Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease

Policy Number: MMP372.10
Last Committee Approval Date: June 12, 2024
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Instructions for Use

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Related Policies

None

Coverage Rationale

Overview

Noninvasive fractional flow reserve deduced from computed tomography (FFR-ct) involves computer-assisted processing of coronary computed tomography angiography (CCTA) images to estimate changes in blood pressure inside coronary arteries that have partial blockages, with the goal of determining how severely the blockages impede blood flow to the heart. FFR-ct is a post-processing software for the clinical quantitative and qualitative analysis of previously acquired computed tomography (CT) Digital Imaging and Communications in Medicine (DICOM) data for clinically stable symptomatic patients with coronary artery disease (CAD). FFR-ct analysis is intended to support the functional evaluation of CAD. The results of this analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries.

CMS National Coverage Determinations (NCDs)

Medicare does not have an NCD for Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease.

CMS Local Coverage Determinations (LCDs) and Articles

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCDs/LCAs, refer to the table for Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease.

For coverage guidelines for states/territories with no LCDs/LCAs, refer to the coverage rationale below.

This service should be performed in clinically stable symptomatic patients with coronary artery disease. FFR-ct should not be used for patients with unstable coronary syndromes, or in patients where urgent and timely workup and evaluation is critical.

This service should not be performed until after the base study (CCTA) has been completed and interpreted. If higher grade stenoses (i.e., greater than 90%) are present, this study is not medically necessary, as the patient should proceed to catheterization. Similarly, low-grade stenoses (less than 40%) do not require additional confirmatory data. This should be performed as an alternative to stress testing.

FDA-approved FFR-ct technology is reasonable and necessary when all of the following criteria are met:

- FFR-ct technology is used in the management of patients with:
  - No prior coronary disease and acute (anginal) chest pain, FFR-ct is indicated in intermediate risk patients (troponin elevation) after a coronary artery stenosis finding on CCTA of 40-90% in a proximal or middle coronary artery; **or**
  - Known coronary artery disease and acute (anginal) chest pain, FFR-ct is indicated for intermediate risk patients (troponin elevation) after a coronary artery stenosis finding on CCTA of 40-90% in a proximal or middle coronary artery; **or**
  - No prior coronary disease and stable (anginal) chest pain, FFR-ct is indicated for intermediate risk patients after a coronary artery stenosis finding on CCTA of 40-90% in proximal or middle coronary artery; **or**
  - Known coronary disease and persistent stable (anginal) chest pain, FFR-ct is indicated after any 40-90% stenosis finding on CCTA

  and
- FFR-ct technology is not used in conjunction with stress testing (unless CCTA was not sufficient quality for FFR-ct, and an alternative study is needed); **and**
- None of the following clinical circumstances are present:
- Prior placement of prosthetic valves.
- Prior placement of grafts in coronary bypass surgery.
- Suspicion of acute coronary syndrome (where MI or unstable angina have not been ruled out).
- Intracoronary metallic stent.
- Status post-heart transplantation.
- Recent MI (30 days or less).
- Prior pacemaker or defibrillator lead placement.
- Newly diagnosed systolic heart failure, with no prior left heart catheterization.
- Non-obstructing stenosis (< 50% of all major epicardial vessels) on CTA or catheterization in the past twelve months, in the absence of a new symptom complex.
- If turnaround times may impact prompt clinical care decisions.

*Intermediate and high-risk as defined in the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service; however, language may be included in the listing below to indicate if a code is non-covered. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
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 (Deleted 12/31/2023 – See 75580)
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 (Deleted 12/31/2023 – See 75580)
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 (Deleted 12/31/2023 – See 75580)

CPT Code	Description
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 (Deleted 12/31/2023 – See 75580)
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional (Effective 01/01/2024)

Diagnosis Code	Description
R93.1	Abnormal findings on diagnostic imaging of heart and coronary circulation

Centers for Medicare and Medicaid Services (CMS) Related Documents

After checking the table below and searching the Medicare Coverage Database, if no NCD, LCD or LCA is found refer to the criteria as noted in the Coverage Rationale section above.

