



**Clinical Review Criteria**

**Coronary Artery Calcium Score with Computed Tomography (CT)**

- Multidetector Computed Tomography (MDCT)

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	<p>05/13/2016 Noridian retired LCD <a href="#">Multidetector Computed Tomography of the Heart and Great Vessels (L34137)</a>. These services still need to meet medical necessity as outlined in the LCD and will require review. LCDs are retired due to lack of evidence of current problems, or in some cases because the material is addressed by a National Coverage Decision (NCD), a coverage provision in a CMS interpretative manual or an LCD. Most LCDs are not retired because they are incorrect. The criteria should be still referenced when making an initial decision. However, if the decision is appealed, the retired LCD cannot be specifically referenced. Maximus instead looks for "medical judgment" which could be based on our commercial criteria or literature search.</p> <p>Per LCD L34137 - ... Until such time as there is more evidence of the medical necessity for quantitative evaluation of coronary calcium, Medicare may not cover the procedure for coronary calcium scoring (75571).</p>
Local Coverage Articles	None

**For Non-Medicare Members**

\*Repeat CAC measurement not indicated within less than 5 years.

*Adapted from KPWA ASCVD Primary Prevention Guideline (Oct 2020)*

Coronary artery calcium scoring may be indicated for asymptomatic patients with **1 or more of the following:**

- Intermediate ASCVD risk\* indicated by ALL of the following
  - Age 40-75 without DM and with LDL-C levels ≥ 70 mg/dL
  - At a 10-year ASCVD risk\* of ≥ 7.5% and < 20 %
  - Risk status or decision about statin therapy is uncertain

For these patients, treatment with statin therapy may be withheld or delayed if CAC = 0, except in cigarette smokers and those with a strong family history of premature ASCVD. A CAC score of 1–99 favors statin therapy, especially in those aged ≥ 55 years. For any patient, if the CAC score is ≥ 100 or ≥ 75th percentile, statin therapy is indicated.

- May be considered in select adults age 40-75 with ALL of the following
  - Borderline elevated ASCVD risk (5-7.4% 10-year ASCVD risk\*)

- The presence of CAC may change decision-making with regard to statin treatment and intensity of ASCVD risk factor modification

Routine CAC measurement is not recommended for:

- Patients at low (< 5% 10-year risk) or high ( $\geq$  20% 10-year risk) ASCVD risk
- Patients who are unlikely to initiate treatment even if CAC is identified

\*[ASCVD Risk Estimator Plus](#) (American College of Cardiology)

**If requesting review for this service, please send the following documentation:**

- Last 6 months of clinical notes from requesting provider &/or specialist
- Documented 10-year ASCVD risk score

\*[ASCVD Risk Estimator Plus](#) (American College of Cardiology)

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

## Background

Coronary heart disease (CHD) remains the leading cause of death among men and women in the United States. It is valuable to detect coronary atherosclerosis early in its course and try to alter its progression by modifying certain identifiable risk factors. The earliest detectable lesion of coronary atherosclerosis is a fatty streak, followed by crescent shaped lipid plaques, which may rupture and produce either progressive stenosis or sudden occlusion with myocardial infarction. It was previously thought that coronary artery calcification was the late result of end stage plaque degeneration. Now it is believed that calcium is present in all stages of plaque formation. Coronary artery calcification occurs in small amounts in the early lesions of atherosclerosis that appear in the second and third decades of life but is found more frequently in advanced lesions in older age (Janowitz 1993). Coronary artery calcium increases with increasing age in men, while women may experience accelerated calcification after menopause (Allison 2004).

The relation of arterial calcification to the probability of plaque rupture is unknown. Some investigators postulate that calcification may actively contribute to the susceptibility of plaque rupture and subsequent events. While others believe that calcification may reflect stabilization and maturation of the plaque that would lead to fewer myocardial infarctions and CHD deaths (Lee 2002). Beckman 2001 reported that although radiographically detected coronary artery calcium can provide an estimate of total coronary plaque burden, calcium does not concentrate exclusively at sites with severe coronary artery stenosis due to arterial remodeling. Other researchers indicated that ultrafast scans cannot detect all calcium and that molecular calcium may go unnoticed. Thus calcium detected by ultrafast scans may represent only the tip of the iceberg (Rumberger 1996). Despite that, some investigators believe coronary artery calcium (CAC) detection may be able to globally define a patient's risk of CHD events.

