

March 6, 2023

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

*Submitted via regulations.gov*

Dear Administrator Brooks-LaSure:

The Society for Cardiovascular Angiography and Interventions (SCAI) and the Association of Black Cardiologists (ABC) are writing in regard to the recently issued “Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies” which has raised concerns related to the CMS policy toward peripheral arterial disease (PAD). Several proposed changes conflict with widely supported clinical protocols involving the importance of early detection and coordinated management of people PAD; especially within minority populations and those living in underserved communities.

PAD is a disease most often manifested in leg arteries where plaque builds up in the blood vessels supplying oxygen rich blood to the legs. If detected early, the disease can be effectively treated with patient friendly and inexpensive therapies such as nutritional counseling, smoking cessation, and supervised exercise therapy. As the disease advances, pharmaceutical, catheter-based, and surgical treatments are required. If left undetected and unmanaged, however, the disease can result in a heart attack, stroke, and/or amputation.

Clinical support for the identification and coordinated management of PAD has been in place for over 25 years across all forms of public and commercial health systems and insurance programs. More specifically, there are well established CPTs codes that reimburse for diagnostic PAD studies in traditional CMS Fee For Service (FFS) Medicare and Medicaid programs (CPT 93922, 93923, and 93924). For patients covered by Medicare Advantage (MA), the diagnosis and management of PAD has been supported through HCC codes (HCC 108, 107, and 106). As a result, many of the MA insurers have undertaken broad efforts to detect PAD in their member population.

The CMS Advance Notice referenced above proposes a new code group that restricts risk adjustment to only the most advanced stages of PAD (HCC 264 and 263). By removing a risk adjustment factor for all but the most severe forms of PAD, we risk failing to detect this progressive

disease early which imperils the health of those already being underserved and imposes an unnecessary cost burden on our Medicare system.

African Americans have a 37% higher prevalence of PAD than the rest of the population, with chronic conditions developing 10 years earlier. They are also more likely to have asymptomatic or atypical disease, which, if detected early, can allow for effective primary and secondary prevention strategies to stop progression to critical limb ischemia and risk of amputation.

Better strategies and policies are necessary to address the disparities in care and outcomes for those with PAD. Limiting risk adjustment to only the most advanced stages of PAD is a step in the wrong direction. African Americans are three times more likely than the rest of Americans to lose limbs to amputation. Native Americans experience double the risk of a non-traumatic limb amputation. Hispanics are 75% more likely to experience amputation. Medical literature has consistently concluded that unmanaged PAD is associated with a high rate of mortality and severe consequences (including heart attack, stroke and amputation).

To align the payer and provider community with early detection and prevention, risk adjustment should start with patients with asymptomatic PAD, then increase with symptomatic (intermittent pain) PAD and conclude with those with the most advanced/severe forms of PAD (those with at-rest pain and those with defined complications).

We ask that you reconsider the implications of the proposed policy on the PAD population and, if there are to be changes, you give strong consideration to the approach of scaling risk adjustment of PAD based on severity.

Sincerely,



Foluso Fakorede, MD  
PAD Initiative Co-Chair  
Association of Black Cardiologists



Lyndon Box, MD  
Government Relations Chair  
SCAI



## **Clinical References:**

### **Industry Voices—Too many minorities are experiencing unnecessary leg amputations, Fierce Healthcare, October 2019**

Research shows that African Americans with diabetes are three times more likely than white patients to have their limbs amputated as a result of PAD. Other communities of color face similar disparities. For example, Hispanics are 75% more likely to have their limbs surgically removed, while Native Americans are more than twice as likely to face non-traumatic amputations. For racial minorities in Mississippi, where I work as a limb salvage specialist, the rates are even higher. Here at the epicenter of the PAD epidemic, nine out of 10 of amputees that I've encountered or evaluated have never had a diagnostic test for PAD or an appropriate vascular evaluation to salvage their limbs.

<https://www.fiercehealthcare.com/hospitals-health-systems/industry-voices-too-many-minorities-are-experiencing-unnecessary-leg>

### **Peripheral Vascular Disease – What is peripheral vascular disease?, Johns Hopkins Medicine**

Peripheral vascular disease (PVD) is a slow and progressive circulation disorder. Narrowing, blockage, or spasms in a blood vessel can cause PVD. PVD may affect any blood vessel outside of the heart including the arteries, veins, or lymphatic vessels. Organs supplied by these vessels, such as the brain, and legs, may not get enough blood flow for proper function. However, the legs and feet are most commonly affected. Peripheral vascular disease is also called peripheral arterial disease.

<https://www.hopkinsmedicine.org/health/conditions-and-diseases/peripheral-vascular-disease>

### **Risk of peripheral artery disease significantly higher in African-Americans, NIH - September, 2019**

Researchers are reporting that African-Americans have a significantly higher lifetime risk of peripheral artery disease (P.A.D.)—a condition in which plaque builds up in the leg arteries—than whites and Hispanics. The findings demonstrate that race is a strong factor in P.A.D. risk, they say.

