



PERSONNEL AND
READINESS

OFFICE OF THE UNDER SECRETARY OF DEFENSE
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AUG - 1 2019

The Honorable Adam Smith
Chairman
Committee on Armed Services
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

The enclosed report is in response to House Report 115-676, page 137, accompanying H.R. 5515, the National Defense Authorization Act for Fiscal Year 2019, which requests the Director, Defense Health Agency (DHA), provide a report to the House Committee on Armed Services that reviews and assesses the clinical efficacy of coronary computed tomography angiography (cCTA) and fractional flow reserved computed tomography (FFR_{CT}) as a new noninvasive technology for the diagnosis of coronary artery disease, and how they may be incorporated throughout the Military Health System.

At present, my Health Affairs experts have completed the initial review of scientific literature, met with industry representatives regarding this technology, and conducted a formal medical benefit determination (MBD) to determine if the use of cCTA and FFR_{CT}, with U.S. Food and Drug Administration-approved software, is safe and effective in the detection of coronary artery disease. The result of this study is detailed in the enclosed report. The MBD was recently completed, and is currently under review. Upon completion of the review, the Director, DHA, will decide on the benefit coverage of cCTA and FFR_{CT} by TRICARE.

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,

James N. Stewart
Assistant Secretary of Defense for Manpower
and Reserve Affairs, Performing the Duties
of the Under Secretary of Defense for
Personnel and Readiness

Enclosure:
As stated

cc:
The Honorable William M. "Mac" Thornberry
Ranking Member

Report to the Committee on Armed Services of the House of Representatives



Study of Coronary Computed Tomography Angiography and Fractional Flow Reserve Computed Tomography in the Military Health System

**Requested by: House Report 115–676, page 137, to accompany H.R.
5515, the National Defense Authorization Act for Fiscal Year 2019**

Office of the Secretary of Defense

The estimated cost of this report or study for the Department of Defense (DoD) is approximately \$4,900.00 in Fiscal Years 2018-2019. This includes \$0 in expenses and \$4,900.00 in DoD labor.

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1. PURPOSE

This report is in response to House Report 115–676, page 137, to accompany H.R. 5515, the National Defense Authorization Act for Fiscal Year 2019, which requests the Director, Defense Health Agency (DHA) provide a report that reviews and assesses the clinical efficacy of coronary Computed Tomography Angiography (cCTA) and Fractional Flow Reserve Computed Tomography (FFR_{CT}), and how they may be incorporated throughout the Military Health System.

This report describes the potential benefits and limitations of FFR_{CT} for use in patients with symptoms of coronary artery disease (CAD). It also describes the research to date on FFR_{CT} for use in patients with symptoms of CAD and the benefits and limitations of the technology. The DHA is preparing a Medical Benefit Determination (MBD) using TRICARE’s hierarchy of reliable evidence to assess the safety and efficacy of this technology.

2. BACKGROUND

Invasively measured Fractional Flow Reserve (FFR) evaluates the severity of ischemia caused by coronary artery obstructions and can predict when revascularization may be beneficial. In a perfectly normal, non-obstructed coronary artery, the FFR “value” is 1.0. A value less than 1.0 indicates that an obstruction is reducing blood flow through the coronary artery. The lower the FFR value, the more significantly the obstruction is restricting blood flow. Patients with obstructive CAD with $FFR \leq 0.80$ have been shown in multiple prospective randomized trials to benefit from revascularization (Percutaneous Coronary Intervention or Coronary Artery Bypass Graft). Patients with $FFR > 0.80$ have been shown to be best managed with medications and lifestyle modifications alone, with no benefit from invasive evaluation or revascularization. Invasive FFR is rarely used in the United States because of patient risk, inconvenience, and expense.⁵

Stress testing, including treadmill electrocardiogram, stress echocardiography, and nuclear myocardial perfusion imaging are the traditional noninvasive tests used to evaluate patients with CAD. However, these tests have significant limitations; stress tests have known false positives and negatives along with not detecting the early state of disease. A noninvasive pathway that correctly identifies patients with early stage CAD and determines the best treatment strategy is essential to optimizing outcomes and efficiency in value-based healthcare systems.

FFR_{CT} analysis is a non-invasive tool designed to aid clinicians in determining the functional impact of CAD in patients with chest pain. FFR_{CT} is calculated using image data from a previously acquired cCTA. FFR_{CT} may allow evaluation of each coronary stenosis for its flow-limiting significance by adding a physiological dimension to the anatomical information provided by the cCTA. This added information may provide clinicians meaningful insight to determine the right management option for patients with CAD. The manufacturer of FFR_{CT} claims that use of FFR_{CT} allows for a safer, more efficient diagnostic pathway, reducing dependence on invasive procedures, such as Invasive Coronary Angiography (ICA). The ideal diagnostic pathway manages the spectrum of patients with suspected CAD by: 1) ruling out

patients who do not have disease; 2) identifying those with early stage disease who require medical management and lifestyle modification; and 3) directing those who are most likely to benefit from invasive assessment and/or revascularization to the catheterization lab.