NCD	LCD	Article	Contractor Type	Contractor Name
Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease				
N/A	L38771 Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	A58359 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	Part A and B MAC	CGS
	L39075 Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	A58814 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	Part A and B MAC	NGS
	L38613 Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	A58095 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	Part A and B MAC	Noridian
	L38615 Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	A58097 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	Part A and B MAC	Noridian
	L38278 Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease	A58406 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease	Part A and B MAC	Palmetto**
	L38839 Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	A58473 Billing and Coding: Non-Invasive Fractional Flow Reserve (FFR) for Ischemic Heart Disease	Part A and B MAC	WPS*

Medicare Administrative Contractor (MAC) With Corresponding States/Territories	
MAC Name (Abbreviation)	**States/Territories**
CGS Administrators, LLC (CGS)	KY, OH
First Coast Service Options, Inc. (First Coast)	FL, PR, VI
National Government Services, Inc. (NGS)	CT, IL, ME, MA, MN, NH, NY, RI, VT, WI
Noridian Healthcare Solutions, LLC (Noridian)	AS, AK, AZ, CA, GU, HI, ID, MT, NV, ND, Northern Mariana Islands, OR, SD, UT, WA, WY
Novitas Solutions, Inc. (Novitas)	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX, VA**
Palmetto GBA (Palmetto)	AL, GA, NC, SC, TN, VA**, WV
Wisconsin Physicians Service Insurance Corporation (WPS)*	IA, IN, KS, MI, MO, NE
Notes	
*Wisconsin Physicians Service Insurance Corporation: Contract Number 05901 applies only to WPS Legacy Mutual of Omaha MAC A Providers. **For the state of Virginia: Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction.	

Clinical Evidence

The analysis of coronary artery disease (CAD) by noninvasive fractional flow reserve derived from computed tomography coronary angiography (FFRct) has been limited by a relatively small number of randomized controlled trials. The addition of computer derived fractional flow analysis of CTA data has demonstrated potential for a noninvasive test that offers both anatomic and functional data. The clinical utility of this emerging technology shows promise in reducing the need for invasive cardiac procedures, and their associated risks.

An ECRI Health Technology Assessment entitled FFRct Software (HeartFlow, Inc.) for Evaluating Coronary Artery Disease (CAD) states that the evidence shows FFRct is useful for guiding treatment in patients with CAD and those suspected of having CAD. The assessment notes FFRct provides actionable information in up to 66% of patients and may allow safe invasive coronary angiography (ICA) deferral in up to 61% of patients with suspected CAD (ECRI, 2023).

In a 2021 open label, multi-center randomized controlled trial (FORECAST), Curzen et al. evaluated the total cardiac costs and improved clinical outcomes in patients receiving fractional flow reserve derived from computed tomography coronary angiography (FFRct) compared to the standard of care set forth by National Institute for Health and Care Guidance (NICE) Recent-onset chest pain of suspected cardiac origin: assessment and diagnosis Clinical guideline [CG95]. This is the first randomized trial to assess FFRct as a tool for assessment of chest pain. A total of 1,400 patients with stable chest pain were randomized as follows: 700 to initial testing utilizing computed tomography coronary angiography (CTCA) with selective FFRct (Experimental Group) and 700 to standard clinical pathways (e.g., CTCA without FFRct, Stress test, Invasive angiogram) based on NICE guidance (Standard Group). Participants consisted of 48% women, average age of 59 years with diabetes, hypertension, history of smoking, hyperlipidemia, and family history of ischemic heart disease among the clinical characteristics. During the 9 month follow up, invasive coronary angiography use was 22% lower in the experimental group. However, there was no significant difference in the number of hospitalizations, visits to outpatient clinics, and emergency departments. Changes in medication use from enrollment to 9 months were similar in the 2 groups for aspirin, statins, antiplatelets, ACE inhibitors, beta blockers, and angiotensin receptor blockers. Additionally, the rate of coronary revascularization (e.g., percutaneous coronary intervention (PCI) and coronary artery bypass graft), major adverse cardiac events (MACE), angina status, and quality of life (QOL) did not vary greatly between the two groups. The authors concluded a strategy of CTCA with selective FFRct in patients with stable chest pain did not differ significantly from standard clinical pathways in clinical outcomes or QOL improvements; however, it did decrease the use of invasive coronary angiography. This finding is consistent with previous observational studies. This review is limited by conflicts of interest among authors and potential bias. Further independent research is needed to identify the optimal use of FFRct in routine clinical practice.

