First Coast Service Options
Attn: Juan Schaening, MD
532 Riverside Avenue
Jacksonville, FL 32202

December 11, 2020

Re: DRAFT Local Coverage Article: Billing and Coding: Cardiology Non-emergent Outpatient Stress Testing (L38396)

Dear Dr. Schaening,

On behalf of the American Society of Nuclear Cardiology, I write regarding the recently posted DRAFT Local Coverage Determination for Cardiology Non-emergent Outpatient Stress Testing (L38396). ASNC is supportive of the draft policy overall but offers suggestions for improving the clarity of specific aspects of the policy prior to its implementation.

As the policy demonstrates, several non-invasive test options exist for the evaluation of coronary artery disease, ranging from non-imaging stress testing to exercise or pharmacologic stress testing with imaging including stress echocardiography, single photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), positron emission tomography (PET) MPI, and cardiac magnetic resonance imaging (CMR).

At this point, I want to emphasize that all stress imaging studies work toward a goal of diagnosis and risk stratification of patients with known or suspected coronary artery disease, but in clinical practice the choice of testing is specific to each patient based on medical decision making and a dialogue between the physician and patient. In this regard, it is important that the ability of a physician to choose the appropriate test be preserved.

Medical Reasonableness and Necessity for Stress Testing with Cardiac Imaging

Dual Diagnosis

The draft LCD states stress testing with cardiac imaging will be considered medically reasonable and necessary for patients experiencing new, recurrent, or worsening cardiac symptoms, including otherwise unexplained angina equivalent symptoms, AND any one of the 12 criteria listed in the LCD. While the LCD appears to be clear in this regard, ASNC suggests this

requirement should be better highlighted to avoid claims denials for stress testing with cardiac imaging that would otherwise be appropriate except for a diagnosis coding error.

Cardiac Sarcoidosis

The LCD cites Ramirez and Sgard articles to support the requirement that F-18 FDG PET is indicated if the patient is unable to undergo MRI. The LCD reasons that MRI can be safely performed on patients with intracardiac devices and advanced renal disease and is appropriate to predict and assess response under therapy. MRI is not preferred in patients with implanted cardiac devices and advanced renal disease.[12] FDG PET should be a first line test in each of those cases. While MRI can be done in most patients with modern devices, it creates substantial artifacts that preclude adequate assessment of the myocardium. In patients with renal disease, the traditional gadolinium-based contrast agent used is associated with nephrogenic systemic fibrosis.[3] There is a newer agent with lower risk but it is unclear what the availability throughout the country is and it still carries the FDA black box warning.[4]

An abnormal MRI is an appropriate reason to obtain an FDG PET to see if active inflammation is present as an MRI is only able to detect scar tissue. An FDG PET is often needed without an MRI while sarcoidosis is being treated to see if the inflammation is improving.[5] ***ASNC believes that FDG PET should be considered a first-line test for the assessment of inflammation in Cardiac Sarcoidosis or when MRI is contraindicated or unavailable. FDG-PET is required in cases of known or newly diagnosed cardiac sarcoidosis for anti-inflammatory therapy, as regional wall motion abnormality or late gadolinium enhancement on MRI do not distinguish inflammation from fibrosis.[6]***

Atrial Fibrillation

According to the *Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease*, MPI may be appropriate in initial evaluation of a symptomatic patient with atrial fibrillation/ flutter (not for purposes of precardioversion evaluation).[7] In cases where the patient has atrial fibrillation doctors often need

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[1] Indik et al., *2017 HRS Expert Consensus Statement on Magnetic Resonance Imaging and Radiation Exposure in Patients with Cardiovascular Implantable Electronic Devices*, Heart Rhythm, Vol 14, No 7, July 2017.
[2] Weinreb, et al. *Use of Intravenous Gadolinium-based Contrast Media in Patients with Kidney Disease: Consensus Statements from the American College of Radiology and the National Kidney Foundation*, Radiology 2020; 00:1-8
[3] FDA DRUG SAFETY COMMUNICATION:NEW WARNINGS FOR GADOLINIUM-BASED CONTRAST AGENTS IN PATIENTS WITH KIDNEY DYSFUNCTION (2010) *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-new-warnings-using-gadolinium-based-contrast-agents-patients-kidney
[4] HIGHLIGHTS OF PRESCRIBING INFORMATION: DOTAREM (2013). *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/204781s008lbl.pdf
[5] Blankstein R, Osborne M, Naya M, Waller A, Kim CK, Murthy V, et al. Cardiac positron emission tomography enhances prognostic assessments of patients with suspected cardiac sarcoidosis. J Am Coll Cardiol 2014;63:329–36.
[6] Birnie et al. *HRS Expert Consensus Statement on the Diagnosis and Management of Arrythmias Associated with Cardiac Sarcoidosis, Heart Rhythm*, Vol 11, No 7, July 2014.
[7] Doherty, et al. Appropriate Use Criteria for Multimodality Imaging in the Assessment of Cardiac Structure and Function in Nonvalvular Heart Disease. J Am Coll Cardiol. 2019 Jan, 73 (4) 488-516.

to rule out ischemia where they are considering giving the patient antiarrhythmic drugs. ***Given that the ACC's multimodality guidelines find it appropriate to look for ischemia using MPI in cases of atrial fibrillation, we ask the atrial fibrillation ICD-10 codes be included in the Outpatient Stress Testing LCD as well.***

ASNC appreciates the opportunity to comment on the proposed LCD for Non-Emergent Outpatient Stress testing and is pleased that First Coast Service Options seeks out input from physician stakeholders as it develops policy that will have significant effects on patient care. Please do not hesitate to reach out to Georgia Lawrence, Director, Regulatory Affairs for ASNC at glawrence@asnc.org if you have any questions or would like additional information.

Sincerely,

Sharmila Dorbala, MD
President,
American Society of Nuclear Cardiology