Now that some believe that calcification can be used as a marker of the atherosclerotic process, and because calcific deposits are radio-opaque, numerous radiographic techniques have been used in the search for a noninvasive screening test for coronary artery disease. Fluoroscopy was used for decades to detect coronary artery calcium. However, its routine use for identifying patients with coronary artery disease is limited due to its low sensitivity to detect small amounts of coronary calcium that can be observed pathologically in complex atherosclerotic plaques. Conventional computed tomography (CT) have an advantage over fluoroscopy in its improved resolution, which is limited however when moving structures are imaged. This limitation has been overcome by the electron beam computed tomography (EBCT), and multidetector computed tomography (MDCT). Both technologies yield thin slice CT imaging using fast scan speeds that reduce motion artifact. 30-40 adjacent axial scans are usually obtained. The fast time scan allows the entire heart to be imaged over one or two breath holds. Images can be reconstructed to form three-dimensional or cross-sectional images. There are three methods for calcium quantification and scoring: The Agatston method, the volumetric method, and quantification of calcium mass. Agatston method is the most commonly used and is obtained by the summation of areas of the calcified lesions multiplied by a scaling cofactor; an Agatston score of zero indicates absence of coronary calcium,

1-99 is considered low, 10-400 is intermediate, and 400 high (Sanz 2006). Calcium scores can be calculated for a coronary artery segment, a coronary artery, or summed for the whole coronary system.

Ultrafast CT scanners became commercially available in 1983, before the first study of their use was published in 1989. In the 1990s, another form of CT, the helical or spiral computed tomography has been developed. In helical tomography, continuous scanning is performed in combination with a continuous table feed. Thus, the x-ray beam traces a spiral path through the patient. The entire heart can be imaged with 3 mm non-overlapping slices, within one breath hold (30 sec). The initial goal of using cardiac computed tomography was to identify patients at risk of coronary artery disease based on the amount of calcium present. However, in the past 5-10 years these ultrafast scans have been used to: 1) Assist in CHD risk assessment in asymptomatic individuals, and, 2) To assess the likelihood of the presence of CHD in patients who present with atypical symptoms that could be consistent with myocardial ischemia.

The EBCT scanners currently used are produced by GE Imatron, South San Francisco California. They were approved by the FDA as Class II devices.

The use of EBCT for CAC scoring was reviewed by MTAC in 2002 and 2004 and did not meet its evaluation criteria. It is being re-reviewed due to the recent publications of studies with clinically important outcomes.

## Medical Technology Assessment Committee (MTAC)

### **Ultrafast CT in the Screening and Diagnosis of CAD**

#### **02/11/2002: MTAC REVIEW**

**Evidence Conclusion:** There is insufficient published evidence to determine the value of Ultrafast CT as a screening test for coronary artery disease among asymptomatic patients. In the studies reviewed, ultrafast CT and angiography were done among patients because of suspected coronary artery disease. The prevalence of CAD in these studies was high and it may not be appropriate to extrapolate these results to scans done in the population at large, or those done for screening purposes. The studies reviewed show that ultrafast CT scanning had a high sensitivity and low specificity in detecting coronary artery disease among the participants. The sensitivity increased with age and was highest for symptomatic patients older than 50 years. The specificity on the other hand, increased with the number of calcified vessels and was highest among patients with 4-vessel calcification. The majority of studies did not address clinical end-points, as their primary outcome. Detrano, et al (1996) however, followed-up the patients for a mean of 30 months, to determine the relative prognostic value of coronary calcification for predicting CHD events among symptomatic patients. They found that cardiac events and deaths tended to be more frequent in the higher quartiles of calcium score. In conclusion, the results of these studies indicate that in a population where CAD is more prevalent, the absence of coronary calcification is more helpful in ruling out CAD than is the detection of calcium in confirming the presence of CAD. Ultrafast CT seems promising, but as yet, there is no evidence that it may substitute angiography, but can be helpful in excluding or increasing the likelihood of significant CAD in certain situations.

**Articles:** The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See [Evidence Table](#). Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See [Evidence Table](#). Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. *AJR* 1996; 167:439-444. See [Evidence Table](#).