Norgaard et al. (2021) conducted a systematic review and meta-analysis to assess clinical outcomes of CT-derived calculation of FFR (FFRct) in patients with stable coronary artery disease (CAD). Five studies, including three multi-center prospective and two single-center observational, were included in the review. A total of 5,460 patients were eligible for meta-analysis. Lack of a 12-month follow up or patients overlapping between databases were reasons for patient exclusion. The authors reported all-cause mortality (ACM), or myocardial infarction (MI) occurred in 60 patients: 13 with a

negative FFRct result and 47 with a positive FFRct result. Major adverse cardiovascular events (MACE), MI, spontaneous MI, or unplanned revascularization [percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG)] also occurred more frequently in patients with a positive FFRct result versus patients with a negative FFRct result. Each FFRct unit reduction was associated with a greater risk of ACM or MI. The authors concluded that In patients with stable CAD, a negative FFRct result is associated with a low prevalence of adverse events at 12 months, with a considerably lower risk of death or MI when compared to those with a positive FFRct result. The FFRct numerical value was inversely related to clinical outcomes, suggesting the safety of deferring additional testing in patients with a negative FFRCT result. This review is limited by conflicts of interest among authors and potential bias, and a small number of observational and registry studies analyzed. Furthermore, definitions of clinical outcomes and the length of follow up varied among the studies. Additional independent research with larger scale, randomized controlled trials are needed to validate these findings.

In this retrospective, cross-sectional study, Budde R et al. (2021) evaluated the first cohort of heart transplant patients (HTx) that received FFRct analysis of coronary computed tomography angiography (CCTA) performed for routine annual screening of cardiac allograft vasculopathy (CAV). Seventy-three patients, an average of 11 years post heart transplantation, were included in the study. The cohort consisted of 37% women, average age of 56 years with diabetes, hypertension, and history of smoking among the clinical characteristics. No chest pain was recorded at the time of the study. The authors reported 18 patients had focal stenosis with a positive FFRct result and 55 patients had a positive FFRct result without focal stenosis. At 1-year follow-up, 13 patients had additional testing with invasive coronary angiography (ICA) performed. Additional testing, revascularization, and major adverse cardiac events (MACE) occurred more frequently in those that previously received a positive FFRct result with focal stenosis and in patients at a longer time post-transplant. The authors concluded that FFRct was successfully performed on CCTA scans of HTx patients and 25% had a focal coronary stenosis with a positive FFRct result. However, even in the absence of a focal stenosis, FFRct values were often abnormal in HTx patients. This study is limited by the cross-sectional nature of its design and the potential that patients who were longer post-transplant may represent less severe and/or slower progression of CAV, conflicts of interest among authors and potential bias, and limited follow-up time. Further independent studies with longer follow-up times are needed to validate if FFRct provides the same prognostic value in heart transplant patients as invasive FFR.

Douglas et al. (2016, included in ECRI health technology assessment and Norgaard systematic review above) conducted a prospective, multi-center, consecutive cohort study (PLATFORM) to determine the one-year clinical and quality of life (QOL) outcomes using fractional flow reserve (FFRct) instead of invasive coronary angiography (ICA) in patients with stable, new onset chest pain with suspected coronary artery disease (CAD). Five hundred and eighty four patients were assigned as follows: 204 to receive noninvasive testing, of which 100 received standard noninvasive testing and 104 received FFRct, and 380 received ICA. The cohort consisted of 40% women, average age of 61 years with diabetes, hypertension, history of smoking and dyslipidemia among the clinical characteristics. The one-year follow up was completed in 581 participants via a clinical visit in 97.4% and chart review in the remainder. During the one- year follow up, 2 major adverse cardiovascular event events (MACE) occurred within 90 days in the group receiving FFRct. In the group that received usual care, 2 MACE events and two vascular complications occurred during the follow up period. QOL improved from baseline to 12 months of follow-up in the planned invasive group and the improvements were similar in the patients in the FFRCT and usual care groups. Vascular complications were infrequent in both groups. Changes in medication use from enrollment to 1 year were similar in the 2 arms for aspirin, statins, and P2Y12 inhibitors. The authors concluded that when used as an alternative diagnostic strategy to guide patient care with planned invasive catheterization, CTA with selective FFRct was associated with a significantly lower rate of angiography showing no obstructive CAD, low rates of clinical outcomes and similar QOL improvements. When used in those with planned noninvasive testing, clinical events were rare and there were similar improvements in QOL outcomes. This study is limited by conflicts of interest among authors and potential bias, and a lack of randomization. Additional independent randomized studies are needed to validate these findings.

