AmeriHealth Caritas Pennsylvania has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Pennsylvania’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Pennsylvania when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Pennsylvania’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Pennsylvania’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Pennsylvania will update its clinical policies as necessary. AmeriHealth Caritas Pennsylvania’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Pennsylvania considers the use of computed tomography (CT) of coronary arteries for coronary artery disease (CAD) to be clinically proven and, therefore, medically necessary when performed for evaluation and diagnosis of stable acute chest pain in low risk patients and for safe exclusion of acute coronary syndrome (ACS).

Limitations:

All other uses of computed tomographic arteriography (CTA) for CAD are not medically necessary. The use of CTA for screening for CAD is considered investigational, and therefore not medically necessary. The use of CTA for non-coronary evaluation (e.g., congenital anomalies, pericardial diseases, cardiac mass) does not fall within the scope of this policy.

AmeriHealth Caritas Pennsylvania considers the use of coronary calcium measurement to be investigational and, therefore, not medically necessary.
Alternative covered services:

In-network visits to primary care providers, pediatric and adult cardiology specialists, and interventional radiologists, as well as routine diagnostic and follow-up laboratory and radiographic evaluations.

Background

Cardiovascular imaging has been proposed as a noninvasive method of diagnosis for CAD with great potential to impact management of this condition.

Among the noninvasive cardiac imaging technologies for the diagnosis of CAD are:

- Cardiac magnetic resonance imaging (CMRI).
- Single photon emission computed tomography (SPECT).
- Computed tomographic angiography (CTA).
- Stress echocardiography.
- Stress echocardiography with contrast.

CTA assesses the presence or absence, as well as the extent, of coronary artery stenosis for the diagnosis of CAD. The advantage of CTA over coronary angiography (CA), the gold standard for the diagnosis of CAD, is that it is relatively less invasive and may serve as a test in determining which patients are best suited for CA (which requires insertion of a catheter through an artery in the arm or leg up to the area being studied). Both tests involve contrast agents and radiation exposure.

Searches

AmeriHealth Caritas Pennsylvania searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 30, 2017. Search terms were: “coronary artery,” “computed tomography,” and “coronary CT.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews.**
• **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Abundant studies have compared CTA with quantitative CA for evidence of efficacy and patient safety in the diagnosis of CAD. A number of qualitatively sound systematic reviews have found the former to be a reliable tool for detection of CAD when using a cut-off of ≥50 percent diameter stenosis in an elderly population (Yang 2015, Fischer 2013, Salavati 2012, Dennie 2009). This technology seems to provide a capable and anodyne means of diagnosing CAD and reducing the need for hospital admission and more invasive means of testing; however, by all estimations, CTA is dependent on adequate technology and local expertise (Andreini 2016, Stein 2008, Sun 2008, Hamon 2007). Attempts to correlate a coronary artery calcification (CAC) score to patient outcomes have yet to demonstrate consistently superior predictive value compared to traditional measures of coronary risk (Kavousi 2016, Zeb 2014, Waugh 2006). The identification of patients for whom CTA or CA is more appropriate may help to avoid more invasive tests, treatment delays, and unnecessary radiation exposure (Health Quality Ontario 2010, Janne 2008, Jacobs 2006).

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Kavousi (2016)</td>
<td><strong>Key points:</strong></td>
</tr>
</tbody>
</table>
| Prevalence and prognostic implications of coronary artery calcification in low-risk women: a meta-analysis | - Systematic review and meta-analysis examined preventative role of coronary artery calcium (CAC) testing in 6,739 women ages 44 to 63 years with 10-year atherosclerotic CVD (ASCVD) risk lower than 7.5%.
- Main outcome was incident ASCVD, including nonfatal myocardial infarction, coronary heart disease (CHD) death, and stroke.
- CAC was present in 36.1% where median follow-up ranged from 7.0 to 11.6 years.
- A total of 165 ASCVD events occurred (64 nonfatal myocardial infarctions, 29 CHD deaths, and 72 strokes).
- Incidence rates ranged from 1.5 to 6.0 per 1,000 person-years.
- Compared with the absence of CAC (CAC = 0), presence of CAC (CAC >0) was associated with an increased risk of ASCVD (incidence rates per 1,000 person-years, 1.41 for CAC absence vs 4.33 for CAC presence; difference, 2.92 [95% CI, 2.02–3.83]; multivariable-adjusted hazard ratio, 2.04 [95% CI, 1.44–2.90]).
- The addition of CAC to traditional risk factors improved the C statistic from 0.73 (95% CI, 0.69–0.77) to 0.77 (95% CI, 0.74–0.81) and provided a cNRI of 0.20 (95% CI, 0.09–0.31) for ASCVD prediction.
- Authors concluded that among women at low ASCVD risk, CAC was present in approximately one-third and was associated with an increased risk of ASCVD and modest improvement in prognostic accuracy compared with traditional risk factors. |