The development, validation, and adoption of FFR_{CT} analysis has been extensive and established internationally in Canada, Japan, and the United Kingdom. The American College of Cardiology includes the use for FFR_{CT} in its guideline for the diagnosis of CAD.

3. POTENTIAL BENEFITS

When using invasive FFR as the reference standard, FFR_{CT} has the highest accuracy compared to other diagnostic tests, including cCTA and ICA. Use of FFR_{CT} allows physicians to safely choose the most appropriate treatment for their patients. Use of FFR_{CT} information has been demonstrated to change patient management in 63 percent of cases and has allowed safe avoidance of ICA in > 60 percent cases where ICA was initially intended. Clinical pathways that utilize FFR_{CT} reduce healthcare costs.⁵

FFR_{CT} shows higher diagnostic performance than standard cCTA, Single Photon Emission Computed Tomography, and Positron Emission Tomography (PET) scan for vessel-specific ischemia, provided cCTA images were evaluable by FFR_{CT}, whereas PET had a favorable performance in per-patient and intention-to-diagnose analysis. FFR_{CT} holds clinical potential to provide anatomic and hemodynamic significance of coronary lesions.¹ FFR_{CT} is associated with less negative ICA, predicted revascularization, and identified subjects at lower risk of adverse events through 90 days.² In patients with intermediate-range coronary stenosis, FFR_{CT} is effective in differentiating patients who do not require further diagnostic testing or intervention (FFR_{CT} > 0.80) from higher-risk patients (FFR_{CT} ≤ 0.80) in whom further testing with ICA and possibly intervention may be needed.³ Frontline cCTA with selective FFR_{CT} testing in stable patients with typical angina pectoris in real-world practice is associated with a high rate of safe cancellation of planned ICAs.⁴

¹ Driessen RS, et al. “Comparison of Coronary Computed Tomography Angiography, Fractional Flow Reserve, and Perfusion Imaging for Ischemia Diagnosis.” *J AM Coll Cardiol*, 73(2) (22 Jan. 2019). 161-173.

² Fairbairn TA, et al. “Real-World Clinical Utility and Impact on Clinical Decision-Making of Coronary Computed Tomography Angiography-Derived Fractional Flow Reserve: Lessons from the ADVANCE Registry.” *Eur Heart J*, 39(41) (1 Nov. 2018). 3701-3711.

³ Nørgaard BL, et al. “Coronary CT Angiographic and Flow Reserve-Guided Management of Patients with Stable Ischemic Heart Disease.” *J AM Coll Cardiol*, 72(18) (30 Oct. 2018). 2123-2134.

⁴ Jensen JM, et al. “Computed tomography derived fractional flow reserve testing in stable patients with typical angina pectoris: influence on downstream rate of invasive coronary angiography.” *Eur Heart J Cardiovasc Imaging*, 19(4) (1 Apr. 2018). 405-414.

⁵ HeartFlow, Inc., “HeartFlow® FFR_{CT} Analysis Clinical Dossier: Fractional Flow Reserve from Coronary Computed Tomography Angiography (cCTA).” (2018).

4. LIMITATIONS

Only the HeartFlow® brand of FFR_{CT} software has been cleared by the U.S. Food and Drug Administration at this time. Imaging analyses require transmitting data to a central location for analysis, taking 1-to-3 days to complete. Other prototype software is workstation-based with onsite analyses. FFR_{CT} requires at least 64-slice cCTA and cannot be calculated when images lack sufficient quality (11 percent to 13 percent in recent studies), including obese individuals (i.e., body mass index > 35 kg/m²).

5. CONCLUSION

An MBD was recently completed using TRICARE’s hierarchy of reliable evidence to assess the safety and efficacy of this technology. The MBD is currently under review. Once complete, the Director, DHA will decide on coverage by TRICARE. If approved, it will be a covered TRICARE benefit available to all beneficiaries. The DHA will issue a change order to the managed care support contractors for implementation in the TRICARE network, and policy guidance to the military medical treatment facilities for implementation in those applicable locations within the direct care system. The DHA Chief Medical Officer will address educating our provider/clinical communities to inform them of these changes.

6. ACRONYMS

CAD	Coronary Artery Disease
cCTA	Coronary Computed Tomography Angiography
DHA	Defense Health Agency
FFR	Fractional Flow Reserve
FFR _{CT}	Fractional Flow Reserve Computed Tomography
ICA	Invasive Coronary Angiography
MBD	Medical Benefit Determination
PET	Positron Emission Tomography