

Medical Coverage Policy

Effective Date: 02/24/2021 Revision Date: 02/24/2021 Review Date: 02/24/2021 Policy Number: HCS-0350-018

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Change Summary: Updated Coverage Determination, References

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Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. Refer to the CMS website. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from Humana.

Description

Coronary artery calcium (CAC) scoring is a noninvasive test that has been reported to detect the presence of subclinical coronary artery disease (CAD) by measuring the location, extent and characterization of calcium in the coronary arteries. Purportedly, the presence of CAC has been shown to be strongly correlated with the extent of atherosclerotic plaque as well as the severity of CAD.⁵⁷ Tests to determine CAC scoring include:

- Electron beam computed tomography (EBCT), also known as ultrafast computed tomography (UFCT) (Refer to Coverage Limitations section)
- Multi-slice CT (Refer to Coverage Limitations section)

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Coronary computed tomography angiography (CCTA) is a noninvasive imaging modality designed to be an alternative to invasive cardiac angiography (cardiac catheterization) for diagnosing CAD by visualizing the blood flow in arterial and venous vessels. The gold standard for diagnosing coronary artery stenosis is cardiac catheterization.

Automated software to work in conjunction with CCTA has been proposed to assist in quantifying and characterizing atherosclerotic plaques in an effort to determine severity of CAD. (Refer to Coverage Limitations section)

Fractional flow reserve (FFR) is the ratio between maximum blood flow in a narrowed coronary artery and the maximum blood flow in a normal artery, and has previously been attainable only from invasive cardiac angiography. The HeartFlow FFR_{CT} Analysis is an example of an FDA-approved software device that obtains this ratio (FFR_{CT}) noninvasively from previously acquired CCTA image data used to create three-dimensional (3D) images of the coronary arteries. Test results may assist cardiologists in determining the individual's need for intervention such as angioplasty or stenting.

The HeartFlow Planner utilizes a coronary anatomy model and physiology simulation created from the HeartFlow Analysis. Physicians are purportedly able to identify stenoses and virtually modify the vessel. For each treatment scenario, HeartFlow Planner will display the modified FFR_{CT} values in real time to enable physicians to understand the impact of the modeled treatment strategy. Common scenarios for using HeartFlow Planner include focal stenoses, serial stenoses, and borderline cases. (Refer to Coverage Limitations section)

Coverage Determination

Humana members may be eligible under the Plan for **CCTA** when the following criteria are met:

- All studies must be prescribed by a treating physician or a qualified nonphysician practitioner; AND
- Coverage of this modality for coronary artery assessment is limited to scanners that process thin, high resolution slices (1 mm or less). The multidetector row scanner must have at least 64 slices per rotation capability (collimations of at

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least 32x2 or 64x1) and with gantry rotation times of 420 milliseconds or less should be utilized; **AND**

- As an alternative to the following:
 - Invasive coronary angiography in individuals with hypertrophic cardiomyopathy who are at risk of coronary atherosclerosis before performing surgical myectomy; OR
 - Invasive coronary angiography in individuals with hypertrophic cardiomyopathy and symptoms or evidence of myocardial ischemia¹³; OR
 - Stress echocardiography or stress radionuclide scanning in <u>low to</u> <u>intermediate risk</u>* individuals with chest pain who have an equivocal or suspected inaccurate stress electrocardiogram (EKG); **OR**
- Assessment of right ventricular function and morphology in individuals with suspected arrhythmogenic right ventricular dysplasia (ARVD); OR
- Evaluation of the following:
 - Cardiac anatomy in preparation for electrophysiological procedures including electrophysiological testing, ablation and intervention; OR
 - Cause of chest pain or other symptoms that may be related to an angina equivalent (such as dyspnea) in individuals with prior bypass surgery or intracoronary artery stent placement; OR
 - Individuals with bicuspid aortic valve when morphology of the aortic sinuses, sinotabular junction or ascending aorta cannot be assessed accurately or fully by echocardiography¹²; OR
 - Low to intermediate risk* individuals with chest pain who are without known
 CAD in an outpatient setting (includes emergency department); OR
 - Native or prosthetic cardiac valvular mass and pericardial dysfunction and inadequate visualization with other noninvasive methods; OR

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- If stress echocardiography or stress radionuclide scanning is equivocal or indeterminate or has artifact; OR
- Left bundle branch block, congestive heart failure or myocardial systolic or diastolic dysfunction to exclude significant CAD as a cause of these presentations; OR
- Preoperative assessment of the aortic valve annulus prior to anticipated transcatheter aortic valve replacement (TAVR) (For information regarding coverage determination/limitations for TAVR, please refer to <u>Transcatheter Valve</u> <u>Procedures</u> Medical Coverage Policy); **OR**
- Suspected congenital anomalies of the coronary circulation

*Please refer to <u>CVD risk calculator</u> for additional information regarding cardiovascular risk stratification

Humana members may be eligible under the Plan for **FFR**_{CT} when the following criteria are met:

- Absence of <u>contraindications</u> listed in the Coverage Limitations section; AND
- Evaluation of individuals with a CCTA which has shown CAD with 30-90% stenosis

Note: The criteria for **CCTA** are not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the <u>CMS website</u> for additional information.

