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CGS J15 Open Draft LCD Meeting

Meeting Date and Time:	February 22, 2022 at 3:00 pm CST
Facilitator:	Dr. Meredith Loveless
Location:	Teleconference

Dr. Loveless briefly explained the single policy to be reviewed during the open meeting. Non-Invasive Fractional Flow Reserve (FFR) for Stable Ischemic Heart Disease Revision (L38771) is an existing policy that was revised. This policy was revised based on the 2022 American Heart Association and other organizations for the Evaluation and Diagnosis of Chest Pain Executive Summary. The committee provided a moderate strength recommendation does not expand the role for FFRct in specific clinical settings as an alternative to stress test.

A few of the changes to the policy include:

FDA-approved FFRct technology may be considered reasonable and necessary in the management of patients with:

- Intermediate risk* patients with acute chest pain and no known coronary artery disease, with coronary artery stenosis of 40-90% in proximal or middle coronary artery on CCTA
- Intermediate risk with acute chest pain and known coronary artery stenosis of 40-90% in a proximal or middle segment on CCTA
- Stable nonobstructive coronary artery disease with persistent symptoms requiring further test, and 40-90% stenosis on CCTA
- Not in conjunction with stress testing (unless FFRCT was not high quality and alternative study needed)
- Intermediate and high-risk is as defined in the 2021 Guideline for the Evaluation and Diagnosis of Chest Pain

The limitation section was also updated including some changes to the limitation.

- This service should not be performed in patients with stable coronary symptoms.
- It should not be performed until after the base study (CCTA) has been completed and interpreted.
- It should not for use in high-risk patients or when myocardial infarction has not been excluded.
- If higher grade stenoses are present, this study is not medical necessary, as the patient should proceed to catheterization.
- Love-grade stenoses do not require additional confirmatory data.

Changes made to the policy:

1. Expands stenosis range 40-90% and alters vessel specific limitation to align with guidelines
2. Removes the limitation on BMI based on new data
3. Defines intermediate and high risk by 2021 guidelines
4. Allows FFRct as an alternative, but not in conjunction, to stress test

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Comments can be submitted in writing until March 27, 2022

- Complete the PDF form and submit the supporting literature
- The comment submission form is available on the CGS website under Medical Polices

Presenter 1, Dr. Rabbat

FFR is the gold standard used to invasively identify appropriate vessels for stent placement or percutaneous intervention. FFR has been shown to improve our patients' outcomes and reduce health care costs. FFR RCT has proven itself as a reliable non-invasive test and can be derived from a static CT dataset. The combination of coronary CTA and FFR CT provides a non-invasive test that offers both anatomic and functional data and has been validated through a number of accuracy studies and multiple large clinical trials.

The American Heart Association and American College of Cardiology guideline for the Evaluation and Diagnosis Chest Pain Statement recently elevated coronary CTA has a class one-a non-invasive test and recognized FFR CT as a class level B evidence.

- the synopsis ranges included in these trials and in the recent American Heart Association and American College of Cardiology Guideline statement is from 40 to 90% stenosis, not 40 to 70% stenosis.

In over 400 patients:

- FFR CT was feasible, was conclusive result in greater than 90% of individuals
- a diagnostic strategy of coronary CTA plus FFR CT was associated with less invasive procedures in patients with coronary artery disease
- Among those who deferred invasive coronary angiogram, there were no major adverse cardiac events demonstrating its safety
- Those who underwent invasive coronary angiography were revascularized, resulting in higher diagnostic ICA yield, and more efficient utilization of the catheterization lab resources.

Stenosis ranges of 40 to 90% is supported, and this expansion is in line with the updated American College of Cardiology and American Heart Association guidelines.

For the majority of cases prosthetic thousand prior permanent pacemakers and defibrillators leads do not alter image quality of the coronary arteries. Thus, the Society of Cardiovascular CT is requesting removal of the following exclusions:

- Prior placement of prosthetics values
- Prior pacemaker or defibrillator lead placement.

Recommendation

Exclusions

- Heartflow reviews all of the images and if the CTA image is not adequate to create the FFR CT, the images returned and there's no charge.
- The Society of Cardiovascular CT recommends only excluding anatomy that would affect human dynamic accuracy.
- NSREMI/STEMI/UA less than 30 days
- New systolic heart failure with no prior invasive catheterization.

Inclusions

- Support expanding stenosis ranges with coronary stenosis of uncertain functional significance to 40 to 90%.

Presenter 2, Dr. Raible

A tremendous improvement in our ability to identify significance stenosis causing ischemia and avoid going cardiac invasive angiography with intermediate stenosis appear to be slightly less than 50%.

Previous data showed that invasive FFR had a significant number of patients that had lesions in the 70 to 90% range had normal FFR value greater than eight.

According to the Advance Registry, 70 to 90% stenosis range, 83% of those patients CTA is read as 70 to 90%.

Recommendation to increase range for CT FFR from 40 to 90% as this follows with chest pain guidelines that will decrease angiographic false positives. It is also useful in patients that have very significant calcification, which makes the CTA harder to read by itself.

Presenter 3, Dr. Rogers

Guidelines are broken down into four sections for patients who have either stable or acute chest pain then those who had suspected coronary artery disease, or those who have known coronary artery disease.

Recommendation of Indications

- Suggest revision of verbiage to include stable testing as well, being consistent with the guidelines as published. Combine the scenarios into one indication
  - » Proposed revised wording:
- Intermediate risk with stable or acute chest pain with known coronary artery stenosis from 40-90% on CCTA
- Not in conjunction with stress testing (unless FFR CT was not high quality and alternative study needed)
  - » Suggested wording:
- Not in conjunction with stress testing (unless CCTA was not of adequate quality for FFR CT and alternative study needed
- Coverage Guidance support paragraph
  - » Suggest revision from stable to stable or acute
  - » If higher grade stenoses (i.e., greater than 90%) are present, and no other stenoses 40%-90% are identified, this study is not medically necessary
  - » Revision of less than 30% to less than 40% for consistency
  - » Removal of the last statement in the support paragraph. High plaque volume does not necessarily impair CCTA quality

Image Quality

- All of the major vessels are reviewed and graded for image quality and there's a quantitative method for scoring image quality
  - » If the image quality is not sufficient, Heartflow does not complete an analysis or charge for the cases that had failed to meet the image quality threshold

Restrictions

- Intracoronary metallic stent
  - » Suggest revision to "Prior coronary stents in the following cases
- Metallic stent present in Left main coronary artery
- Left Main coronary artery stenosis greater than 30% and one or more metallic stents in the left system
- Two or more systems with metallic stents present"

Closing

- Comments with supporting literature are greatly appreciated
- Currently seeking anyone who is interested in serving as an exhibitor or sponsor for an upcoming Passport to Medicare event that will be held in Columbus, OH on April 6 and April 7, 2022
  - » Visit Part A or Part B Education and Events Section to sign up
- Multi-Jurisdictional Contract Advisory Committee will be held on March 10, 2022

