

Prepared Statement of Dr. Jeffery Marshall for the Society for Cardiovascular Angiography and Interventions for the National Government Services, Inc. Open Public Meeting on Local Coverage Decisions – June 24, 2021

My name is Jeffery Marshall and I have no conflicts to declare.

I am here representing the Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 4,500 members representing interventional cardiologists. SCAI promotes excellence in interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

SCAI believes that there is strong scientific evidence for the diagnostic performance of FFRct as a noninvasive screening tool. We are pleased that this proposed local coverage decision (LCD) does not place restrictions on the coverage of invasive FFR procedures when non-invasive FFRct is performed. In many, but not all situations the greater precision of invasive FFR can be used to avoid unnecessary and costly interventions.

Generally speaking, interventionalists who are performing invasive FFRs are seeking data that may clarify the need for interventional procedures. There is no financial incentive to perform unnecessary invasive FFR procedures.

There are significant differences in the accuracy of these two diagnostic tests. The ReASSESS Study shows in tables 3 and 4 that many cases that are FFRct positive end up being FFR negative and do not need intervention. FFRct is a very sensitive test -- so by default it will have more false positives. The reverse is true as well.

As demonstrated in two attached review articles, FFR is demonstrated to be the most reliable way (the Gold Standard) for accessing complex coronary disease during invasive angiography and the best way to accurately access serial lesions and accompanied by clinical outcomes data.

I am not here to review the details of the restrictions on coverage of FFRct that are contained in the proposed LCD. We defer to the experts on non-invasive cardiovascular imaging that may be discussed.

In summary, we support NGS's proposal to codify coverage of FFRct and are pleased that the proposal does not restrict the coverage of invasive FFR procedures. If NGS identifies individuals who are routinely billing for both procedures, it should investigate. FFRct is complementary to invasive physiology, not a complete substitution.

We thank Drs. Joaquin Cigarroa and Deepali Nivas Tukaye for their efforts in developing this response. If we can be of any assistance as National Government Services continues to

consider and review this proposed local coverage decision, please do not hesitate to contact Wayne Powell at 703.772.7910 or [wpowell@scai.org](mailto:wpowell@scai.org).