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **12/08/2004: MTAC REVIEW**

### **Ultrafast CT in the Screening and Diagnosis of CAD**

**Evidence Conclusion:** A screening test for preclinical coronary artery disease among asymptomatic individuals, and A diagnostic test for coronary artery disease among symptomatic patients. [Use of EBCT for coronary artery disease screening among asymptomatic individuals](#): There is insufficient published evidence to determine the

value of EBCT (Ultrafast CT) as a screening test for coronary artery disease among asymptomatic individuals. Ideally, a screening test should be highly sensitive in detecting previously undiagnosed disease and should lead to changes in management that improves outcomes. The meta-analysis and observational studies reviewed evaluated EBCT coronary artery calcium as a risk predictor of future coronary events among asymptomatic individuals. These studies suggest that coronary artery calcium detected by EBCT may be an independent predictor for coronary events and may add to the information provided by the Framingham risk score. However, the studies had some threats to validity that may limit generalization of the results. The majority is office-based and included self-referred individuals or others at high risk referred by their primary care physicians for further evaluation. Risk factors were self-reported and not measured in more than one study. Different techniques and scans were used, and there was no established cut-off level for calcium scores. The endpoints included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. The endpoint in one of the studies was all-cause mortality that might be due to other causes than coronary atherosclerotic diseases. None of these observational studies examined the influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. There is no evidence that more effective therapy or management could be provided by evaluating CAC score beyond that provided based on FRS. A recent RCT showed that the detection of coronary artery calcium among asymptomatic individuals was not associated with behavior modification or reduction of their cardiac risk scores. This RCT also had its limitations. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients: The studies reviewed show that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies reviewed in the meta-analysis, and the more recent study. The sensitivity was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results.

**Articles:** The search yielded 39 articles, many of which were review articles, opinion pieces, or dealt with technical aspects of the scan. The search did not reveal any study that evaluated ultrafast scanning as a screening test for coronary heart disease. There were four studies that compared the Ultrafast CT scan with angiography and a few others that did not use a defined gold standard for comparison. There was only one study on the newer helical CT scan. The two studies with the stronger methodology, and larger sample sizes were selected for critical appraisal. Broderick's study that evaluated the performance of the helical CT scan was also reviewed. Budoff MJ, Georgiou D, Brody A, et al. Ultrafast computed tomography as a diagnostic modality in the detection of coronary artery disease. A multicenter study. *Circulation* 1996; 93:898-904. See [Evidence Table](#). Detrano R, Hsiai T, Wang S, et al. Prognostic value of coronary calcification and angiographic stenoses in patients undergoing coronary angiography. *J Am Coll Cardiol* 1996; 27:285-90. See [Evidence Table](#). Broderick LS, Shemesh J, Wilensky RL, et al. Measurement of coronary artery calcium with dual-slice helical CT compared with coronary angiography: Evaluation of CT scoring methods, observer variations, and reproducibility. *AJR* 1996; 167:439-444. See [Evidence Table](#).

The use of ultrafast CT in the screening and diagnosis of CAD does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### **04/02/2007: MTAC REVIEW**

##### **Ultrafast CT in the Screening and Diagnosis of CAD**

**Evidence Conclusion:** This report focuses on the use of electron beam computed tomography for detecting calcium deposits in coronary arteries as 1. A screening test for preclinical coronary artery disease among asymptomatic individuals, and 2. A diagnostic test for coronary artery disease among symptomatic patients. Use of EBCT for coronary artery disease screening among asymptomatic individuals: Ideally a screening test for predicting outcomes should not only prove to independently contribute to risk stratification, but also to provide further prognostic information beyond and above the traditional risk factors i.e. in this case, the Framingham Risk Stratification. Constructing the Receiver Operator Characteristic (ROC) curves and measuring the Area Under the ROC curve (AUC) would determine if a new marker or test has an additive benefit. An ideal screening test would also lead to changes in the management that will improve health outcomes e.g. fewer events, extended life or better quality of life. Fletcher's meta-analysis (2004), reviewed for the previous update, offered some support that there is a linear relationship between CAC and CHD events, but the analysis did not address whether CAC adds any incremental value to Framingham Risk Score (FRS) for CHD risk prediction. Greenland and colleagues (2007) pooled the results of 6 observational studies published after Fletcher's meta-analysis. There was some heterogeneity between the studies in the assessment of risk factors, cut-off levels used for calcium scores, as well as in the endpoints. The latter included revascularization in several trials, which could have been performed at a higher rate based on the results of the scan. None of the studies included in the meta-analysis examined the

