

## Fractional Flow Reserve Computed Tomography (FFR<sub>CT</sub>) Is Not an Image Processing Service

Under the 2018 Medicare hospital outpatient prospective payment system proposed rule, FFR<sub>CT</sub> would be packaged with coronary computed tomography angiography (CCTA) for payment. As set forth below, as well as in timely submitted comments, this proposed policy is based on a misreading of the packaging regulation, and would subject approximately **a quarter of a million beneficiaries annually** to the risk of an unnecessary invasive coronary angiogram (ICA) at an avoidable cost to Medicare of almost **a billion dollars annually**.

FFR<sub>CT</sub> is an FDA-cleared device developed by HeartFlow that is used in a **non-invasive** diagnostic procedure that helps a doctor determine whether invasive treatment for coronary artery disease (CAD) is appropriate. More specifically, FFR<sub>CT</sub> assesses fractional flow reserve (FFR), i.e., the drop in pressure across a narrowing in a coronary artery, which helps a doctor determine whether the narrowing is unduly blocking the delivery of oxygen to the heart. The only other method for assessing FFR is an ICA, an **invasive** diagnostic procedure that, **over half the time**, shows that invasive treatment for CAD is not appropriate. Every year, approximately 413,000 elective ICAs are performed on the Medicare population. Thus, every year, approximately 252,000 beneficiaries are unnecessarily subjected to the risk of heart attack, stroke, and death attendant to this invasive procedure. Avoiding these unnecessary ICAs would yield approximately \$873 million in annual savings to Medicare (in addition to overall savings to beneficiaries in reduced cost-sharing).

FFR<sub>CT</sub> is widely accessible to those with commercial coverage. The proposed policy would block access to FFR<sub>CT</sub> by Medicare beneficiaries. As set forth below, as well as in timely submitted comments, under CMS's own guidance, FFR<sub>CT</sub> is not an image processing service and thus should not be packaged with CCTA or any other service, and should instead be paid for separately.

### I. Background

When a patient presents with unexplained stable chest pain, a doctor typically starts by ordering non-invasive stress testing to try to determine whether the patient has CAD. Stress testing, however, provides a limited or imprecise assessment such that further evaluation is often required. Often, the next step is an ICA, in which a catheter is inserted into the body and directed through the blood vessels into the heart. During this invasive procedure, FFR is typically assessed. FFR is the most accurate and reliable measure for determining the functional significance of a coronary lesion (i.e., whether it is unduly blocking the delivery of oxygen to the heart) and therefore determining appropriate care. However, over half of patients who undergo an ICA are found not to have obstructive CAD and therefore not to require invasive treatment, which means that, in retrospect, the invasive procedure was not needed, though the doctor could not have known that at the time the ICA was ordered.

FFR<sub>CT</sub> assesses FFR non-invasively. FFR<sub>CT</sub> is performed after a CCTA image has been obtained and interpreted by a doctor. Computerized physiological algorithms are applied to a model of the coronary arteries, derived in part from the CCTA image, and these algorithms result in FFR values at each point in the coronary anatomy. These FFR values quantify reductions in coronary blood flow, helping a doctor to determine whether revascularization (e.g., bypass surgery), as opposed to treatment through medication, is required. FFR<sub>CT</sub> yields the same type of diagnostic information as an ICA (and, indeed, does so more accurately), without the risk and cost of an invasive procedure.

In communications with HeartFlow, CMS has stated that separate payment for FFR<sub>CT</sub> would be inappropriate because, “[a]ccording to the Code of Federal Regulations in section 419.2(b)(13), all image guidance, processing, supervision, and interpretation services are considered to be packaged into the related Computed Tomography (CT).” Under that regulation, CMS packages

payment for “[i]mage guidance, processing, supervision, and interpretation services” with payment for “the related procedures or services.” CMS has clarified that it views FFR<sub>CT</sub> as a type of image processing service.

## II. The FFR<sub>CT</sub> Service Is Not an Image Processing Service

Under CMS’s own guidance, the FFR<sub>CT</sub> service is not an image processing service and thus should not be packaged with CCTA or any other service, and should instead be paid for separately.

### A. *The FFR<sub>CT</sub> service does not fit CMS’s **definition** of image processing services*

CMS has defined image processing services as “supportive dependent services to process and integrate diagnostic test data in the development of images, performed concurrently or after the independent service is complete.”<sup>1</sup> Even a cursory parsing of this carefully described definition reveals that the FFR<sub>CT</sub> service does not satisfy essential prongs of the definition.

*First*, the FFR<sub>CT</sub> service does not process or integrate diagnostic test data “in the development of images.” The diagnostic output of the FFR<sub>CT</sub> service is not anatomic images. Rather, the FFR<sub>CT</sub> service yields functional values (i.e., FFR), which reflect the drop in pressure across a narrowing in a coronary artery and thereby help a doctor determine whether the narrowing is unduly blocking the delivery of oxygen to the heart. This is quantitative diagnostic information about the function of the coronary arteries that is impossible to derive from examining anatomic images of the arteries. In short, given that the diagnostic output of the FFR<sub>CT</sub> service is not anatomic images, it is simply not a service that “develop[s] . . . images.”<sup>2</sup>

*Second*, CMS appears to be focused on whether the FFR<sub>CT</sub> service is a “dependent” service relative to CCTA. In doing so, CMS is overlooking the equally determinative inquiry of whether the FFR<sub>CT</sub> service is also a “supportive” service relative to CCTA. The FFR<sub>CT</sub> service in no way supports the diagnostic output of CCTA – an anatomic image. The FFR<sub>CT</sub> service does not enhance the ability of the doctor to derive diagnostic information from examining that anatomic image. This is necessarily so because the diagnostic output of the FFR<sub>CT</sub> service is functional values that are impossible to derive from examining anatomic images, and that are supplied, not as anatomic information, but rather as numerical values ranging from 0.0 to 1.0. As further evidence of the absence of dependency, the clinical practice appropriateness guidelines recently published by the American College of Cardiology indicate that FFR values are key determinants of appropriate care, but do not identify CCTA findings as determinants of appropriateness.