| Andreini (2016) | **Key points:**                                                                                   |
Clinical recommendations on Cardiac-CT in 2015: a position paper of the Working Group on Cardiac-CT and Nuclear Cardiology of the Italian Society of Cardiology

- Guidelines from the Italian Society of Cardiology on cardiac-computed tomography (CCT) endorsed using a score assessing whether the use of CCT for various indications is appropriate, uncertain, or inappropriate, among them coronary and noncoronary evaluation.
- Safely discharging patients with suspected acute coronary syndromes from the emergency department, CCT stress perfusion computed tomography, noninvasive evaluation of fractional flow reserve, and CCT use in athletes were addressed.
- The authors noted that the diagnostic performance of coronary computed tomography angiography (CCTA) is strictly dependent on adequate technology and local expertise.

Yang (2015)
Diagnostic accuracy of coronary angiography using 64-slice computed tomography in coronary artery disease

- A systematic review and meta-analysis of 579 patients investigated the diagnostic value of 64-slice computed tomography (CT) angiography for diagnosing coronary artery disease (CAD).
- Coronary artery stenosis was defined as ≥50% diameter stenosis.
- Pooled sensitivity value was 90% (95% confidence interval [CI]: 83–95%), specificity was 91% (95% CI: 61–98%), PLR value was 9.7 (95% CI: 1.8–53.3), and NLR value was 0.11 (95% CI: 0.05–0.22) for CAS. Optimal cut-off point of sensitivity was 90%, and specificity under the SROC curve was 91%.
- The AUC value was 0.94.
- The authors concluded that 64-slice CT angiography is a reliable tool for detection of CAD when using a cut-off of more than or equal to 50% diameter stenosis in elderly population.

Zeb (2014)
Coronary computed tomography as a cost-effective test strategy for coronary artery disease assessment

- A systematic review found CCTA either as a first line or as a layering test may represent a cost-effective strategy for initial evaluation of patients with CAD prevalence of 10–50% in both near-term and long-term diagnostic periods.
- For CAD prevalence ≥70%, ICA as an initial test may represent a cost-effective strategy for diagnosis of stable chest pain.
- CCTA may represent a cost-effective strategy when performed as a layering test to equivocal initial stress imaging before performing ICA.
- Use of CCTA is cost- and time-effective strategy for evaluation of low risk (<30% CAD prevalence) acute chest pain patients in emergency department and can be used for safe exclusion of acute coronary syndrome (ACS).
- Use of coronary calcium score as an initial test may require further evidence to be deemed cost-effective strategy.
- CCTA may represent a cost-effective strategy and may be associated with less downstream testing for diagnosis of stable chest pain patients in low-to-intermediate risk patients, whereas for low-risk acute chest pain patients, use of CCTA is associated with expedited patient management, less cost, and safe exclusion of ACS.

Fischer (2013)
Coronary CT angiography versus intravascular ultrasound for estimation of