influence of detecting coronary artery calcification on the management of the individuals, the health benefits, or effect on outcome. The pooled results of the studies in the meta-analysis showed that patients with any measurable calcium were at a significantly higher risk compared to those with a low-risk CAC (using a score of 0) over a 3-5 years period of observation. This analysis also showed that there was an incremental relationship between CAC and CHD risk. The authors however did not discuss if adding CAC scoring to the traditional factors would significantly increase the AUC. Arad and colleagues published two articles on the St Francis Health Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first was a prospective cohort study that investigated the accuracy of CAC scores in predicting atherosclerotic cardiovascular disease (ASCVD) events independent of standard risk factors. The second article reports on the results of an RCT embedded in the cohort study. This RCT investigated whether lipid-lowering therapy and antioxidants retard the progression of coronary calcification and prevent ASCVD events. The St Francis Health Study enrolled 4,903 mainly White, healthy men and women 50-70 years old. All participants underwent EBCT but only a subset (n=1,357) with CAC score >80th percentile for age and gender, also underwent risk factor assessment. Participants were followed up for an average of 4.3 years for a composite outcome of coronary death, nonfatal MI, surgical or percutaneous coronary revascularization, nonhemorrhagic stroke and peripheral vascular surgery. A multivariate regression analysis showed that CAC scoring predicted CAD events independent of standard risk factors, and that it was strongly predicted by age, male gender, and family history of premature coronary disease. The Receiver Operator Curve (ROC) showed that CAC score predicted CAD events more accurately than Framingham risk stratification (AUC= 0.79 vs. 0.68). It has to be noted however that this comparison was made only for participants with the highest percentiles of CAC, and that this study included all ASCVD outcomes while FRS predicts only the hard CHD outcomes. The majority of the observed events in this study were cardiovascular procedures rather than the traditional cardiac events. One other limitation of the study was low participation rate as only 2% of the eligible subjects were enrolled in the study. The RCT embedded in that study (Arad, Spadaro 2005) randomized 1,005 participants, with CAC score >80th percentile for age and gender, to receive a combination of atorvastatin, vitamin C, and vitamin E or a placebo. All participants in the two groups also received aspirin 80 mg daily. After 4.3 years of follow-up, active treatment group showed nonsignificant reduction in the primary or secondary outcomes. The results also showed no significant change in the progression of CAC. The lack of significant difference in ASCVD events might be due to the small sample size, short follow-up duration, and /or the administration of aspirin to the control as well as the active therapy group. Use of EBCT as a diagnostic test for coronary artery disease among symptomatic patients: There is no new published evidence on the use of coronary calcium scoring as a diagnostic test for CAD. The studies reviewed earlier for the last update showed that compared to coronary angiography as a gold standard; EBCT scanning had a high sensitivity and low specificity in detecting coronary artery disease among symptomatic patients. The sensitivity ranged from 81% to 99% among the studies and was inversely related to the calcium score cutoff points. It was highest at a calcium score 0-10 which on the other hand had a specificity as low as 28%, i.e. high false positives which would be associated with further investigations that might be unnecessary. The studies were conducted among symptomatic patients with a high prevalence of coronary disease, and there is a potential of overestimation of the sensitivity, and positive predictive value, which might limit generalization of the results. *In conclusion:* There is some evidence that CAC may add a prognostic incremental value to Framingham risk score among selected asymptomatic individuals. Indirect evidence suggests that asymptomatic individuals at intermediate risk might potentially benefit from adding CAC to the risk assessment. The majority of the participants in the studies reviewed were Caucasians which may limit generalization of the results. The studies do not provide an optimal coronary calcium threshold. There is no single cutoff value that defines a high score. The coronary calcification differs according to age, sex, and race. There is no evidence to date that CAC scoring would result in an intervention that would improve CHD related health outcomes among individuals at an increased risk for CHD. The test results may lead to unnecessary invasive procedures, or overtreatment in some patients.

**Articles:** The search yielded around 50 articles. Many were review articles, opinion pieces, or dealt with technical aspects of the scan. Use of EBCT for coronary artery disease screening:

The search identified a recent meta-analysis of observational studies (Greenland 2007) and several prospective cohort studies that evaluated EBCT coronary artery calcium (CAC) score as a risk marker predicting the likelihood of future coronary events among asymptomatic patients. It also revealed two articles on the St. Francis Heart Study (Arad, Goodman 2005, and Arad, Spadaro 2005). The first reported on the prospective cohort study, and the second on the RCT embedded in the cohort. The meta-analysis and the two articles on the St. Francis Heart Study were selected for critical appraisal. Use of EBCT for coronary artery disease diagnosis:

