F I S C A L I M P A C T R E P O R T

SPONSOR Trujillo, CH **ORIGINAL DATE** 2/03/17 **LAST UPDATED** 3/07/17 **HB** 11

SHORT TITLE Artery Screening Coverage **SB**

ANALYST Boerner/Chilton

ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)

	FY17	FY18	FY19	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
State share	$0.0	$720.5	$720.5	$1,401.0	Recurring	General Fund
Federal share	$0.0	$2,679.5	$2,679.5	$5,459.0	Recurring	Federal Funds

(Parenthesis ( ) Indicate Expenditure Decreases)

SOURCES OF INFORMATION
LFC Files

Responses Received From
Department of Health (DOH)
Retiree Health Care Authority (RHCA)
Office of the Superintendent of Insurance (OSI)
Public School Insurance Authority (PSIA)
Human Services Department (HSD)

SUMMARY

Synopsis of Bill

House Bill 11 (HB11) adds new sections to the Health Care Purchasing Act, the Public Assistance Act, the New Mexico Insurance Code, the Health Maintenance Organization Law and the Nonprofit Health Care Plan Law to require coverage of artery calcification screening for early detection of cardiovascular disease in certain individuals.

HB11 would require Medicaid coverage of an artery calcification screening for an eligible recipient once every five years.

The bill defines "artery calcification screening" as a computed tomography scan measuring coronary artery calcification for atherosclerosis and abnormal artery structure and function.

The bill defines “eligible recipient" as the following:

1. a male older than thirty years of age and younger than seventy-six years of age
2. a female older than forty years of age and younger than seventy-six years of age; and
3. who has a risk of developing coronary heart disease based on at least one of the following:
    a. hypertension
    b. hyperlipidemia
    c. diabetes
    d. smoking
    e. family history of heart disease

The various sections of the bill refer to different types of health insurance, but make the same requirement for each. The following table indicates the sections and their application to the various types of insurance:

Section of HB 11	Type of Insurance covered
1	Group health coverage, including self-insurance, issued or renewed through the Health Care Purchasing Act
2	Medicaid
3	Individual or group health insurance policies, health care plans, and certificates of insurance
4	Group or blanket health care policies, health care plans, and certificates of insurance
5	Individual or group health maintenance organization
6	Non-profit health care plans

FISCAL IMPLICATIONS

While the bill contains no appropriation, HSD anticipates additional operating budget impact. HSD estimated the additional impact by multiplying the Medicare reimbursement rate for this procedure by the estimated number of Medicaid enrollees eligible for this procedure, as follows:

> The estimated additional operating budget impact was calculated by multiplying the Medicare reimbursement rate for this procedure by the estimated number of Medicaid enrollees eligible for this procedure. HSD provided cost impact to the categories of eligibility that would be applicable, which are the full Medicaid eligibility categories. CMS would not approve for limited benefit categories, such as family planning and categories for which we contribute Medicare premiums. To calculate the financial impact HSD had 79,615 Medicaid members with full Medicaid benefits in the age range of this test. Approximately 75% (59,712) of members would meet the risk factor criteria to qualify for the test. The frequency of the test is every 5 years therefore HSD allocated 1/5 of the expenses per year for a cost of $3,400,000 per year.

HSD's analysis does not and cannot take into account the likely cost savings that might take place from making coronary artery calcium screening available to Medicaid recipients at increased risk. In an article written by University of New Mexico internists, specialists, and researchers R. Philip Eaton MD,, Mark R. Burge MD,, George Comerci MD, Brendan

Cavanaugh MD, Barry Ramo MDand David S. Schade MD in the American Journal of Medicine to be published in 2017 but now available (see attachment), coronary artery screening is indicated to be the best available test for risk of heart attacks; finding an abnormal coronary artery screen result would allow for intensive medical treatment, which would be very likely to lead to economic benefits to the patient and to the health care system that would be greater than the cost of the test.