- A systematic review and meta-analysis assessed the ability of coronary CTA to quantify coronary and plaque measurements in 1,360 patients (75% men; mean age, 59 years).
- No significant difference was found between coronary CTA and IVUS measurements of
<table>
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| coronary stenosis and atherosclerotic plaque burden | vessel lumen cross-sectional area, plaque area, percentage of area stenosis, or plaque volume within the overall cohort and no difference for the measurement of cross-sectional area and plaque volume among a subgroup that used automated or semiautomated measurement techniques.  
- Sensitivity and specificity of coronary CTA to detect any plaque compared with IVUS were 93% and 92%, respectively, with an area under the receiver-operating curve of 0.97.  
- The authors concluded that compared with IVUS, coronary CTA appears to be highly accurate for estimation of luminal area, percentage of area stenosis, plaque volume, and plaque area and for detection of plaque. |
| Salavati (2012) | Key points:  
- A systematic review and meta-analysis evaluated the diagnostic accuracy of dual-source computed tomography (DSCT) in the diagnosis of 2,303 patients with coronary artery disease (CAD).  
- The pooled sensitivity was 99% [95% confidence interval (CI), 97%–99%] with specificity of 89% (95% CI, 84%–92%). The summary positive (+LR) and negative (−LR) likelihood ratios were 8.6 (95% CI, 6.4–11.6) and 0.02 (95% CI, 0.01–0.03), respectively.  
- In per-segment analysis (n = 32,615), pooled sensitivity was 94% (95% CI, 92%–96%) with specificity of 97% (95% CI, 96%–98%).  
- Summary +LR and −LR were 30.2 (95% CI, 22.1–43.5) and 0.06 (95% CI, 0.04–0.08), respectively. |
| Health Quality Ontario (2010) | Key points:  
- The Canadian Medical Advisory Secretariat (MAS) created an evidence-based review of the literature surrounding different cardiac imaging modalities for CAD to determine the accuracy of CTA compared to CA in stable (non-emergent) symptomatic patients.  
- The authors concluded that:  
  - CTA is almost as good as CA in detecting true positives but poorer in the rate of false positives.  
  - The main value of CTA may be in ruling out significant CAD.  
  - Increased prevalence of CAD decreases study specificity, whereas specificity is increased in the presence of increased arterial calcification even in lower prevalence studies.  
  - Positive CT angiograms may require additional tests such as stress tests or the more invasive CA, partly to identify false positives.  
  - Radiation exposure is an important safety concern that needs to be considered, particularly the cumulative exposures from repeat CTAs. |
| Dennie (2009) | Key points:  
- Canadian Association of Radiologists (CAR) guidelines for CCT advise that 64-detector CCTA outperforms 16-detector CCTA, which in turn outperforms 4-detector CCTA.  
- Sixty-four detector CCTA detects coronary stenoses of 50% or greater with a high sensitivity and high negative predictive value.  
- Positive predictive value is lower in populations with low disease prevalence.  
- Coronary calcification, high heart rate, variable heart rate, and obesity have a negative |
Impact on the diagnostic performance of 64-detector CCTA.

- Results of inexperienced centers may not replicate those published by experienced academic centers.
- A significant percentage of coronary stenoses of 50% or greater is not associated with ischemia.
- CCTA compares favorably with IVUS for detection of plaque in a population with high disease prevalence, but compares less favorably when disease is less prevalent.
- A significant percentage of coronary stents prove to be unassessable by 64-detector CCTA.
- 64-detector CCTA has a high negative predictive value for detection of in-stent stenosis of 50% or greater.
- CCTA has excellent negative predictive value and very good positive predictive value for detection of coronary artery bypass graft stenosis of 50% or greater.
- A small percentage of grafts are unassessable by 64-detector CCTA.
- CCTA determination of the status of the run-off vessels and native coronary arteries is relatively poor.
- CAR supports the use of coronary CTA in:
  - Symptomatic patients with low-to-intermediate pretest probability of obstructive coronary artery disease who otherwise would be considered for conventional coronary angiography. This typically would be patients with chest pain and an equivocal or uninterpretable stress test.
  - Patients at low-to-intermediate risk of coronary artery disease with planned surgery for valvular or structural heart disease who otherwise would require preoperative conventional coronary angiography.
- CAR supports the use of CCT in the investigation of pericardial disease or cardiac masses when:
  - The findings on echo or MRI are inconclusive.
  - There is a contraindication to MRI such as the presence of a pacemaker, claustrophobia, or the inability to tolerate the examination.
  - CT is required to complete the staging of a probable cardiac malignancy.
- For diagnostic-quality CCT, a CT scanner should meet or exceed the following specifications:
  - For contrast-enhanced CCTA a scanner must be capable of achieving in-plane resolution of less than 0.5 mm axial, z-axis spatial resolution of less than 1 mm longitudinal, and temporal resolution of less than 0.25 seconds.
  - Tube heat capacity that allows for a single acquisition greater than 20 seconds.
  - All active CT facilities must have dose-reduction strategies in place.
  - Minimum section thickness no greater than 3 mm for calcium score CT and no greater than 1.5 mm for CTA.

