

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 has grown to include over 2,000 members across the cardiology community. ABC strives to promote the prevention and treatment of cardiovascular disease in Black and minority communities by eliminating gaps in our healthcare system. We work to close these gaps through advocacy that speaks to the inconsistent care in medicine, by promoting minority populations in clinical trials, by supporting patient access and adherence, and by combating barriers to existing and emerging technologies.

**Background**

As clinicians who care for populations disproportionately burdened by hypertension, cardiovascular disease, and related health issues these diseases cause, we believe this proposal represents a critical opportunity to improve care and outcomes for our patients, particularly for older Black adults, who are more likely to have treatment-resistant hypertension, experience poorer blood pressure control, and suffer more severe consequences such as stroke and heart failure.

**Hypertension among Black patients is a public health crisis.** Hypertension affects approximately 55% of Black Americans, which is the highest rate of any racial or ethnic group in the United States. In fact, more than three in four Black adults will develop hypertension,

contributing to disproportionate rates of stroke, heart failure, and chronic kidney disease.<sup>1</sup> As CMS notes in the proposed decision memo, Black individuals have a higher prevalence of hypertension than whites, Latinos, or Asians (42.4% vs. 29.2%, 29%, and 27%, respectively). Hypertension was somewhat more prevalent in men than women (31.5% vs. 29.3%, respectively), but men were much more likely to have uncontrolled hypertension (60.9% vs. 46.7%).<sup>2</sup>

Despite this, Black patients 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”.<sup>3</sup> 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 higher prevalence of resistant hypertension compared to other groups.<sup>4</sup>

### **ABC Comments on RDN NCD**

**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. 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

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<sup>1</sup> 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>.

<sup>2</sup> Centers for Disease Control. Hypertension among adults aged 20 and over, by selected characteristics: United States, selected years 1988–1994 through 2013–2016 Table 054 2017 [updated October 30, 2024]. Available from: <https://www.cdc.gov/nchs/hus/data-finder.htm?year=2017&table=Table%20054>.

<sup>3</sup> 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.

<sup>4</sup> Id.

- Reports enrollment and outcomes data by race and ethnicity.

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

These steps will help ensure that 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 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 unnecessary 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 can be deployed to greatly benefit this population. We believe that renal denervation offers a safe and effective treatment for some of our highest-risk patients, particularly those who struggle with medication adherence or side effects.

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 that Black patients can be comprehensively included in the adoption of new technologies.

Thank you for your time and attention in this matter. Please contact [name of contact] with any questions or concerns.

Sincerely,