Clinical Practice Guidelines

American College of Cardiology (ACC)/American Heart Association (AHA)

The ACC and AHA developed a joint clinical practice guideline for the evaluation and diagnosis of chest pain that recommends:

FFR-CT for diagnosis of vessel-specific ischemia and to guide decision-making regarding the use of coronary revascularization for the following patients:

- Intermediate-risk with acute chest pain and previously unknown CAD with coronary stenosis of 40-90% in proximal or middle coronary artery on CCTA.

- Intermediate-risk with stable chest pain and previously unknown CAD with coronary stenosis of 40-90% in proximal or middle coronary artery on CCTA.
- Intermediate-risk with acute chest pain and known CAD with coronary stenosis of 40-90% in proximal or middle coronary artery on CCTA.
- Known nonobstructive CAD with stable chest pain and stenosis from 40-90% on CCTA.

In the clinical pathways, FFR-CT or stress test is recommended. The guidelines state an advantage of FFR-CT is that additional testing for the patient is not required. However, FFR-CT should not be ordered in cases where CCTA imaging is suboptimal or if extensive plaque is present and a high-quality CCTA is unlikely to be achieved. FFR-CT should also not be considered when a delay in the results could impact patient care (Gulati M et al., 2021).

Class IIA – Moderate strength recommendation. Benefits are felt to outweigh risk.

Level of evidence B-NR – Moderate quality evidence from one or more well-designed, non-randomized study and/or meta-analysis of such studies.

For patients with unknown CAD who are symptomatic with chest pain likely to be angina, refer to the following AHA 2021 guideline: Pretest Probabilities of Obstructive CAD in Symptomatic Patients, figure 11, page 78. (Accessed May 6, 2024)

National Institute for Health and Care Excellence (NICE)

In a 2017 guideline on HeartFlow FFRct for estimating fractional flow reserve from coronary CT angiography, NICE recommends the following:

- HeartFlow FFRct is safe and has a high level of diagnostic accuracy.
- HeartFlow FFRct should be given consideration for patients with stable, recent-onset chest pain who are offered CCTA in accordance with the NICE guideline on chest pain. The use of HeartFlow FFRct may avoid the need for invasive coronary angiography and revascularization. For correct use, HeartFlow FFRct requires access to 64-slice (or above) CCTA facilities.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

HeartFlow FFRct was granted FDA 510(k) marketing clearance in October 2022, based on its substantial equivalence to a prior FFRct version. FDA granted de novo classification to the HeartFlow FFRct version 1.4 as a coronary physiologic simulation software device in November 2013.

According to the FDA's indications for use, HeartFlow FFRct is a post-processing software for the clinical quantitative and qualitative analysis of previously acquired Computed Tomography (CT) DICOM data for clinically stable symptomatic patients with coronary artery disease. It provides FFRct, a mathematically derived quantity, computed from simulated pressure, velocity and blood flow information obtained from a 3D computer model generated from static coronary CT images. FFRct analysis is intended to support the functional evaluation of coronary artery disease. The results of this analysis are provided to support qualified clinicians to aid in the evaluation and assessment of coronary arteries. The results of HeartFlow FFRct are intended to be used by qualified clinicians in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the clinician's professional judgment. The device is only for prescription use.

