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

Association of Black Cardiologists, Inc.
2400 N Street, NW
Suite 200
Washington, DC 20037
(800) 753-9222
www.abcardio.org

Paul Underwood, MD
Board Chair

Anthony Fletcher, MD
President

Melissa Burroughs, MD, MS
Treasurer

Kevin Kwaku, MD, PhD
Secretary

Barbara Hutchinson, MD, PhD
Immediate Past Board Chair

Anekwe Onwuanyi, MD
Immediate Past President

Cassandra McCullough, MBA
Chief Executive Officer

Rachel Bond, MD

Garth Graham, MD, MPH

Kathryn Harris, MD
Fellows Representative

Lee Kirksey, MD, MBA

Eldrin Lewis, MD, MPH

Sabra Lewsey, MD, MPH

Modele Ogunniyi, MD, MPH

Sue Peschin, MHS

Joseph Poku, MD
Chair, Nominating Committee

Gloria Wilson Shelton, Esq.
Chair, Bylaws Committee

J. Gwendolyn Taylor, MBA

Marlene Williams, MD

Richard Allen Williams, MD
Founder

ABC MISSION:
To promote the prevention and treatment of cardiovascular disease, including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

August 8, 2025

Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Comments on the Proposed Decision Memo for Renal Denervation (CAG-00465N)

Dear Administrator Oz:

The Association of Black Cardiologists (ABC) writes to express our strong support for the Centers for Medicare & Medicaid Services' (CMS) proposal to cover radiofrequency and ultrasound-based renal denervation (RDN) under Coverage with Evidence Development (CED).

About ABC

Since our founding 50 years ago, the Association of Black Cardiologists strives to promote the prevention and treatment of cardiovascular disease in Black and other communities experiencing barriers to optimal health by eliminating gaps in our healthcare ecosystem. We close these gaps through advocacy aimed at consistent guideline-based, culturally-focused medical care , representation in clinical trials, insuring patient access and adherence to therapy, and by tackling barriers to patient access to current state-of-the-art technologies.

Background

High blood pressure contributes greatly to the excess cardiovascular morbidity and mortality experienced by the African American community. As clinicians concerned and responsible for the care of minoritized communities, we believe the addition of renal denervation to the therapeutic armamentarium to treat severe, resistant hypertension will improve care for our patients. Older Black adults are disproportionately more likely to have treatment-resistant hypertension, experience poorer blood pressure control, and suffer more from heart failure and stroke.[i]

Hypertension among Black patients is a public health crisis. Hypertension affects approximately 57% of Black Americans, the highest rate of any racial or ethnic group in the United States and approximately 30% higher than whites, this contributes to the contributes to the disproportionate rates of hypertensive consequences: stroke, heart failure, and chronic kidney disease.[ii]

- Black women are twice as likely to have a stroke than white women and Black men are 70% more likely to die from a stroke.[iii]
- African Americans under 50 experience twice the risk of heart failure related hospitalizations and death.[iv]
- Blacks are 3 times more likely to require hemodialysis for end stage renal disease than whites in America.[v]

As CMS noted in the proposed decision memo, Blacks have a higher prevalence of hypertension than whites, Latinos, or Asians. The prevalence of resistant hypertension is rising in all demographic groups; however Blacks, as well as those with lower income and education levels also have a substantially higher rates when compared with the overall population.[vi] Additionally the comorbid conditions associated with resistant hypertension (diabetes, obesity, sleep apnea, chronic kidney disease and history of occlusive vascular disease) not only increase risk for resistant hypertension but also complicate management and prognosis.

