November 22, 2019

The Honorable Richard Neal  
Chairman  
Committee on Ways and Means  
U.S. House of Representatives  
Washington, D.C.  20510

The Honorable Kevin Brady  
Ranking Member  
Committee on Ways and Means  
U.S. House of Representatives  
Washington, D.C.  20510

Dear Chairman Neal and Ranking Member Brady:

The Association of Black Cardiologists (ABC) appreciates your commitment and that of the Committee’s Rural and Underserved Communities Health Task Force to identify policy approaches to improving health care outcomes in underserved communities.

In 2006, ABC convened the Improving Healthcare Access for Minority and High-Risk Populations Roundtable. The Roundtable brought together experts in various cardiovascular diseases (such as heart failure, stroke, hyperlipidemia) that adversely affect underserved communities and minority populations in the attempt to provide solutions and influence policies that impact access and outcomes. Participants ultimately identified five consensus-driven solutions that can enhance access and positively impact minority and high-risk communities. Those solutions are highlighted in this letter.

Further, the ABC welcomes the opportunity to share a successful model related to peripheral artery disease (PAD) that has shown a demonstrable, positive impact on health outcomes within an underserved community.

MANAGEMENT OF PERIPHERAL ARTERY DISEASE IN THE UNDERSERVED COMMUNITY

PAD is often a complication of diabetes which affects more than 30 million Americans.\(^1\) When diabetes is not managed well, the risk of developing PAD increases. PAD develops when arteries become clogged with plaque resulting in reduced blood flow to the legs which puts patients at a dramatically higher risk of limb amputation and this condition is often associated with disease in other vessels of the body resulting in the concomitant risk of a heart attack or stroke.

It is estimated that one out of three people with diabetes 50 years of age or older has PAD, and African Americans are more than twice as likely to have PAD as their white counterparts.\(^2\)

PAD treatment often involves lifestyle changes and medication; yet, only 20-30 percent of patients with PAD are being treated.\(^3\) Revascularization often becomes necessary to improve the blood circulation to the legs.

Race, income, insurance status, first point of medical contact, geographical location, and modifiable diseases all determine patient outcomes. For patients with PAD, these factors also determine whether the outcome is a limb amputation. Every day, 230 Americans with diabetes will undergo an amputation.\(^4\)
Yet, many PAD-related amputations are preventable if these individuals are aggressively screened. The practice of unnecessary amputations disproportionately affects patients located in medically underserved communities. For example, in rural areas of the southeastern United States, amputation rates, especially among black patients with diabetes, are high. In these regions, the risks of major amputation are often three to four times the national average.\(^5\)

The majority of these patients are Medicare and Medicaid recipients who could have been productive in the workforce if screened earlier and their limbs could have been salvaged. If PAD is caught in time, and patients referred in a timely manner, significant benefit could be derived from a peripheral vascular intervention. This involves a vascular specialist performing an angiogram to assess the blood flow to the limb, identifying vessels narrowed by plaque, and restoring blood flow to the limb by special techniques. If blood flow is restored and an existing wound is given time to heal, amputation is prevented. This procedure usually takes 90 minutes and ideally is performed as an outpatient procedure due to its cost benefits. Timely referral for an angiogram AND intervention reduces the probability of an amputation by 90 percent.\(^6\)

The cost of unnecessary amputations is a financial burden on our health care system, at a more than $10 billion annual cost.\(^7\) It is a burden on our workforce. And, if you consider the ripple effect of each amputation on family members and communities, it is an extraordinary financial burden to our economy as well.

Mississippi is an epicenter for PAD, amputations and all other cardiovascular diseases, and it has had the lowest reduction in the probability of dying from cardiovascular disease during the period between 1990-2016.\(^8\) Mississippi also has the lowest number of physicians per capita and it is the poorest state, with an annual household income of $36,900 per year. In Mississippi, ABC member and cardiologist Foluso Fakorede, MD led an initiative that has led to a decrease in the rate of amputations in a focal region of the Mississippi delta by 87.5 percent over the last 3.5 years. This benefit was realized largely through the use of angiograms in the management of these patients. Prior to that, the hospital in that same region performed 56 major amputations and zero angiograms. Last year, that same institution performed 7 amputations and almost 500 angiograms. Other hotspots around the country for PAD include rural areas of Texas, Arkansas, Oregon, and North Dakota, among others (please see appendix).