According to the FDA's De Novo Summary, the safety and effectiveness of the FFRct analysis has not been evaluated for the following populations:

- Suspicion of acute coronary syndrome (where acute myocardial infarction or unstable angina have not been ruled out).
- Recent prior myocardial infarction within 30 days.
- Complex congenital heart disease.
- Prior coronary artery bypass graft (CABG) surgery.
- Patients with a Body Mass Index > 35.
- Patients who require emergent procedures or have any evidence of ongoing or active clinical instability, including acute chest pain (sudden onset), cardiogenic shock, unstable blood pressure with systolic blood pressure < 90 mmHg, severe congestive heart failure (New York Heart Association [NYHA] III or IV) or acute pulmonary edema.

Due to the potential for artifacts in the CT data or degradation of CT data quality, the safety and effectiveness of the FFRct analysis has not been evaluated for the following populations:

- Patients with intracoronary metallic stents.
- Patients with prior pacemaker or internal defibrillator lead implantation.
- Patients with prosthetic heart valves.
- Patients with significant arrhythmias or tachycardia (uncontrolled by medication) that would preclude CT acquisition.
- Coronary vessels with excessive calcification.

FFRct results may be adversely affected by the following:

- Marginal quality of the submitted imaging data (motion, blooming, misregistration, etc.).
- Grossly incorrect brachial pressure (like cath measured FFR, FFRct is somewhat insensitive to pressure but wide discrepancies will affect the FFRct results).
- Regionalized or global myocardial dysfunction.
- Myocardial mass abnormalities (Hypertrophic right ventricle for example).
- Abnormal patient physiology (e.g., severe congenital disease or excess calcification).

Refer to the following website for more information at:
https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN130045.pdf. (Accessed Jan. 16, 2024)

References

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Policy History/Revision Information

Date	Summary of Changes
10/01/2024	**Centers for Medicare & Medicaid (CMS) Related Documents** • Added notation for the state of Virginia to indicate “Part B services for the city of Alexandria and the counties of Arlington and Fairfax are excluded for the Palmetto GBA jurisdiction and included within the Novitas Solutions, Inc. jurisdiction”
08/01/2024	**Applicable Codes** • Clarified introduction language
07/01/2024	**Title Change/Template Update** • Previously titled *Coronary Fractional Flow Reserve Using Computed Tomography (FFR-ct)* • Reformatted and reorganized policy; transferred content to new template

Date	Summary of Changes

	• Changed policy type classification from “Policy Guideline” to “Medical Policy”
	• Added *Clinical Evidence, FDA, and References sections*
	• Updated *Instructions for Use*
	Related Policies
	• Removed reference link to the UnitedHealthcare Medicare Advantage Policy Guideline titled *Category III CPT Codes*
	Coverage Rationale
	• Removed content/language addressing documentation requirements
	Centers for Medicare & Medicaid (CMS) National Coverage Determinations (NCDs)
	• Added language to indicate Medicare does not have a NCD for non-invasive fractional flow reserve (FFR) for ischemic heart disease
	CMS Local Coverage Determinations (LCDs) and Articles
	• Added language to indicate:
	  ○ LCDs/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable; for specific LCDs/LCAs, refer to the table [in the *Centers for Medicare & Medicaid Services (CMS) Related Documents* section of the policy]
	  ○ For coverage guidelines for states/territories with no LCDs/LCAs, refer to the *Coverage Rationale* [section of the policy]
	  ○ FFR-ct should not be used for patients with unstable coronary syndromes, or in patients where urgent and timely workup and evaluation is critical
	• Added instruction to refer to the *Clinical Evidence* section [of the policy] for the definition of intermediate and high-risk chest pain, as defined by the *American College of Cardiology (ACC)/American Heart Association (AHA)*
	• Replaced language indicating:
	  ○ “[FFR-ct] should be performed in patients with *stable coronary symptoms*” with “[FFR-ct] should be performed in *clinically stable symptomatic* patients *with coronary artery disease*”
	  ○ “FDA-approved FFR-ct technology *may be considered* reasonable and necessary” with “FDA-approved FFR-ct technology *is* reasonable and necessary *when all of the [listed] criteria are met*”
	• Revised criteria for reasonable and necessary use of FDA-approved FFR-ct technology to reflect/include:
	  ○ FFR-ct technology is used in the management of patients with:
	  ▪ No prior coronary disease and acute (anginal) chest pain; FFR-ct is indicated in intermediate risk patients (troponin elevation) after a coronary artery stenosis finding on CCTA of 40-90% in a proximal or middle coronary artery; or
	  ▪ Known coronary artery disease and acute (anginal) chest pain; FFR-ct is indicated for intermediate risk patients (troponin elevation) after a coronary artery stenosis finding on CCTA of 40-90% in a proximal or middle coronary artery; or
	  ▪ No prior coronary disease and stable (anginal) chest pain; FFR-ct is indicated for intermediate risk patients after a coronary artery stenosis finding on CCTA of 40-90% in proximal or middle coronary artery; or
	  ▪ Known coronary disease and persistent stable (anginal) chest pain; FFR-ct is indicated after any 40-90% stenosis finding on CCTA
	  and
	  ○ FFR-ct technology is not in conjunction with stress testing (unless CCTA was not sufficient quality for FFR-ct and an alternative study is needed; **and**
	  ○ None of the following clinical circumstances are present:
	  ▪ Prior placement of prosthetic valves
	  ▪ Prior placement of grafts in coronary bypass surgery
	  ▪ Suspicion of acute coronary syndrome (where MI or unstable angina have not been ruled out)
	  ▪ Intracoronary metallic stent
	  ▪ Status post-heart transplantation
	  ▪ Recent MI (30 days or less)
	  ▪ Prior pacemaker or defibrillator lead placement
	  ▪ Newly diagnosed systolic heart failure, with no prior left heart catheterization