DOH states that "Self-insured entities, such as state agencies, will realize costs related to CAC [coronary artery calcium] scans for its covered employees and their family members. In the Albuquerque area, a recent estimate of charges for CAC scans ranged from $150 to $300. Additional testing or medical interventions that may result from CAC scan results could also significantly add to healthcare costs."

Furthermore, costs of a diagnostic test are not limited just to the test itself – they also include the costs of follow-up tests, especially where the test is "non-specific," meaning that many people without actual real increased risk of disease undergo further testing to assure that they are in the category of "false positives", rather than "true positives," the ones truly at increased risk. For many tests with low specificity, the costs of the initial test itself are dwarfed by the follow-up tests. As noted below under "Significant Issues", coronary artery testing has low specificity.

SIGNIFICANT ISSUES

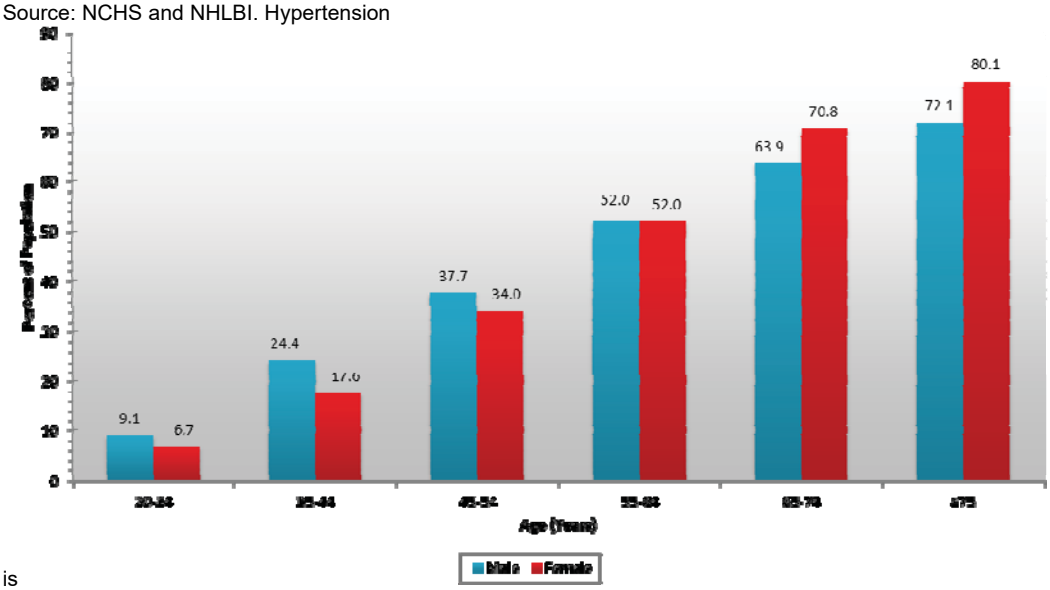
HSD pointed out the managed care programs through Centennial Care are not currently required to provide the specific services identified in this bill to cover artery calcification screening; however, passage of this bill would require the coverage specified. Consequently, by adding coverage of these services under the Medicaid benefit package, the Medicaid program would experience increased costs for these services and the additional service would be considered an expansion of the Medicaid Program.

The bill defines eligible enrollees as anyone between 30 and 75 years of age and being of increased risk of developing heart disease "based on at least one the following: hypertension, hyperlipidemia, diabetes, smoking, or family history of heart disease." Depending especially on the unspecified definitions of "hypertension" and of "family history of heart disease," a very large proportion of American adults would fit into the description of being at increased risk.

One of the most common of the disorders listed in House Bill 11 as causing a "risk of developing heart disease" is hypertension. As defined by the National Heart Lung and Brain Institute, a large proportion of American adults can be defined as having hypertension:

Prevalence of High Blood Pressure in Adults Age 20 and Older
NHANES: 2007–2010

Source: NCHS and NHLBI. Hypertension



is defined as SBP 140 mm Hg or DBP 90 mmHg, taking antihypertensive medication, or being told twice by a physician or other professional that one has hypertension.

