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patient's risk and/or the calculated risk of the patient having or developing ASCVD is still unknown to different interpretations, despite having been produced utilizing formal risk estimation mechanism consistent with existing ACC/AHA methodologies.

### Policy Position

Given the existing body of evidence on the procedure's clinical effectiveness in certain situations the AHA support efforts to expand coverage of and appropriate payment of Ortesta across the payor continuum, especially for patients who might benefit from knowing their score and having it considered in care decisions made by their physician or team of healthcare providers.

- x Men and women of all ages with high cholesterol who are reluctant to begin statin therapy and who want to understand their risks and potential benefits of medication therapy more precisely;
- x Men and women of all ages with high cholesterol who are concerned about starting statin



AHA Policy Approaches for Consideration

<i>Mechanism</i>	<i>Impacted Market(s)</i>	<i>Explanation / Notes</i>
<p>Formal submission of a National Coverage Determination (NCD) request to the Centers for Medicare &amp; Medicaid Services (CMS)</p>	<p>Medicare</p>	<p>On the federal level, the Centers for Medicare and Medicaid Services (CMS) periodically issues or reviews Medicare coverage decisions through federal directives known as NCDs. Reviews of petitioners' requests undergo an extensive review, with opportunities for public participation involving a close examination of any supporting evidentiary documentation provided as a component of the request and information provided that addresses the relevance, usefulness, and/or benefits of the item or service to the Medicare population.</p> <p>The Society for Heart Attack Prevention &amp; Eradication (SHAPE) submitted an NCD request (i.e., a Formal Request for a National Coverage Determination for Coronary Artery Calcium Testing) to CMS on January 7, 2019 that is currently in the review stage.</p>
<p>Formal submission of a Local Coverage Determination (LCD) request to regional Medicare contractor with jurisdictional authority over an assigned region</p>	<p>Medicare; regional in scope.</p>	<p>In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on an LCD. The processes and mechanism by which interested parties within a contractor's jurisdiction may request a new LCD or reconsideration request for an active LCD differs slightly from one contractor to the next. With that said, petitioners must adhere to the submission requirements and criteria established by both CMS and the contractor being petitioned.</p> <p>Several contractors have existing LCDs in effect pertaining to CAC scoring and, as far as the AHA is aware, no petitions have been filed by SHAPE or other stakeholders subsequent to the release of the 2018 ACC/AHA guidelines.</p>

<p>Petitioning the U.S. Preventive Services Task Force (USPSTF)</p>	<p>Medicaid Medicare Private health plans</p>	<p>The USPSTF is an independent panel of experts in primary care and prevention who systematically reviews the evidence of effectiveness and develops recommendations for clinical preventive services. A key provision of the Affordable Care Act (ACA) is the requirement that private insurance plans cover services for adults that have a USPSTF rating of “A” or “B” without any patient cost sharing. With the exception of “grandfathered” or “grandmothered” health plans, the preventative services rules apply to all private plans (i.e., individual, small group, large group and self-insured plans). Further, individuals participating in Medicare and the Medicaid expansion population (i.e., the new adult group) are required to be provided with access to preventive services without cost sharing.</p> <p>Note that the USPSTF concluded in 2018 that the current evidence was insufficient to assess the balance of benefits and harms of CACs moving to traditional risk assessment for cardiovascular disease (CVD) in asymptomatic adults to prevent CVD events.<sup>4</sup> With that said, the ACC/AHA guidelines released in November 2018, as well as the evidence considered in developing said guidelines, were not considered in that review.</p>
<p>Supporting the introduction and passage of state-specific benefit mandates</p>	<p>Variable; depends on the text of a bill, statute and/or regulations</p>	<p>As it currently stands, only Texas has an existing mandate related to the coverage of and payment for CAC tests. SHAP is leading efforts for legislative mandates in several other states, including California and South Carolina, but none have yet succeeded to the point of legislative</p>

passage, being signed into law, and being  
codified into state statutes and

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