November 18, 2020

Meredith Loveless, MD
CGS Medicare
Attn: Medical Review
26 Century Blvd., Ste ST610
Nashville, TN 37214-3685
cmd.inquiry@cgadmin.com

Re: Proposed Local Coverage Determination (LCD): Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease (DL38771)

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 CTffr as a noninvasive screening tool. We object to the proposed restriction on coverage of both FFRct and invasive FFR procedures. Before the “Summary of the Evidence” section in this proposed LCD it states that:

“Medicare will not pay for both CT-derived Fractional Flow Reserve data, and Fractional Flow Reserve data obtained by pressure wire at catheterization in the context of the same clinical evaluation, or onset of a new symptom complex. Both concurrent studies may be covered with submitted documentation of discordant clinical data, or the onset of a new symptom complex.”

We fail to see the reason to require the submission of documentation for both of these procedures in 100% of the instances when both are performed. Does CGS have any evidence that a significant number of inappropriate invasive FFR procedures are being performed after FFRct procedures (or vice versa)? 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.
Operationally, we are also concerned that there is no time limit on this restriction. A provider planning to perform an invasive FFR procedure may not have access to FFRct results done weeks or even months earlier. Additionally, over time symptoms change and one test may have been done weeks or even months before the next procedure. The biology of coronary plaques and their impact on coronary blood flow can change, necessitating re-evaluation by invasive FFR at the time of revascularization.

Another operational complexity to this coverage policy is identifying which procedure will be non-covered and how that determination is made. These procedures are commonly done by different providers and they may not be part of the same medical group. Will all the burden be placed on the provider who gets his claim in last even if the clinical and pathophysiologic scenario actually indicates that invasive FFR is a more relevant test for optimal patient treatment and outcome?

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 CTFRR positive end up being FFR negative and do not need intervention. CTFr is a very sensitive test; so by default will have more false positives. The reverse is true as well.

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

In summary, we support CGS’s proposal to codify coverage of CTFr but find restrictions on the coverage of invasive FFR to be unnecessary and possibly deleterious to patient care. If CGS identifies individuals who are routinely billing for both procedures, it should investigate. A blanket requirement that both procedures provide documentation in support of these procedures is both unnecessary and unworkable. CTFr is complementary to invasive physiology, not a substitution.

We thank Drs. Joaquin Cigarroa, Jeff Marshall and Deepali Nivas Tukaye for their efforts in developing this response. If we can be of any assistance as CGS continues to consider and review this policy, please do not hesitate to contact Wayne Powell at 703.772.7910 or wpowell@scai.org.

Sincerely

Cindy L. Grines, MD, MScAI
President

Lyndon Box, MD, FSCAI
Chair of Government Relations Committee