The United States Preventive Services Task Force (USPSTF), the American Academy of Family Physicians, the American College of Cardiology and the American Heart Association do not support coronary artery calcium screening for the general public, although the USPSTF is considering the issue again in light of new data, which should be released soon. From its website, https://www.uspreventiveservicestaskforce.org/Page/Document/final-research-plan/coronary-heart-disease-screening-using-non-traditional-risk-assessment, the final research plan is available, but not the research results. From that information, a copy of the questions USPSTF wants to answer, based on data that have become available since its previous review are as follows:

Key Questions to Be Systematically Reviewed

1. Compared with the Pooled Cohort Equations tool or Framingham risk factors alone, does risk assessment of asymptomatic adults using nontraditional risk factors—followed by treatment specific to risk level—lead to reduced incidence of cardiovascular events (e.g., myocardial infarction, cerebrovascular accident) and/or mortality?
2. Does use of nontraditional risk factors in addition to traditional risk factors to predict cardiovascular disease risk improve measures of calibration, discrimination, and risk reclassification?
3. What are the harms of nontraditional risk factor assessment?
4. Does treatment guided by nontraditional risk factors in addition to traditional risk factors lead to reduced incidence of cardiovascular events (e.g., myocardial infarction, cerebrovascular accident) and/or mortality?
5. What are the harms of treatment guided by nontraditional risk factors?

As stated in the current USPSTF report, "The consequences of false-positive tests potentially may outweigh the benefits of screening. False-positive tests are common among asymptomatic adults, especially women, and may lead to unnecessary diagnostic testing, overtreatment, and

labeling. Because the sensitivity of these tests is limited, screening also could result in false-negative results. A negative test does not rule out the presence of severe CAS or a future CHD event. The USPSTF recommends against routine screening with resting electrocardiography (ECG), exercise treadmill test (ETT), or electron-beam computerized tomography (EBCT) scanning for coronary calcium for either the presence of severe coronary artery stenosis (CAS) or the prediction of coronary heart disease (CHD) events in adults at low risk for CHD events.**"** **(**http://www.aafp.org/afp/2004/0615/p2891.html)

The majority of the members of the Writing Group would not recommend EBCT for diagnosing obstructive CAD because of its low specificity (high percentage of false-positive results), which can result in additional expensive and unnecessary testing to rule out a diagnosis of CAD. The 1999 ACC/AHA [American College of Cardiology/American Heart Association Coronary Angiography Guideline Committee reached a similar conclusion (1). (American College of Cardiology/American Heart Association Expert Consensus Document on Electron-Beam Computed Tomography for the Diagnosis and Prognosis of Coronary Artery Disease).

As discussed by the Department of Health, the most recent statement from the American Heart Association on the subject, dated March 7, 2012, does not support coronary artery calcium screening, as follows:

> In an effort to reduce the high morbidity and heavy financial burden of CHD among their residents, four states have recently proposed or passed legislation mandating that health insurers offer coverage of certain imaging tests to screen asymptomatic adults for CHD risk. These tests include scans to determine the amount of coronary artery calcification (CAC) scans and the thickness of arterial walls by measuring carotid intima-media thickness (carotid IMT) ultrasound screenings, both of which are markers for CHD risk.
>
> While identifying persons at increased risk of developing CHD is an important goal for the American Heart Association (AHA), these recent state efforts are currently not supported adequately with sufficient evidence to show that widespread screening of asymptomatic adults is clinically appropriate. The AHA will continue to evaluate the developing science in this area to inform future policy efforts around population-based screening.
>
> Until stronger and more granular evidence for the efficacy of coronary artery calcification (CAC) scans and carotid IMT ultrasound screenings for CHD in the asymptomatic adult population is established, the AHA does not support state efforts to mandate coverage for these CHD screening methods. Instead, AHA recommends that individual patients should discuss alternative guideline recommended CHD screening options with their physicians and make decisions that are consistent with the best available information based on the current science.

