SCAI
Society for Cardiovascular Angiography & Interventions

September 23, 2022

Submitted electronically via: http://www.regulations.gov

Office of Regulations and Reports Clearance
Social Security Administration
3100 West High Rise
6401 Security Boulevard
Baltimore, Maryland 21235-6401

RE: SSA–2019–0013
Revised Medical Criteria for Evaluating Cardiovascular Disorders

To Whom It May Concern:

The Society for Cardiovascular Angiography and Interventions (SCAI) has dedicated its work to advancing the profession and is the designated society for guidance, representation, professional recognition, education, and research opportunities for invasive and interventional cardiology professionals. For more than 40 years, SCAI has personified professional excellence and innovation globally, fostering a trusted community of more than 5000 members dedicated to medical advancement and lifesaving care for adults and children with cardiovascular disease. SCAI appreciates the opportunity to comment on this proposed rulemaking.

Overall, SCAI applauds the Social Security Administration (SSA) for undertaking these changes and agrees with the majority of the amendments to the criteria. SCAI submits the following comments on specific sections of the document:

Proposed Changes to the Adult Cardiovascular Disorders

400.D1a
The SSA proposes to add a more descriptive definition of ejection fraction (EF). However, it is important that SSA also makes sure to elaborate that

congestive heart failure (CHF) can be due to reduced left ventricular (LV) EF (HFrEF; EF <40%), mid-range EF (HFmrEF; (EF 40-49%), and preserved EF (HFpEF;EF >50%).[1]

402.a1

Proposed criterion 4.02a1 requires an increased left ventricular end diastolic dimension (LVEDD) equal to or greater than 7.0 centimeters (cm) instead of the current criterion of an LVEDD greater than 6.0 cm. This change would exclude many patients with chronic heart failure and significant left ventricular dysfunction. Only patients with the most severe forms of heart failure would be captured under the proposed rule change. Seven cm is a threshold often times used to exclude patients from heart failure therapies (i.e., mitral valve edge to edge repair) because of medical futility. Six cm is likely a appropriate threshold to delineate those patients who will benefit from some advanced cardiovascular therapies, but SSA should also be considering including an LV volume index in addition to or instead of LVEDD. The SSA should also consider having separate cutoffs for men and women.[2]

402.a2

In 402.a2, SSA proposes to consider an elevated left atrial volume index (LAVi) measurement. A volume index 34ml/m2 should be the cutoff, and SSA should also add diastolic function requirements as an alternative.[3] Another option for assessing CHF could also be an elevated b-type Natriuretic peptide (BNP) level. Since the guidelines list hemoglobin levels to objectively assess hypoxemia, a BNP level can be an objective blood test to evaluate for heart failure and LV dysfunction.

---

[1]Heidenreich, Paul A., et al. "2022 AHA/ACC/HFSA guideline for the management of heart failure: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines." Journal of the American College of Cardiology 79.17 (2022): e263-e421. https://www.jacc.org/doi/pdf/10.1016/j.jacc.2021.12.012?_gl=1*1qkemw5*_ga*Mjc0MTU3NTcuMTY0NjMzNzE0Mg..*_ga_2V8VW4Y237*MTY2MDY3MDQ5NC4xMi4wLjE2NjA2NzA0OTUuNTk.&_ga=2.259868942.546602183.1660587056-27415757.1646337142

[2] Aleong, Ryan G., et al. "Left ventricular dilatation increases the risk of ventricular arrhythmias in patients with reduced systolic function." Journal of the American Heart Association 4.8 (2015): e001566. https://www.ahajournals.org/doi/10.1161/JAHA.114.001566

[3] Nagueh, Sherif F., et al. "Recommendations for the evaluation of left ventricular diastolic function by echocardiography: an update from the American Society of Echocardiography and the European Association of Cardiovascular Imaging." European Journal of Echocardiography 17.12 (2016): 1321-1360. https://asecho.org/wp-content/uploads/2016/03/2016_LVDiastolicFunction.pdf

402.B3

Proposed 4.02B3 would evaluate exacerbations or complications of CHF, requiring three hospitalizations within a consecutive 12-month period and at least 30 days apart. An impairment resulting in exacerbations or complications that require this number of hospitalizations in 12 months is a very severe impairment. SSA would require these hospitalizations to be at least 30 days apart to ensure evaluation of separate episodes of exacerbations or complications. The requirement to wait 30 days for each episode of heart failure to be considered a "separate" exacerbation is arbitrary and does not take into account specific considerations. SCAI would propose each heart failure hospitalization be treated as such irrespective of the time elapsed between them.