<https://www.nhlbi.nih.gov/news/2019/risk-peripheral-artery-disease-significantly-higher-african-americans#:~:text=Researchers%20are%20reporting%20that%20African,risk%2C%20they%20say>

### **Epidemiology of Peripheral Artery Disease, AHA Circulation Research – April, 2015**

After adjustment for known CVD risk factors, PAD is associated with an increased risk of incident coronary and cerebrovascular disease morbidity and mortality. With the aging of the global population, it seems likely that PAD will be increasingly common in the future. The diagnosis and treatment of PAD in its asymptomatic stage may prove highly beneficial, particularly with respect to interventions aimed at ameliorating risk factors common to atherosclerotic disease of various vascular beds.

<https://www.ahajournals.org/doi/full/10.1161/circresaha.116.303849>

### **Comparing Detection, Treatment, Outcomes, and Spending for Patients with Type 2 Diabetes Between Medicare Advantage and Fee-For-Service Medicare, Avalere Health – January, 2023**

Findings:

- Among patients with prediabetes who developed type 2 diabetes:
  - o MA patients received a type 2 diabetes diagnosis earlier (relative to the date of the prediabetes diagnosis) than FFS patients, and
  - o MA patients had a lower diabetes severity score at diagnosis than FFS patients.
- Among patients with incident diabetes, MA patients were more likely than FFS patients to fill prescriptions for medications to treat diabetes and related conditions within the first year of diagnosis.
  - o Similarly high shares of MA and FFS patients filled prescriptions for blood pressure and cholesterol medications.
- Among patients with chronic diabetes:
  - o Similarly high shares of MA and FFS patients visited primary care providers,
  - o MA patients were more likely than FFS patients to receive preventive care, including diabetes related office visits and testing for kidney disease, and
  - o MA patients were less likely than FFS patients to require dialysis.
- Among patients with prediabetes and diabetes:
  - o MA patients had fewer emergency department visits and hospital admissions than FFS patients,
  - o Both MA and FFS patients rarely had avoidable hospital admissions, and
  - o Total medical spending was lower for MA patients than FFS patients. However, among patients with diabetes, MA patients had higher diabetes-related spending than FFS patients.
- Among dual eligible patients with diabetes (i.e., patients who are enrolled in both Medicare and Medicaid), MA patients were more likely than FFS patients to visit a primary care provider and fill prescriptions for diabetes medications. Total medical spending was lower for these MA patients than these FFS patients.

### **Clinical Benefit, Harm, and Cost Effectiveness of Screening Men for Peripheral Artery Disease: A Markov Model Based on the VIVA Trial, European Journal of Vascular and Endovascular Surgery - June 2021**

<https://www.sciencedirect.com/science/article/pii/S107858842100191X>

Screening of men for PAD is likely to be both clinically effective and cost effective in a lifetime perspective.

### **Peripheral Artery Disease (PAD) National Action Plan**

Peripheral artery disease (PAD), a progressive atherosclerotic disease in which one or more peripheral arteries, typically in the lower limbs, are partially or completely obstructed afflicts 8-10 million people in the United States. Each year, approximately 150,000 leg amputations are performed in the United States and residents of rural areas, Black and Native American people and those of low socioeconomic status are at the highest risk of amputation. Yet many Americans — even some clinicians — remain unaware of the disease and its devastating impact on individuals, their families and communities. The time is NOW Because this preventable, treatable condition causes so much unnecessary suffering and death, the American Heart Association and more than 70 representatives from over 25 organizations committed to improving vascular health outcomes in 2018. During the time since that commitment was made, countless hours of work and passion have been put into developing a PAD National Action Plan.

[https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-resources/pad-action-plan?utm\\_source=GoogleAds&utm\\_medium=search&utm\\_campaign=22%7cQuad%7cPAD&utm\\_content=PADNAP&gclid=Cj0KCQjwmoZBhDSARIsALYcouq3SjTZpcT-FRIfyLZLebxkNWQrrAQF7mH57QILH\\_pB21znkWCKTfvIaAkBtEALw\\_wcB&gclsrc=aw.ds](https://www.heart.org/en/health-topics/peripheral-artery-disease/pad-resources/pad-action-plan?utm_source=GoogleAds&utm_medium=search&utm_campaign=22%7cQuad%7cPAD&utm_content=PADNAP&gclid=Cj0KCQjwmoZBhDSARIsALYcouq3SjTZpcT-FRIfyLZLebxkNWQrrAQF7mH57QILH_pB21znkWCKTfvIaAkBtEALw_wcB&gclsrc=aw.ds)