Date	Summary of Changes
	▪ Non-obstructing stenosis (< 50% of all major epicardial vessels) on CTA or catheterization in the past twelve months, in the absence of a new symptom complex ▪ If turnaround times may impact prompt clinical care decisions **Centers for Medicare & Medicaid Services (CMS) Related Documents** • Updated list of documents available in the *Medicare Coverage Database* to reflect the most current information • Added list of applicable *Medicare Administrative Contractors (MACs) with Corresponding States/Territories* **Supporting Information** • Archived previous policy version MPG372.09

Instructions for Use

The Medicare Advantage Policy documents are generally used to support UnitedHealthcare coverage decisions. It is expected providers retain or have access to appropriate documentation when requested to support coverage. This document may be used as a guide to help determine applicable:

- Medical necessity coverage guidelines; including documentation requirements, and/or
- Medicare coding or billing requirements.

Medicare Advantage Policies are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates. This Policy is provided for informational purposes and does not constitute medical advice. It is intended to serve only as a general reference and is not intended to address every aspect of a clinical situation. Physicians and patients should not rely on this information in making health care decisions. Physicians and patients must exercise their independent clinical discretion and judgment in determining care. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes this policy. For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.

Medicare Advantage Policies are developed as needed, are regularly reviewed, and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policies at any time by publishing a new version on this website. Medicare source materials used to develop these policies may include, but are not limited to, CMS statutes, regulations, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. The information presented in this Policy is believed to be accurate and current as of the date of publication. Where there is a conflict between this document and Medicare source materials, the Medicare source materials apply. Medicare Advantage Policies are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

UnitedHealthcare follows Medicare coverage guidelines found in statutes, regulations, NCDs, and LCDs to determine coverage. The clinical coverage criteria governing certain items or services referenced in this Medical Policy have not been fully established in applicable Medicare guidelines because there is an absence of any applicable Medicare statutes, regulations, NCDs, or LCDs setting forth coverage criteria and/or the applicable NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD. As a result, in these circumstances, UnitedHealthcare applies internal coverage criteria as referenced in this Medical Policy. The internal coverage criteria in this Medical Policy was developed through an evaluation of the current relevant clinical evidence in acceptable clinical literature and/or widely used treatment guidelines. UnitedHealthcare evaluated the evidence to determine whether it was of sufficient quality to support a finding that the items or services discussed in the policy might, under certain circumstances, be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

You are responsible for submission of accurate claims. Medicare Advantage Policies are intended to ensure that coverage decisions are made accurately. UnitedHealthcare Medicare Advantage Policies use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT®

or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

For members in UnitedHealthcare Medicare Advantage plans where a delegate manages utilization management and prior authorization requirements, the delegate's requirements need to be followed.