Stein (2008)

64-slice CT for diagnosis of coronary artery disease

Key points:

- Systematic review to assess the accuracy of 64-slice CT coronary angiography for the diagnosis of CAD demonstrated there is a sensitivity of 64-slice CT for significant (≥50%) stenosis, based on pooled data of ≥90% in patient-based evaluations, named vessels, segments, and coronary artery bypass grafts, except the left circumflex (sensitivity 88%), distal segments (80%), and stents (88%).
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<tr>
<th>Citation</th>
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<tr>
<td></td>
<td>• Specificity was 88% in patient-based evaluations, and ≥90% at individual sites.</td>
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<td>• Positive predictive values for patient-based evaluations, left main coronary artery, and coronary artery bypass grafts ranged from 91% to 93%, but elsewhere ranged from 69% to 84%.</td>
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<tr>
<td></td>
<td>• Negative predictive values were 96% to 100%.</td>
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<td>• Positive likelihood ratios for patient-based evaluations were 8.0 and, at specific sites, were ≥9.7. Negative likelihood ratios, except for distal segments, were &lt;0.1.</td>
</tr>
<tr>
<td></td>
<td>• The authors concluded that a negative 64-slice CT reliably excluded significant coronary disease.</td>
</tr>
<tr>
<td></td>
<td>• However, the data suggest that stenoses shown on 64-slice CT require confirmation.</td>
</tr>
<tr>
<td>Sun (2008)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>Diagnostic value of 64-slice CT angiography in coronary artery disease</td>
<td>• Systematic review of 15 studies of 64-multislice CT (MSCT) angiography in the detection of CAD when compared to CA found pooled sensitivity, specificity, positive predictive value, and negative predictive value as well as 95% confidence interval (CI) were 97% (94 and 99%), 88% (79 and 97%), 94% (91 and 97%), and 95% (90 and 99%) for patient-based assessment; 92% (85 and 99%), 92% (85 and 99%), 78% (66 and 91%), and 98% (96 and 99%) for vessel-based assessment; and 90% (85 and 94%), 96% (95 and 97%), 75%(68 and 82%), and 98% (98 and 99%) for segment-based assessment, respectively.</td>
</tr>
<tr>
<td>Janne (2008)</td>
<td><strong>Key points:</strong></td>
</tr>
<tr>
<td>A systematic review on diagnostic accuracy of CT-based detection of significant coronary artery disease</td>
<td>• Systematic review of diagnostic accuracy of contrast enhanced coronary computed tomography (CE-CCT) inclusive of 2,515 patients (75% males; mean age: 59 years, CAS prevalence: 59%).</td>
</tr>
<tr>
<td>Janne (2008)</td>
<td>• Analysis of all coronary segments yielded a sensitivity of 95% (80%, 89%, 86%, 98% for electron beam CT, 4/8-slice, 16-slice, and 64-slice MDCT, respectively) for a specificity of 85% (77%, 84%, 95%, 91%). Analysis limited to segments deemed assessable by CT showed sensitivity of 96% (86%, 85%, 98%, 97%) for a specificity of 95% (90%, 96%, 96%, 96%).</td>
</tr>
<tr>
<td>Janne (2008)</td>
<td>• Per patient, sensitivity was 99% (90%, 97%, 99%, 98%) and specificity was 76% (59%, 81%, 83%, 92%). Heterogeneity was quantitatively important but not explainable by patient group characteristics or study methodology.</td>
</tr>
<tr>
<td>Janne (2008)</td>
<td>• The authors concluded that the diagnostic accuracy of CE-CCT is high. Advances in CT technology have resulted in increases in diagnostic accuracy and proportion of assessable coronary segments. However, per patient, accuracy may be lower and CT may have more limited clinical utility in populations at high risk for CAD.</td>
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<tr>
<td>Hamon (2007)</td>
<td><strong>Key points:</strong></td>
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<tr>
<td>Coronary arteries: diagnostic performance of 16- versus 64-section spiral CT compared with invasive coronary angiography</td>
<td>• Systematic review of multisection spiral CT as a diagnostic test for obstructive CAD versus the use of coronary angiography as the reference standard for diagnosing obstructive CAD (&gt;50% diameter stenosis) in 1,987 patients.</td>
</tr>
</tbody>
</table>
| Hamon (2007) | • The results for 16-section CT versus 64-section CT were 95% (95% confidence interval [CI]: 93%, 96%) versus 97% (95% CI: 95%, 98%) for sensitivity (P = 0.03), 69% (95%
<table>
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<tr>