Despite this, these vulnerable populations have been significantly underrepresented in RDN trials. In fact, CMS highlighted that "enrollment of different racial and ethnic groups was limited across studies, with most participants being white," and that "resistant hypertension is more prevalent in African Americans".[vii] In the studies where race was reported the percentage of African American participants was generally consistent with their share of the U.S. population. However, African Americans experience a much higher prevalence of resistant hypertension compared to other groups.[viii]

<u>ABC Comments on RDN NCD</u>

ABC supports the CED pathway and recommends several enhancements to strengthen implementation. We appreciate CMS's decision to pursue a CED approach for renal denervation, balancing timely access with continued evidence generation. To ensure the success of this approach and generate data that reflects the full Medicare population, we offer the following recommendations:

1. **CMS should improve representation of high-risk patient populations in CED studies.**

Black patients experience some of the highest rates of uncontrolled hypertension and associated complications. Yet, as CMS notes, they were underrepresented in pivotal RDN trials and consequently scientifically powered analyses are not possible. To better understand the therapy's real-world effectiveness and safety, we urge CMS to require that the CED study:

- Includes outreach and recruitment efforts focused on high-risk populations, including Black patients; and
- Reports enrollment and outcomes data by race and ethnicity.

ABC is highly supportive of the proposed requirement to analyze study results stratified by key patient characteristics like age, race, and medical conditions.

These steps will help ensure the evidence base developed through CED is applicable to all Medicare beneficiaries who are most likely to benefit from the therapy.

2. **CMS should ensure broader facility participation in the CED program.**

We are concerned that the proposed requirement for participation through a multidisciplinary hypertension program could unintentionally exclude hospitals and outpatient centers that serve a large number of patients with uncontrolled hypertension. We recommend that CMS allow broader participation by facilities that:

- Have the capabilities necessary for RDN;

- Routinely provide evidence based medical care for patients with high blood pressure and who may benefit from this therapy; and
- Can meet care coordination requirements through clinical partnerships.

This will help avoid unintended access barriers and ensure the CED program is feasible across a variety of practice settings.

3. **ABC supports patient-facing tools that improve understanding and choice.**

We support CMS's emphasis on shared decision-making and recommend the development of patient-facing tools that are tailored to a variety of cultural and educational backgrounds. These tools should help patients better understand the risks, benefits, and alternatives to RDN and support productive conversations with their care teams.

Conclusion

While hypertension is the most common cardiovascular condition among Black Americans, current solutions, if correctly deployed, can greatly benefit all patients who have treatment resistant hypertension. We believe that renal denervation offers a safe and effective treatment for some of our highest-risk patients, particularly those who struggle with medication tolerance and adherence.

We applaud CMS's thoughtful, evidence-based approach and respectfully request that the final policy include clear expectations around access, enrollment, and outcome reporting so all people experiencing treatment-resistant hypertensive can be comprehensively included in the adoption of new technologies.

Thank you for your time and attention in this matter. Please contact Kennedy Peoples at KPeoples@abcardio.org with any questions or concerns.

Sincerely,

Cassandra McCullough, MBA
Chief Executive Officer

---

[i] J Flack, M Buhnerkempe & K Moore..Resistant Hypertension: Disease Burden and Emerging Treatment Options. Current Hypertension Reports Vol 26 (2024).

[ii] Carson, A. P., Howard, G., Burke, G. L., Shea, S., Levitan, E. B., & Muntner, P. (2018). **Incident hypertension and hypertension control in relation to risk of cardiovascular disease and mortality.** *Journal of the American Heart Association*, 7(14), e007988. https://doi.org/10.1161/JAHA.117.007988.

[iii] Eagan B. Burden of hypertension in Black individuals. Up to Date. June 2025.

[iv] Id.

[v] Arun a, Sawano, Echols M, Yancey C et al. Excess CV Mortality Among Black Americans 2000-2022. Journal of the American College of Cardiology (JACC), Vol 84, 2024.

[vi] Carey R, Sakhuja S, Calhoun D et al. Prevalence of Apparent Treatment Resistant Hypertension in the United States: Comparison of the 2008 and 2018 American Heart Association Statements of Resistant Hypertension. Hypertension. Voll 73. 2019.

[vii] Sarafidis PA, Georgianos P, Bakris GL. Resistant hypertension—its identification and epidemiology. Nat Rev Nephrol. 2013;9(1):51-8. Epub 20121120. doi: 10.1038/nrneph.2012.260. PubMed PMID: 23165303.

[viii] Id.