

AMERICAN
COLLEGE of
CARDIOLOGY

Juan L. Schaening, MD
First Coast Service Options, Inc.
P.O. Box 2078
Jacksonville, FL 32231-0048

July 21, 2017

Dear Dr. Schaening,

I write regarding First Coast Service Options' FCSO LCD L36209 Cardiology- non-emergent outpatient testing: Exercise stress test, stress echo, MPI SPECT, and Cardiac PET. ASNC agrees that PET is medically necessary in patients who meet the criterion outlined in First Coast's policy. However, we are concerned that access to PET may be unnecessarily limited given that there are patients who need PET for clinical reasons not fully captured by the indications in First Coast's policy. ASNC respectfully requests that First Coast Service Options reconsider its policy in light of recommendations in the ASNC/ SNMMI Position Statement and given Cahaba's recent retirement of a similar local coverage determination.

The First Coast Service Options (FCSO) LCD (L36209 effective date 10/2015) adds to the CMS NCD an additional prerequisite to approve cardiac PET for MPI:

PET is medically necessary, provided the scans meet either one of the following 2 criteria:

- a. PET is used in place of, but not in addition to, a SPECT, *in persons with conditions that may cause attenuation problems with SPECT, e.g., obesity/BMI greater than 35, large breasts, breast implants, left mastectomy, chest wall deformity, pleural or pericardial effusion; OR*
- b. The PET scan (whether at rest alone or rest with stress) is used following a SPECT scan that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

We ask that FCSO reconsider certain parts of its local coverage determination (LCD) for cardiac Positron Emission Tomographic (PET) myocardial perfusion imaging (MPI) and make the following changes in its LCD.

Suggested Changes in LCD:

In accordance with the recently released ASNC/SNMMI JOINT POSITION STATEMENT, the proposed changes to the Cahaba LCD reflect these recommendations and are consistent with the CMS implantation of quality initiatives to assure quality care. The recommendations are detailed in the position statement as follows:

1. Rest-stress myocardial perfusion PET is a first line preferred test for patients with known or suspected CAD who meet appropriate criteria for a stress imaging test and are unable to complete a diagnostic level exercise stress imaging study. There are no clinical scenarios where PET should not be considered a preferred test for patients who meet appropriate criteria for a stress imaging test and who required pharmacologic stress.
2. Rest-stress myocardial perfusion PET is also recommended for patients with suspected active CAD who meet appropriate criteria for stress imaging and who also meet one or more of the following criteria:
 - a. Prior stress imaging study was poor quality, equivocal or inconclusive.
 - b. Body characteristics that commonly affect image quality. Some examples include large breasts, breast implants, obesity (i.e. BMI > 30), protuberant abdomen, chest wall deformities, pleural effusions and inability for proper body positioning.
 - c. High risk patients in whom diagnostic errors carry even greater clinical implications (i.e. chronic kidney disease, diabetes mellitus, known or suspected potentially high risk CAD [left main disease, multivessel, proximal LAD disease, CABG], suspected transplant coronary vasculopathy, left ventricular dysfunction and patients for whom revascularization carries increased morbidity and mortality risk.
 - d. Young patients with established CAD who are anticipated to need repeated exposures to radiation-associated cardiac imaging procedures, in order to minimize accumulated life-time exposure.
 - e. Patients in whom myocardial blood flow quantification is identified by clinicians to be a needed adjunct to the image findings, to better identify or exclude multivessel CAD, for improved risk stratification, and when assessment of microcirculatory function is needed for clinical decision making.

We agree that the two indications cited in the LCD are valuable reasons to perform PET, but our members collective experience with PET imaging in Florida indicates that these criteria may limit access to PET in ways that deny this benefit to patients who would benefit from PET. In fact, our members helped the Health Care Financing Administration (HCFA, the predecessor of CMS) write these criteria and others that were in the initial G-codes used to support the National Coverage Determination (NCD) for cardiac PET in 1994-5, including the selected parts of that document that were extracted to become the current FCSO LCD. We believe the intent of then HCFA now the Centers for Medicare and Medicaid Services (CMS) was not to restrict access to PET only to patients who fit into these criteria.

In addition, on November 1, 2016 Cahaba Government Benefit Administrators, LLC retired LCD ID L34281 Radiology: PET for Myocardial Perfusion Imaging (MPI) and Myocardial Viability (MV). The language in Cahaba's LCD closely tracks that of the First Coast Services Options.

ASNC would welcome the opportunity to discuss concerns with our leadership and staff via conference call or at an in-person meeting. Should you have additional questions or concerns or wish to schedule a meeting please contact Georgia Lawrence, Senior Specialist, Regulatory Affairs at glawrence@asnc.org.

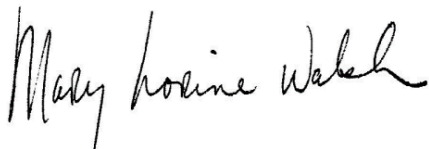
Sincerely,



Raymond Russell, MD
President,
American Society of Nuclear Cardiology



Bennett S. Greenspan, MD, MS, FACNM, FACR,
President,
Society of Nuclear Medicine and Molecular Imaging



Mary Norine Walsh, MD, FACC
President, American College of Cardiology