



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

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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.

April 2, 2019

The Honorable Alex M. Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244-8013

Dear Secretary Azar and Administrator Verma:

The price of life-saving pharmaceuticals is a major contributor of health care costs; yet, cost reduction is a complex matter that should be designed to achieve equity while avoiding unintended consequences and disproportional financial burden. Currently implementation of cost containment measures has resulted in the widespread deployment of tools, such as tiering, prior authorization, step therapy, and payment models that don't fully assess clinical outcomes along with economic value as criteria in the price and value of products. Evidence-based guidelines and the availability of peer-to-peer specialty review can accelerate the delivery of appropriate treatment to patients, as well as shared-decision making, price transparency and avail health-literate tools to patients. While there is no one single solution, bold and innovative approaches, such as those being explored by the Department, are welcomed and appreciated.

Cholesterol-lowering drugs are important effective and preventive treatment interventions. The Association of Black Cardiologists (ABC) asks for your help to make treatment for heart disease prevention more affordable to populations that are economically disadvantaged, as well as to racial and ethnic minorities whose risks and complications of cardiovascular disease and stroke are persistently greater than that of white men and women.

Founded in 1974, the ABC is a nonprofit organization with an international membership of 1,700 health professionals, lay members of the community (Community Health Advocates), corporate members, and institutional members. The ABC is dedicated to eliminating the disparities related to cardiovascular disease in all people of color. ABC adheres to the vision that all people regardless of race, ethnicity or gender should benefit equally from reduction in the frequency, duration and impact of diseases of the heart and blood vessels.

A key aim of the Department's proposal to remove safe harbor protection for prescription drug rebates is to close the gap between the list and net prices of pharmaceuticals and to achieve additional price concessions from drug manufacturers, with the end result being lower premiums and out-of-pocket costs to beneficiaries. Consistent with this aim, the ABC was pleased when Amgen, and then Sanofi and Regeneron, decided to lower the list price of their PCSK9 inhibitors, Repatha and Praluent, respectively, by 60 percent with the goal of moving their cholesterol-lowering drugs from specialty tiers to a fix-dollar cost-sharing tier. Unfortunately, ABC members are still observing that patients continue to be denied access to PCSK9 inhibitors and/or are not benefiting from lower list prices.

ABC asks the Department to take steps to increase access to PCSK9 inhibitors for high-risk patients, such as those with familial hypercholesterolemia, including by requiring Medicare plans and pharmacy benefit managers to use the lowest list price available for the two available PCSK9 inhibitors.

According to newly released data from the Institute for Patient Access¹, PCSK9 inhibitor claims were initially rejected by Medicare in 35 percent of cases, which dropped 12 percent (or 407,539 claims) on appeal. Commercial rejections included high-risk patients who meet

¹ Institute for Patient Access; http://instituteforpatientaccess.org/wp-content/uploads/2019/03/IPA_National-Report-Card_PCSK9-Access_March-2019.pdf?utm_source=PACH+Newsletter&utm_campaign=59ec2aae1f-EMAIL_CAMPAIGN_2019_03_14_05_07&utm_medium=email&utm_term=0_b7ed05fcb9-59ec2aae1f-1227539493

the criteria for PCSK9 inhibitors, including those with prior statin use, cardiovascular disease, the criteria for PCSK9 inhibitors, including those with prior statin use, cardiovascular disease, heart attack or stroke, or familial hypercholesterolemia. African Americans disproportionately have difficulty accessing PCSK9 inhibitors. According to commercial claims data, the initial rejection rate for African Americans was 61.28 percent dropping to 41.74 percent on appeal. Comparatively, the initial rejection rates for whites was 55.73 percent, dropping to 35.92 percent on appeal. We hope that lower list prices will not only make currently available PCSK9 inhibitors more accessible to patients but that it will lead to a loosening of unnecessarily restrictive utilization management controls that result in barriers to access and tremendous administrative burden to providers.

The actions by Amgen, Sanofi and Regeneron that made cutting-edge medicines more affordable to patients is an example of the importance of the partnership between the federal government and pharmaceutical manufacturers that provided an innovative means that enabled health care to be more affordable for more Americans, specifically minority populations, for which barriers to treatment are more pronounced. The ABC stands ready to serve as a resource to the Department. In the meantime, we request swift action that will result in the lowest list price of PCSK9 inhibitors thus facilitating their availability to patients with or at risk of heart disease.

Should you have any questions or desire additional information, please contact Cassandra McCullough, ABC CEO and Executive Director at cmccullough@abcardio.org or 800-753-9222.

Sincerely,

A handwritten signature in black ink, appearing to read "John M. Fontaine", with a small flourish at the end.

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