The search did not reveal any newly published large valid study on the use of CAC scoring in the detection of coronary artery stenosis among symptomatic patients. *The following articles were critically appraised:* Greenland P, Raggi P, Harrington R, et al. ACC/AHA 2007 clinical expert consensus document on coronary artery calcium scoring by computed tomography in global cardiovascular risk assessment in an evaluation of patients with chest pain. *J Am Coll Cardiol.* 2007; 49:378-402. See [Evidence Table](#). Arad Y, Goodman KJ, Roth M, et al. Coronary calcification, coronary disease risk factors, C-reactive protein, and atherosclerotic cardiovascular disease events. The St. Francis Heart Study. *J Am Coll Cardiol.* 2005; 46:158-165. See [Evidence](#)

[Table](#). Arad Y, Spadaro LA, Roth M, et al. Treatment of asymptomatic adults with elevated coronary calcium scores with atorvastatin, vitamin C, and vitamin E. The St. Francis Heart Study randomized clinical trial. J Am Coll Cardiol.2005;46:166-172. See [Evidence Table](#).

The use of EBCT in the treatment of coronary artery calcium scoring does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

**CORONARY ARTERY CALCIUM (CAC) SCORING WITH COMPUTED TOMOGRAPHY, FOR CARDIOVASCULAR DISEASE RISK ASSESSMENT**

**Date: 10/12/2020**

**Evidence Conclusion:**

- There is evidence from published long-term large longitudinal population studies indicating that:
  - CAC is strongly associated and in a graded fashion with 10-year risk of incident ASCVD in asymptomatic White, Black, Hispanic and Chinese American men and women 45-84 years of age with no known history of CHD.
  - CAC scoring provides additional predictive information on ASCVD events and mortality, beyond the traditional risk factors, in men and women at different age groups, races, ethnic background, at different levels of risk, and in the presence or absence of comorbid conditions such as diabetes mellitus.
- There is insufficient published evidence, to date, from valid RCTs with long-term follow-up to determine that treatment guided by CAC scoring levels in addition to the traditional risk factors have an impact on patient management and /or health outcomes in asymptomatic adults at intermediate CV risk.

**Articles:** The literature search identified multiple large long-term population-based observational studies conducted in the US and Europe published over the last 20 years, that examined the association between CAC scoring and incidental CVD events and mortality in asymptomatic individual with no known coronary artery disease and its potential utility for CVD risk stratification in asymptomatic population. the largest population cohorts and/or those with longest follow-up duration were included in the review. The search did not identify any recent RCT with important clinical outcomes to determine the impact of CAC on guiding statin therapy an improving outcome in individuals at intermediate ASCVD risk.

The use of Coronary Artery Calcium (CAC) Scoring with Computed Tomography, for Cardiovascular Disease Risk Assessment does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

**Applicable Codes**

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

**\*Considered Not Medically Necessary (prior to 8/1/2021):**

CPT® Codes	Description
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)

**\*Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**\*\*To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).**

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Date Created	Date Reviewed	Date Last Revised
12/11/2002	Established annual review for Medicare criteria 05/03/2011 <sup>MDCRPC</sup> , 09/06/2011 <sup>MDCRPC</sup> , 07/03/2012 <sup>MDCRPC</sup> , 05/07/2013 <sup>MDCRPC</sup> , 06/04/2013 <sup>MDCRPC</sup> , 03/04/2014 <sup>MPC</sup> , 01/06/2015 <sup>MPC</sup> , 11/03/2015 <sup>MPC</sup> , 09/06/2016 <sup>MPC</sup> , 07/11/2017 <sup>MPC</sup> , 05/01/2018 <sup>MPC</sup> , 05/07/2019 <sup>MPC</sup> , 05/05/2020 <sup>MPC</sup> , 05/04/2021 <sup>MPC</sup> , 05/03/2022 <sup>MPC</sup> , 05/02/2023 <sup>MPC</sup>	09/10/2021

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Policy Committee

<b>Revision History</b>	<b>Description</b>
09/01/2015	Revised LCD Multidetector Computed Tomography of the Heart and Great Vessels (L34137)
09/06/2016	Adopted retired LCD policy for Medicare members
04/24/2018	Added Medicare non-coverage language from LCD
03/02/2021	Added October 2020 MTAC Review. MPC approved criteria for Coronary Artery Calcium Scoring for non-Medicare members. The criteria are based on the KPWA ASCVD Primary Prevention Guideline. Removed Electron Beam Computed Tomography (EBCT), Helical or Spiral Computed Tomography, and Ultrafast Computed Tomography from criteria. Requires 60-day notice, effective date 08/01/2021.
09/10/2021	Added additional documentation requirements