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **CAC** scoring tests or **HeartFlow Planner**. These are considered experimental/investigational as they are not identified as widely used and generally accepted for the proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may **NOT** be eligible under the Plan for **CCTA** for any indications other than those listed above, including but may not be limited to:

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- The test is never covered for screening; OR
- The selection of the test should be made within the context of other testing modalities such as stress myocardial perfusion images or cardiac ultrasound results so that the resulting information facilitates the management decision and does not merely add a new layer of testing; OR
- If there is pretest knowledge of sufficiently extensive coronary artery calcification, which would diminish the interpretive value or the presence of arrhythmia; OR
- Individuals with an allergy or intolerance to iodinated contrast material; OR
- Use of software programs in conjunction with CCTA for automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease

These are considered not medically necessary as defined in the member's individual certificate. Please refer to the member's individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for **FFR**_{CT} for any indications other than those listed above, including but may not be limited to, the following:

- CCTA does not demonstrate CAD with at least 30% stenosis; OR
- Use in individuals known to have the following:
 - A body mass index greater than 35; OR
 - Complex congenital heart disease; OR
 - Coronary vessels with excessive calcification; OR
 - o Intracoronary metallic stents; OR
 - Prior coronary artery bypass graft (CABG) surgery; OR

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- Prior pacemaker or internal defibrillator lead implantation; OR
- Prosthetic heart valves; OR
- o Recent prior myocardial infarction within 30 days; OR
- Require emergent procedures or have any evidence of ongoing or active clinical instability, including sudden onset acute chest pain, cardiogenic shock, unstable blood pressure with systolic blood pressure less than 90 mmHg, severe congestive heart failure (New York Heart Association NYHA] III or IV) or acute pulmonary edema; OR
- Significant arrhythmias or tachycardia (uncontrolled by medication) that would preclude CT acquisition; OR
- Suspicion of acute coronary syndrome (ACS) where acute myocardial infarction or unstable angina have not been ruled out⁸⁴

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Background

Additional information about **CAD** may be found from the following websites:

- American Heart Association
- National Library of Medicine

Medical Alternatives

Alternatives to **CAC scoring, CCTA or FFR**_{CT} include, but may not be limited to, the following:

- Coronary angiogram
- Fractional flow reserve (as component of coronary angiogram)
- Stress echocardiography

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- Stress EKG
- Stress radionuclide myocardial perfusion imaging (SPECT or PET)

Physician consultation is advised to make an informed decision based on an individual's health needs.

Codes

Provider Claims Any CPT, HCPCS or ICD codes listed on this medical coverage policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
75571	Computed tomography, heart, without contrast material, with quantitative evaluation of coronary calcium	Not Covered
75572	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology (including 3D image postprocessing, assessment of cardiac function, and evaluation of venous structures, if performed)	Not Covered if used to report CCTA performed as a screening test
75573	Computed tomography, heart, with contrast material, for evaluation of cardiac structure and morphology in the setting of congenital heart disease (including 3D image postprocessing, assessment of LV cardiac function, RV structure and function and evaluation of venous structures, if performed)	Not Covered if used to report CCTA performed as a screening test
75574	Computed 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)	Not Covered if used to report CCTA performed as a screening test
93799	Unlisted cardiovascular service or procedure	Not Covered if used to report any test outlined in Coverage Limitations section

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CPT® Category III Code(s)	Description	Comments
0501T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission, analysis of fluid dynamics and simulated maximal coronary hyperemia, generation of estimated FFR model, with anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report	
0502T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; data preparation and transmission	
0503T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated FFR model	
0504T	Noninvasive estimated coronary fractional flow reserve (FFR) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; anatomical data review in comparison with estimated FFR model to reconcile discordant data, interpretation and report	

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0523T	Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (List separately in addition to code for primary procedure)	
0623T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report	Not Covered New Code Effective 01/01/2021
0624T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission	Not Covered New Code Effective 01/01/2021
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	Not Covered New Code Effective 01/01/2021
0626T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report	Not Covered New Code Effective 01/01/2021
HCPCS Code(s)	Description	Comments
S8092	Electron beam computed tomography (also known as ultrafast CT, cine CT)	Not Covered

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Appendix A:

New York Heart Association (NYHA) Functional Classification System – A system developed to help physicians in clinical practice to evaluate the effects of cardiac symptoms on an individual's daily activities. The classifications are:

- Class I (mild) No limitations on physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath) or anginal pain.
- Class II (mild) Slight limitation of physical activity; comfortable at rest; ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
- Class III (moderate) Marked limitation of physical activity; comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
- Class IV (severe) Inability to carry on any physical activity without discomfort; symptoms of cardiac insufficiency may be present even at rest. If any physical activity is undertaken, discomfort increases.