review through May 31, 2015; references 17-19 removed; reference 24 added. No change to policy statement. CPT codes 93880 &amp; 93882 removed; these are not reviewed.</td>
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<tr>
<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. Policy updated with literature review through June 20, 2016. USPSTF recommendation updated. Reference added.</td>
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<tr>
<td>10/24/17</td>
<td>Policy moved to new format, no changes to policy statement.</td>
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**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review
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**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  - Qualified interpreters
  - Information written in other languages

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PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

Getting Help in Other Languages

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Oromoo (Cushite):

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Ilokano (Ilocano):
Daytoy a Pakdaak ket naglaon iti Napateg nga Impormasion. Daytoy a pakdaak mabalin nga adda ket naglaon iti napateg nga impormasion maiyanggep iti aplikasyonono wennyo coverage babaen iti Premera Blue Cross. Daytoy ket mabalin dagiti importante a petsa iti daytoy a pakdaak. Mabalin nga adda rumbeng nga aramidenyo nga addang sakbay dagiti partikular a naituding nga adda aldaw tapno mapagtalainderyo ti coverage ti salun-atyo wennyo tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga impormasion ken tulong ti bukodyo a pagasao nga awan ti bayadanyo. Tumawig ti numero nga 800-722-1471 (TTY: 800-842-5357).

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Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbero esserci date chiave in questo avviso. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamà 800-722-1471 (TTY: 800-842-5357).

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保險的重要訊息。本通知可能會有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357)。

037338 (07-2016)

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