This successful model was the result of a team of individuals who used aggressive early screening, diagnosis and treatment of modifiable cardiovascular risk factors in at-risk patients and advocated for angiograms before amputations. They promoted patient medical literacy and advocacy via a faith-based approach – building community navigators, educating the community about PAD and stressing the importance of prevention over cure. They also recognized the social determinants of health and discussed solutions with stakeholders on local and state levels. The results in Mississippi can be realized elsewhere. Taking this as an example that amputation reduction is possible, there is the need to publish research and to develop real-world treatment algorithms to effect change in other underserved communities.

In summary, unnecessary amputation results from the failure to perform early screening, failure to provide early treatment of at-risk patients, and the lack of a multidisciplinary approach. This is reflective of low-value care which should end. The practice of unnecessary amputations must be disincentivized and must be publicized. Policies are needed that will incentivize physicians to offer patients a chance of limb salvage before amputation, that is, "no amputation without vascular evaluation.” Further, the U.S. Preventive Services Task Force should adopt a screening protocol for at-risk patients that is effective in reducing amputation rates. The techniques to save limbs already exists. Help from Congress is needed to develop policies that create a path for Medicare and Medicaid recipients to actually reach a vascular specialist in time to benefit from these techniques. With thoughtful collaboration, this can be accomplished in a cost-effective manner, and the enormous financial costs to Medicare and Medicaid can be markedly reduced.

ABC’s recommendations to improve the management of PAD include:

1. **Increasing PAD Screening for At-Risk Patients.** The U.S. Preventive Services Task Force assigns a grade of I (insufficient evidence) for PAD screening for the general population. However, guidelines issued by the American College of Cardiology and American Heart Association recommend screening of at-risk patients (defined as those who are over age 65, have a history of diabetes, smoking, and/or PAD; or have been diagnosed with other vascular disease). The Congress should request that the U.S. Preventive Services Task Force review the data for patients who are at-risk for PAD in the furtherance of eventual adoption of a PAD screening protocol for at-risk patients that is effective in reducing amputation rates.
2. **No Amputation Without Arterial Testing.** Currently, there is no intragovernmental federal health policy to ensure that patients are assessed for non-amputation treatment options before they suffer limb loss. Congress should enact policies such as use of quality measures, guidelines or appropriate payment incentives to ensure patients receive arterial testing for potential limb-salvage prior to a non-traumatic amputation.

3. **Multidisciplinary Care and PAD Risk Assessment Tools.** Programs such as the Department of Veterans Affairs Preventing Amputations in Veterans Affairs (PAVE) program are comprehensive programs that utilize multidisciplinary approaches and risk assessment protocols to target at-risk patients with the objective of reducing the prevalence of amputations in our nation’s veteran population. Unfortunately, many PAD patients – including a large share of African Americans, Hispanics and Native Americans in rural areas – do not have access to such programs. Medicare and Medicaid programs should implement programs similar to the VA’s PAVE program to reduce amputations in those programs.

**ABC Access Roundtable Solutions to Improve Access and Outcomes in Minority and High-Risk Communities**

1. **Advocate for policy changes that encourage providers to accept Medicare and Medicaid**

A prominent challenge faced by underserved communities in the United States is that those with chronic conditions or high-risk patients are often unable to get appointments to see a primary care provider or specialist. This often occurs because of the lack of primary care providers or specialists in close proximity that accept their Medicaid plans. To meet this challenge, a policy change is needed that incentivizes providers to accept both Medicare (including managed Medicare) and Medicaid plans. The Affordable Care Act expanded Medicaid enrollment in multiple states, which improved access. However, some providers may avoid certain health plans due to poor past experiences with reimbursement. This phenomenon greatly inhibits access. Policy adjustments are needed that will both better support provider reimbursement and, consequently, give patients more health care options.