### B. *The FFR<sub>CT</sub> service is unlike CMS’s **examples** of image processing services*

In the course of defining image processing services, CMS identified specific services as image processing services by identifying “processing” codes in the Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) code sets and otherwise specifying the codes that it considers to be image processing services. CMS identified eleven such codes, including CPT code 93325 (Doppler echocardiography color flow velocity mapping (List

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<sup>1</sup> 72 Fed. Reg. 66,580, 66,625 (Nov. 27, 2007).

<sup>2</sup> Although, to facilitate ready comprehension of the functional values by the doctor, the FFR<sub>CT</sub> service generates a virtual 3D model of a patient’s coronary arteries, the visual itself is not the diagnostic output. Nor is the visual necessary to communicate the diagnostic output. Indeed, the diagnostic output could be communicated instead through a table. It makes no sense to make CMS’s packaging policy turn on whether functional values are communicated to a doctor through a visual or a table. Rather, it makes sense to make CMS’s packaging policy turn on whether images are the diagnostic output.

separately in addition to codes for echocardiography)).<sup>3</sup> Tellingly, all of CMS's examples of image processing services are fundamentally distinguishable from and materially dissimilar to the FFR<sub>CT</sub> service.

*First*, the new CPT codes for the FFR<sub>CT</sub> service are not specified as "processing" codes. For example, the descriptor for new CPT code 0503T makes clear that the FFR<sub>CT</sub> service yields FFR values and makes no mention of processing.<sup>4</sup>

*Second*, CMS's examples uniformly either enhance visualization or facilitate interpretation of an image.<sup>5</sup> For example, with respect to Doppler echocardiography color flow velocity mapping (CPT code 93325), the addition of color simply changes the display of the images that depict the anatomical space. In contrast, the FFR<sub>CT</sub> service does not enhance visualization or facilitate interpretation with respect to CCTA images. Rather, the FFR<sub>CT</sub> service produces a unique data set, entirely distinct from the anatomical images produced by CCTA, for diagnostic purposes.

C. *The FFR<sub>CT</sub> service does not fit CMS's **rationale** for packaging image processing services*

CMS has articulated its rationale for packaging image processing services with related services as follows: "We are particularly concerned with any continuance of current OPPS payment policies that could encourage certain inefficient and more costly service patterns . . . . [P]ackaging encourages hospitals to establish protocols that ensure that services are furnished only when they are medically necessary and to carefully scrutinize the services ordered by practitioners to minimize unnecessary use of hospital resources."<sup>6</sup> Accordingly, CMS's packaging policy represents the laudable public policy objective of encouraging efficient use of hospital resources.

Applying CMS's packaging policy to the FFR<sub>CT</sub> service, however, would necessarily yield the opposite result. A doctor who concludes that FFR must be assessed to determine how best to manage a patient with potential obstructive CAD has only two potential options. Either the doctor must order an ICA, at higher risk and higher cost, or the doctor must order the non-invasive FFR<sub>CT</sub> service, at lower risk and lower cost. Because the application of CMS's packaging policy to the FFR<sub>CT</sub> service would effectively foreclose the availability of that service to Medicare patients, it would necessarily drive the ordering of the higher risk and higher cost procedure, in direct contravention of CMS's stated public policy objective.

D. *The FFR<sub>CT</sub> service does not fit CMS's **cost analysis** of image processing services*

In setting forth its policy on packaging image processing services with related services, CMS emphasized that, "[n]otably, the majority of image processing services that we proposed to package have modest median costs in relationship to the cost of the independent service that they typically

<sup>3</sup> *Id.* at 66,625 (explaining how CMS identified image processing services), 66,659-64 (list of codes including those considered to be image processing services).

<sup>4</sup> The descriptor for 0503T is: "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, generation of estimated FFR model."

<sup>5</sup> CPT codes 76125, 76350, 76376, 76377, 93325, and 93613 enhance visualization of data that can be derived from examining an image. The other five of the eleven image processing codes that CMS identified as image processing services (CPT codes 95957, 0159T, 0174T, and 0175T, and HCPCS code G0288) facilitate interpretation of data that can be derived from examining an image.

<sup>6</sup> 72 Fed. Reg. at 66,625; see also *id.* at 66,626 ("Packaging payment for supportive services that utilize data that were collected during the preceding independent services encourages the most efficient use of hospital resources.").

accompany.”<sup>7</sup> Here, too, the application of CMS’s packaging policy to the FFR<sub>CT</sub> service would yield a result at odds with CMS’s stated policy. The hospital cost associated with the FFR<sub>CT</sub> service (approximately \$1500) is patently not modest relative to that associated with CCTA (\$237.58). Given that, it is hard to conceive of hospitals performing the FFR<sub>CT</sub> service such that the cost of the service can be reflected in the geometric mean cost of any other service.

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For all of these reasons, the FFR<sub>CT</sub> service is not an image processing service and thus should not be packaged with CCTA or any other service, and instead should be paid for separately. Otherwise, approximately **a quarter of a million beneficiaries annually** would continue to be subjected to the risk of an unnecessary invasive procedure at an avoidable cost to Medicare of almost **a billion dollars annually**.

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<sup>7</sup> *Id.* at 66,626.