OSI notes the possibility that one of the Affordable Care Act's provisions might force the state to pay for new mandates enforced on insurance providers.

ADMINISTRATIVE

HSD noted it would have to amend the Medicaid state plan with the Centers for Medicare and Medicaid Services; add program coverage rules by amending the appropriate NMAC rules;

amend existing contracts with the Medicaid managed care organizations, and increase capitation rates for Medicaid managed care organizations.

TECHNICAL ISSUES

Obesity confers an increased risk of coronary artery disease, and is omitted from the list of conditions placing a person at increased risk.

Definitions of “family history of heart disease,” “hypertension”, and “hyperlipidemia” are lacking in the bill.

WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

Some insurance plans would not cover the cost of coronary artery calcification screening by computed tomography scanning.

LAC/sb/al/jle

COMMENTARY

THE AMERICAN JOURNAL of MEDICINE®

Abnormal Coronary Artery Calcium Scans in Asymptomatic Patients

The widespread availability of the coronary artery calcium (CAC) scan to diagnose coronary artery atheroma semi-quantitatively, and its prognostic significance, have generated a dilemma for primary care physicians caring for cardiac asymptomatic patients. Seventy-five percent of the 500,000 deaths from acute coronary thromboses occur in asymptomatic individuals owing to rupture of an unrecognized coronary artery atheroma. The CAC scan represents a noninvasive virtual coronary "biopsy" to identify vulnerability for this number one cause of death. Thus, the correct prognostic interpretation of CAC scores, plus the potential benefits and risks of various therapeutic modalities, need to be explained to the patient. Only then can physicians and patients decide the optimal therapeutic choice, such as risk factor modification, aggressive low-density lipoprotein cholesterol reduction to prevent and/or reverse atheroma formation, cardiovascular stress testing, or cardiology referral.

Coronary artery calcium testing is increasingly being promoted to the public as a means of self-assessment of their cardiovascular risk. Reasons for the popularity of this methodology for identifying atherosclerosis include the following: 1) a physician's order is not always required; 2) the test is noninvasive;[1] 3) the cost is low ($50 to $200 in most cities); 4) the dose of radiation is relatively low (similar to mammography);[1] 5) the high likelihood of improved risk assessment;[2] 6) the excellent predictive value for atherosclerotic cardiovascular disease and mortality;[2,3] and 7) clinical outcome benefit with medical intervention.[4] Furthermore, CAC scans are reimbursable by Medicare in several states (Common Procedural Terminology code 75571) and by state law in Texas. The number of asymptomatic individuals in the high- and intermediate-risk categories in the United States is very large and includes all diabetic individuals and individuals with elevated Framingham risk factors and/or genetic causes of hyperlipidemia.

CAC SCORING

Studies have repeatedly shown that CAC scores are the best predictor of future cardiovascular events in asymptomatic individuals—even more sensitive than coronary angiography.[1,4,5] The Multi-Ethnic Study of Atherosclerosis Study is the most well-known of these studies. In that study, 6722 men and women without clinical cardiovascular disease at entry were followed for a median of 3.8 years. When combined with traditional risk factors, the baseline CAC score predicted future cardiovascular events with improved accuracy. The presence of calcium in coronary arteries is strong evidence of the presence of atherosclerotic plaque.[1] This calcium should be considered a sign of atheroma presence and not necessarily a threat for future cardiovascular events. In fact, the majority of infarction-associated arterial thromboses are due to rupture of noncalcified, nonobstructive plaques.[6]

RISK ASSESSMENT

Once patients have positive CAC scores, primary care physicians need to interpret their significance for their patients. Although most reports include a prognostic interpretation of the score, this information may not be applicable to specific individuals for several reasons. First, the sensitivity and specificity of the score decreases as the score increases.[4] Second, different groups of individuals may have different prognostic outcomes. For example, patients with type 2 diabetes have a worse prognosis than nondiabetic individuals with the same CAC score.[4] Third, CAC scores do not directly incorporate data from other risk scoring modalities, such as the Framingham risk calculator, and these data may alter the prognostic significance of the score. When the Framingham risk score and the CAC score are combined, an improved prognostic outcome can be calculated at www.mesa-nhlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx.

