ABC Association of Black Cardiologists, Inc.
Saving the Hearts and Minds of a Diverse America

February 12, 2025

Acting Administrator Stephanie Carlton
Centers for Medicare and Medicaid Services (CMS)
7500 Security Boulevard
Baltimore, MD 21244

RE: National Coverage Determination for Renal Denervation

Dear Acting Administrator Carlton:

We are writing to support coverage under Medicare for renal denervation therapy, an innovative new treatment option for patients with uncontrolled hypertension. As organizations committed to supporting the cardiovascular health of patients and the providers that care for them, our foundational goal is to prioritize cardiovascular disease prevention by promoting cardiac risk factor reduction. We recognize that achieving a health care system where cardiovascular disease is treated as a serious threat to health, and where policies support providers so they can efficiently treat cardiovascular risk factors, is one of the United States' most daunting challenges.

Cardiovascular disease kills more Americans than any other disease, accounting for one in five U.S. deaths in 2022[1]. About 805,000 Americans suffer a heart attack each year[2]; nearly the same number of Americans suffer strokes. Moreover stroke, perhaps the most feared consequence of uncontrolled hypertension, kills African Americans between 45 and 54 at a rate that is 3 times greater than their white counterparts[3]. Heart disease cost the American health care system $252.2 billion between 2019 and 2020, making it the most financially burdensome disease in our country[4]. We are not making progress when it comes to cardiovascular disease and death prevention. In fact, the death rate due to cardiovascular disease has actually increased in the United States since 2011. As a group of physicians concerned with the health of the people we care for, we desperately request that you facilitate this powerful tool's entry into our therapeutic armamentarium to combat a major contributor to cardiovascular disease, our Nation's leading cause of death for all people.

Put simply, cardiovascular trends are going in the wrong direction. Health care leaders can help reverse this trend by ensuring timely and comprehensive coverage for treatment options that put patients back in control of their cardiovascular health.

Hypertension, or high blood pressure, is widely understood to be one of the most modifiable risk factors for cardiovascular disease. Dubbed "the silent killer," hypertension leaves men twice as likely, and women three times as likely, to suffer heart failure[5]. Hypertension is a pervasive disease that affects 47% of U.S. adults, or 116 million people, but is especially prevalent in communities facing significant barriers to obtain healthcare. About 55% of Black Americans have hypertension, and by age 55, more than three in four will develop it[6]. In hypertension prevalence and outcomes, America's variability in health outcomes challenges are on full display.

Thankfully, this clearly unmet need has received increased attention from public health leaders, elected officials and industry. The Centers for Disease Control and Prevention's Million Hearts Initiative, for example, specifies evidence-based hypertension measuring and treatment as one of its five tenets for optimizing

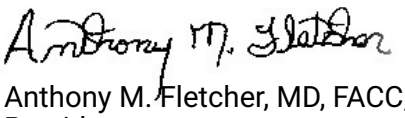
heart care. U.S. Representative Joyce Beatty, herself a stroke survivor and former chair of the Congressional Black Caucus, just this year introduced a resolution in the U.S. House recognizing Hypertension Awareness Month[7]. And multiple life sciences companies are exploring new treatment modalities and options, as one in four Americans with hypertension are still uncontrolled.

For decades, uncontrolled hypertension was treated with lifestyle changes and pharmacological agents, while failures were largely attributed to patient or provider non-compliance. Recently, however, we have seen non-pharmacological approaches to treating uncontrolled hypertension. One novel example is renal denervation, a minimally invasive procedure that reduces blood pressure by limiting activity of the kidney nerves. Renal denervation was approved by the Food and Drug Administration in November 2023 but, nearly a year later, has no formal coverage from the Centers for Medicare and Medicaid Services. The cardiovascular community sees great potential promise in this treatment option for uncontrolled hypertension.

We can make progress toward our goal of cardiovascular disease prevention when we collectively advocate for policies and practices that promote accelerated innovation and evidence-based cardiovascular disease management. In that spirit, we encourage the coverage of this device so that our members have a new, non-pharmacological treatment option for their patients. With an additional 25 million people expected to develop hypertension by 2035[8], Americans need the best cardiovascular care possible.

Thank you for your attention to this matter.

Sincerely,



Anthony M. Fletcher, MD, FACC, FSCAI
President
Association of Black Cardiologists

1 https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html#:~:text=Heart%20disease%20in%20the%20United%20States&text=Heart%20disease%20is%20the%20leading,every%205%20deaths.12
2 https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html
3 https://www.nih.gov/news-events/nih-research-matters/racial-disparities-stroke-incidence-death
4 https://www.cdc.gov/heart-disease/data-research/facts-stats/index.html
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