<td>CI: 66%, 73%) versus 90% (95% CI: 86%, 93%) for specificity (P &lt; 0.001), 79% (95% CI: 76%, 82%) versus 93% (95% CI: 91%, 96%) for positive predictive value (PPV) (P &lt; 0.001), 92% (95% CI: 88%, 94%) versus 96% (95% CI: 92%, 98%) for negative predictive value (P &lt; 0.001), and 72.05 (95% CI: 31.35, 165.56) versus 181.82 (95% CI: 88.70, 372.71) for diagnostic odds ratio (P = 0.1).</td>
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<td>The authors concluded 64-section spiral CT has significantly higher specificity and PPV on a per-patient basis compared with 16-section CT for the detection of greater than 50% stenosis of coronary arteries.</td>
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<tr>
<td>Waugh (2006)</td>
<td>Key points:</td>
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<td>- Systematic review assessed the clinical and cost-effectiveness of CT screening for asymptomatic coronary artery disease and to establish whether coronary artery calcification (CAC) predicts coronary events and adds anything to risk factor scores, and whether measuring CAC changes treatment.</td>
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<td></td>
<td>- No randomized control trials (RCTs) were found that assessed the value of CT screening in reducing cardiac events.</td>
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<td>- Seven studies assessed the association between CAC scores on CT and cardiac outcomes in asymptomatic people and included 30,599 people and found the relative risk of a cardiac event was 4.4 if CAC was present, compared to there being no CAC.</td>
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<tr>
<td></td>
<td>- As CAC score increased, so did the risk of cardiac events. This applied mainly when the CAC scores exceeded 300.</td>
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<td></td>
<td>- There was little difference in event rates among the groups with no CAC, and scores of 1–100 and 101–300.</td>
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<tr>
<td></td>
<td>- No studies were found that showed whether the addition of CAC scores to standard risk factor assessment would improve outcomes.</td>
</tr>
<tr>
<td></td>
<td>- The authors concluded that CT examination of the coronary arteries can detect calcification indicative of arterial disease in asymptomatic people, many of whom would be at low risk when assessed by traditional risk factors.</td>
</tr>
<tr>
<td>Jacobs (2006)</td>
<td>Key points:</td>
</tr>
<tr>
<td>American College of Radiology practice guideline for the performance and interpretation of cardiac computed tomography</td>
<td>- American College of Radiology (ACR) guidelines on CCT advised that this technology enables the assessment of multiple types of cardiac pathology, including intraluminal coronary arterial plaque formation, coronary artery stenosis, congenital anomalies, coronary artery aneurysms, sequelae of cardiac ischemia, and the assessment of prior vascular interventions, while providing information about cardiac and valvular function.</td>
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<td></td>
<td>- Noncardiac structures included in cardiac CT examinations may also be evaluated.</td>
</tr>
</tbody>
</table>

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

L33947 Cardiac Computed Tomography (CCT) and Coronary Computed Tomography Angiography (CCTA). CMS Medicare Coverage Database website. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33947&ver=9&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=coronary&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAAAACAAAAAAA%3d%3d&. Accessed February 23, 2017.


Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>75574</td>
<td>Computerized tomographic angiography, heart, coronary arteries and bypass grafts (when present), with contrast material, including 3D image postprocessing (including evaluation of cardiac structure and morphology, assessment of cardiac function, and evaluation of venous structures, if performed)</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>I25.10</td>
<td>Atherosclerotic heart disease of native coronary artery without angina pectoris</td>
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<tr>
<td>I25.110-</td>
<td>Atherosclerotic heart disease of native coronary artery with angina</td>
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<tr>
<td>I25.119</td>
<td></td>
<td></td>
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<tr>
<td>I25.700-</td>
<td>Atherosclerosis of coronary artery bypass grafts with angina pectoris</td>
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<tr>
<td>I25.799</td>
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<th>HCPCS Level II Code</th>
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