AGGRESSIVE MEDICAL THERAPY

All patients at increased risk for atherosclerotic cardiovascular disease should pursue appropriate lifestyle therapies to reduce their risk. Although the lipid-lowering effects of such interventions may be modest, they are

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effective and complement pharmacologic therapy. Most major professional organizations recommend a low-density lipoprotein cholesterol (LDL-C) level below 70 mg/dL. The LDL-C principle states that the lower the LDL-C concentration, the lower the incidence of a cardiovascular atherosclerotic event.[7] This principle suggests that an LDL-C level of <50 mg/dL should be the goal for everyone with a positive calcium scan to prevent/reverse atheroma formation.[7] Achieving an LDL-C goal of 50 mg/dL is possible in most individuals. No unexpected side effects have been observed at LDL-C levels <50 mg/dL. Because most individuals were born with an LDL-C of approximately 50 mg/dL, this level should not be considered abnormal. In addition, the normal LDL-C range is 50-70 mg/dL for native hunter-gatherers, free-living primates, and other wild mammals, none of whom develop atherosclerosis.[8]

Assuming the LDL-C goal for asymptomatic individuals with a positive calcium score is 50 mg/dL, how should this be achieved? Most outcome trials include a statin, preferably a high potency statin. Both atorvastatin and rosuvastatin are now generic and should be prescribed first. Because side effects of statins are dose related, the lowest possible dose should be used, particularly because the lowest dose (10 mg) achieves the greatest percent reduction in LDL-C (approximately 75%). Furthermore, statins increase PCSK9 protein as the statin dose increases, which impairs their ability to lower LDL-C.[9] In addition, ezetimibe works well with statins by blocking cholesterol absorption from the gut with minimal side effects. On the basis of these data, we recommend 10 mg of ezetimibe and 10 mg of either atorvastatin or rosuvastatin. This combination is well tolerated and results in a very significant reduction of LDL-C within 6 weeks. Unfortunately, some patients are intolerant of statins or do not achieve LDL-C goals despite the addition of ezetimibe to the statin. Such patients are candidates for a PCSK9 inhibitor, but this will likely require preauthorization and a higher tier copay level.

STRESS TESTING

Stress testing involves stressing the cardiovascular system either with exercise or by administering cardiac stimulating medication. The purpose is to identify coronary artery obstructive lesions with greater than 50% luminal obstruction. Unfortunately, stress testing in asymptomatic individuals has low sensitivity and specificity (45%-60%).[4] The cost of the test is approximately $300, and the risk/benefit for adverse events increases in low risk individuals. When radionucleotides are used for stress testing, radiation exposure and the increased cost can be significant.

Many physicians will refer their patients to a cardiologist when stress testing is planned. When the test is positive, the next step is often coronary angiography to identify obstructive lesions. This invasive procedure is problematic because 1) the resolution of angiography is low, 2) the images are 2-dimensional, and 3) the assessment of obstruction does not include the presence of collateral vessels that may provide adequate blood flow past the obstruction.[10] According to the US Preventive Services Task Force,[11] "The primary tangible harm of screening exercise tolerance testing is the potential for medical complications related to cardiac catheterization done to further evaluate a positive result. Coronary angiography is generally considered a safe procedure. Of all persons undergoing outpatient coronary angiography, however, an estimated 0.08% will die as a result of the procedure and 1.8% will experience a complication. Complications of coronary angiography include myocardial infarction, stroke, arrhythmia, dissection of the aorta and coronary artery, retroperitoneal bleeding, femoral artery aneurysm, renal dysfunction, and systemic infection." In addition, the cost of this test is between $5000 and $10,000, and the patient's co-pay for the procedure may approach 50%.