4.04C

SSA specifies that ischemic episodes would include treatment for myocardial infarction (heart attack), unstable angina, or an irregular heartbeat**.** The term irregular heartbeat is nonspecific. SCAI would recommend changing this to an arrhythmia thought to be due to ischemic cause, e.g., ventricular arrhythmia or complete heart block.

404.D1

Proposed 404.D1 would be based upon blood flow in the coronary arteries expressed as fractional flow reserve (FFR). Coronary physiology is an important addition, but reference to "fractional flow reserve" is too restrictive and would exclude other similarly effective measures of coronary physiology which are commonly used (known together as non-hyperemic pressure ratios [NHPR], inclusive of DFR, RFR, iFR, and/or DPR). SCAI would suggest the term "coronary artery physiology" of which FFR is but one example of a class of technologic advances that can determine the adequacy of coronary artery flow.[4]

404.E

Proposed 404.E would evaluate exacerbations or complications of ischemic heart disease (IHD) requiring three hospitalizations within a consecutive 12-month period and at least 30 days apart. Complications of IHD could include complications from the revascularization procedure (i.e., bleeding, stent thrombosis, contrast induced nephropathy) and could require rehospitalization within a 30-day period. These readmissions should be recognized by the SSA

[4] De Maria GL, Garcia HM, Scarsini R, et.al. Novel Indices of Coronary Physiology Do We Need Alternatives to Fractional Flow Reserve? Circ Cardiovasc Interv. 2020;13:e008487. DOI: 10.1161

as complications and not penalize the patient. Perhaps “no more than 2 of the hospitalizations can occur within 30 days” would better capture the intent of the proposal.

4.10

The category 4.10 refers to dissecting aneurysm of the aorta or major branches due to any cause, and lists examples such as atherosclerosis, Marfan’s, and trauma but does not specifically mention other connective tissue disorders or penetrating aortic ulcer as other etiologic factors. SCAI would recommend adding all etiologic factors.

4.12

Section 4.12 proposes to revise the heading of the current listing to evaluate peripheral artery disease (PAD) while the person is on a regimen of prescribed treatment. “Prescribed treatments” lacks clarity. SCAI would recommend changing prescribed to “guideline-recommended.”

Proposed Changes to Congenital Heart Disorders

400.H3

Section 400.H proposes adding additional subheadings to clarify what congenital heart disease is and how it is defined. For H3, instead of the proposed “what is single ventricle,” SCAI proposes the heading “what is unrepaired congenital heart disease” to include definitions of single ventricle.

406.A

While SCAI agrees with the changes to include hypoxemia in the guideline, SCAI also believes that criteria should also exist for those patients that are not cyanotic or hypoxic. The saturation cut off should be set at ≤ 89%.

104.02A

For persistent tachycardia at rest, the SSA proposes to require two or more tachycardia measurements in a consecutive 12-month period. Persistent tachycardia can also include measurement by palpation of pulse, in addition to proposed apical heart rate.

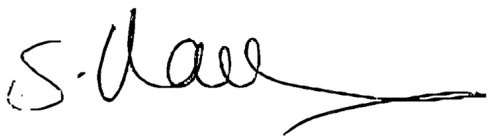
104.13

Section 104.13 proposes to remove and reserve listing 104.13, because rheumatic heart disease is a complication of rheumatic fever, which is rare in the United States, due to widely available treatment with antibiotics. Rheumatic heart disease, though rare in the US, is seen in endemic

regions and in deprived communities. Based on current epidemiology, it should be continued to be listed and not removed. It should not be migrated to 104.02 or 104.05.

SCAI appreciates the opportunity to provide comments on this Proposed Rulemaking, and we look forward to continuing to work with the SSA to address these important issues. If SCAI can be of any assistance as the SSA continues to consider and review these issues, please do not hesitate to contact SCAI's manager for coding and reimbursement, Monica Wright at 202-327-5451 or at mlwright@scai.org if there are any questions or further requests.

Sincerely,



Sunil Rao, MD, FSCAI
President 2022-2023