2. **Standardize and centralize the prior authorization process to decrease paperwork and improve communications**

Multiple stakeholders have described personal experiences with health plan prior authorization processes that have prevented minority and high-risk populations from receiving innovative treatments, thus impacting patient health and outcomes. Stories often referenced common challenges such as lack of transparency, lack of communication, and inconsistencies. Other groups, including a coalition led by the American Medical Association, have also recently highlighted how aggressive prior authorization programs can negatively impact patient-centered care.

Development of a standard process for prior authorization can greatly reduce paperwork and limit ineffective communication between health care providers and health plans or other payers. Appropriately centralizing the process for prior authorizations via designated health plan employees could also serve to improve communication and accountability. Patients with cardiovascular disease and their providers would then have a resource to better navigate the prior authorization process from start to finish.

3. **Advance telemedicine and telehealth practices and resources that can aid minority populations**

Telemedicine and telehealth tools may allow patients to use every day technological tools as a means to support their health and well-being. The virtual platform at the core of telemedicine and telehealth helps to bridge direct and indirect distance challenges that are often unique to minority and high-risk patients, including transportation barriers or geographic access to providers and specialists. There is a great opportunity to use existing telemedicine and telehealth tools to expand access by giving patients more options to address their medication or care needs with a trusted provider or specialist. Telemedicine and telehealth tools also can be used as a means to help patients monitor and store vitals, which can enrich how patients engage with providers. Roundtable participants believe that additional research must first be conducted to evaluate and assess existing telemedicine and telehealth tools and resources. A focus should be placed on tools and resources that are proficient in boosting access in minority communities.
4. **Promulgate pharmacy programs that improve patient access**

Stakeholders across many sectors have agreed that the pharmacy setting is a promising, but as of now, underutilized resource for responding to access and management challenges. Pharmacists are highly trained, integrated into many electronic health systems, and tend to be high-touch with patients, sometimes seeing them multiple times per month. Therefore, pharmacists create strong opportunities for patient engagement, education, and prior authorization assistance for restricted medications. Some exciting pharmacy-based programs related to access are already known, such as those that support specialty pharmacy or biometric testing technologies, which expand access to diagnostics and analytics.

More research can be done, however, to identify, describe and promulgate existing pharmacy- based programs that help reinforce a constructive patient/provider dialog, help patients better understand their drug options and insurance questions, or expand data collection on various diseases or disorders. A focused, multi-sector working group of experts could be convened to further determine which pharmacy-based programs offer critical best practices.

5. **Expand the utilization of community health worker concept to address access challenges**

The community health worker concept was designed to successfully utilize patient engagement to help high-risk and minority individuals navigate a range of health care needs. However, in general, this group remains an underutilized resource. Currently, community health workers specialize in disease-state education and patient outreach. Roundtable participants agree that community health workers can expand their outreach and education capabilities by assisting patients to respond to prior authorization denials, to overcome barriers to seeing health care providers, to better access medications, or to address other common challenges. Community health workers can also aid in collecting and sharing patient data with the community to better inform future solutions. Community health workers are some of the most opportune people to serve as on-the-ground advocates to help mitigate access challenges relevant to their respective communities, thus helping patients with cardiovascular disease better navigate the system.

**CONCLUSION**

The ABC commends you for your leadership on improving patient care and outcomes in rural and underserved areas. We look forward to working with you toward policy-oriented solutions. Should you have any questions or require additional information, please contact Camille Bonta, ABC consultant, at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

John M. Fontaine, MD, MBA, FACC, FHRS  
President  
Association of Black Cardiologists

cc: The Honorable Danny Davis  
The Honorable Terri Sewell  
The Honorable Brad Wenstrup  
The Honorable Jodey Arrington
APPENDIX

Significant racial and ethnic disparities in amputation rates for patients with PAD are substantial. Native Americans in the West are more than twice as likely to be amputated as Caucasians and Hispanics are 50-75 percent more likely to be amputated than Caucasians. African-Americans living with diabetes appear to be subject to the worst disparities in care: African-Americans living with diabetes have amputation risks as much as four times higher the national average. Data from a 2014 Dartmouth Atlas study outlines the scope of the problem.

NATIONWIDE

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1 Industry analysis of the Healthcare Cost and Utilization Project (HCUP) database
2 Variation in the Care of Surgical Conditions: Diabetes and Peripheral Arterial Disease, A Dartmouth Atlas of Health Care Series, 2014