The greatest objection to stress testing and coronary angiography is the fact that the identification of an obstructive lesion does not identify future causative sites of myocardial infarctions. The reason for this discrepancy is that myocardial infarctions almost always result from unstable atherosclerotic plaques that rupture into the coronary artery lumen.[7] These unstable plaques may be far removed from the narrowing lesion observed during coronary angiography. Thus, in asymptomatic individuals who have no anginal symptoms during their normal daily activities, primary care physicians should question what benefit will result from ordering stress testing or coronary angiography for their patients.

MEDICAL THERAPY VERSUS PERCUTANEOUS INTERVENTION

There are no published clinical trials that compare medical therapy alone versus percutaneous coronary intervention (PCI) (usually coronary artery stents) alone in asymptomatic individuals with an elevated CAC score. However, clinical trials are available that compare medical therapy versus PCI plus medical therapy in individuals with stable angina. These individuals usually do not have symptoms of angina at rest but may have angina with exercise. There is no benefit of PCI beyond that achieved with optimal medical treatment except relief of angina, particularly with single-vessel disease.[4] The longest observational study (15 years) also demonstrated no difference in mortality between PCI and medical therapy.[12]

RECOMMENDATIONS

On the basis of the above evidence, our recommendations for individuals with a positive CAC score and no acute symptoms of cardiac ischemia are to immediately initiate lifestyle change plus aggressive LDL-C–lowering therapy

Table Frequently Asked Questions for Treatment of an Asymptomatic (No Ischemic Symptoms) Individual with a (+) Coronary Artery Calcium Scan

Question	Answer	Reference
What is the earliest age at which a CAC scan should be recommended?	If no major risk factors = 50 y/o for females, 40 y/o for males. If diabetes present, a decade earlier	Schade et al[7]
Are higher scores equal to greater risk?	Yes — scores (risk) are usually divided 10-100, 101-200, 201-300, >300	Burge et al[4]
Is cardiac stress testing recommended?	No — no direct patient benefit in the asymptomatic patient	Fowler-Brown et al[11]
Is a cardiology consult recommended?	No — no direct patient benefit in the asymptomatic patient	Topol and Nissen,[10] Fowler-Brown et al[11]
What medical treatment is recommended?	Aggressive lifestyle modifications and multiple risk factor control	Schade et al[7]
What is the best risk factor outcomes predictor?	CAC score plus Framingham risk assessment	McClelland et al[2]
Where can I obtain the best risk factor calculator?	www.mesa-hlbi.org/MESACHDRisk/MesaRiskScore/RiskScore.aspx	McClelland et al[2]
Is coronary calcium detrimental?	Not necessarily — it is only a marker for atherosclerosis	Burge et al[4]
What medications work well with statin therapy?	Ezetimibe works at a different anatomic site than statins and further lowers LDL-C	Cannon et al[13]
What dose of statins is most effective with the fewest side effects?	The lowest dose available (10 mg) achieves ~75% of the maximal therapeutic effect possible	Schade et al[7]
What should be the LDL-C goal?	<70 mg/dL, preferably 50 mg/dL	Schade et al[7]
Why don't statins lower LDL-C proportionally to the dose administered?	Statins increase PCSK9 protein, which negates the benefits of statins on LDL-C by decreasing hepatic LDL-C receptors	Welder et al[9]
What are the benefits of obtaining/utilizing a CAC score?	1) Improved prognostic score, 2) improved adherence to therapy, 3) prevention of unnecessary medical (statin) therapy	Hecht,[1] Burge et al[4]
What are the drawbacks of coronary angiography?	Cost = $5,000-$10,000; death = 0.08%; complications = 1.8%; misinterpretation	Topol and Nissen,[10] Fowler-Brown et al[11]

LDL-C = low-density lipoprotein cholesterol.

with laboratory follow-up within 3 months (**Table**). We withhold referral for cardiology consultation until evidence of unstable angina exists to optimize the clinical and financial risk/benefit impact. Appropriate exercise, diet, and medications should be considered lifelong to counteract the previous long term exposure to risk factors.[4]

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