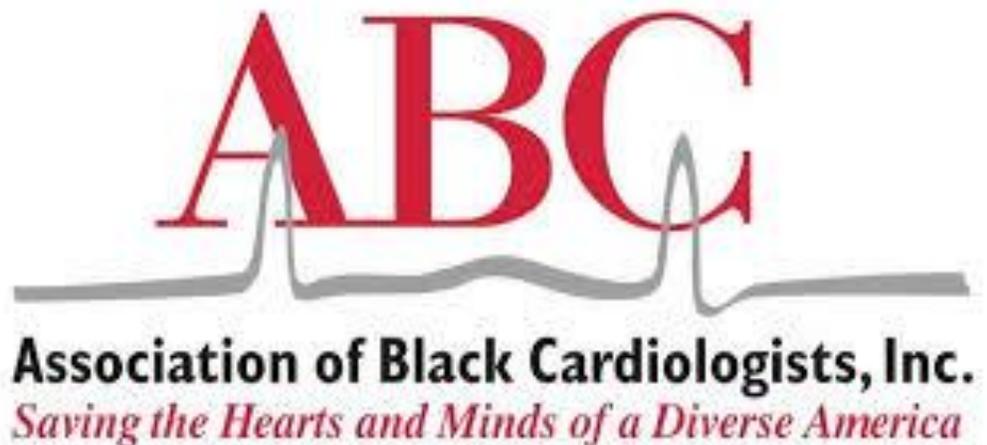


Exploring Issues of Drug Management Processes on Treatment of Underserved and Minority Patients



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Executive Summary

Underserved and minority patients face unique challenges to cardiovascular care and treatment that impact their health outcomes. The ability to access new treatments is often hampered by utilization management processes that are often put in place by insurers in an effort to ensure that these treatments are only approved for appropriate patients. In particular, the need for prior authorization (PA) – the approval from an insurer that may be required before patients receive a device, intervention, or medical treatment to be covered by that insurer – for specific drugs focused on cardiovascular care has been a barrier to treatment and a burdensome process for physicians and other providers. Representatives from ABC, in conjunction with a multisector group of experts¹, hypothesized that lower resource levels at cardiology practices with a majority of patients from underserved and minority populations may pose a unique barrier to responding to PA needs for these patients, further fostering existing treatment disparities. The objective of this white paper is to illustrate the gap in understanding the possible unintended consequences of PA and why additional data and information are required.

Introduction

Within the current cardiovascular environment, an issue that has far-reaching implications for health care providers and their patients is access to care. Research has suggested that access can be impacted by a variety of factors, including insurance status, cost of treatments, patient fees, drug costs, therapy selection, and social determinants of health. Of particular concern are the access barriers faced by underserved and minority populations, and, in particular, access to newer medications or devices. From a health equity perspective, comparable health care and health outcomes will not be achieved as long as barriers to access exist for these groups of patients. These barriers may further limit treatment for groups that are already undertreated.

In cardiovascular disease, inequities in the quality and types of treatment made available to racial and ethnic minorities have been well documented.² Over a decade

¹Association of Black Cardiologists Roundtable: Improving Health Care Access for Minority and High-Risk Populations. Meeting held November 11, 2016.

²Mozaffarian D Benjamin EJ Go AS Arnett DK Blaha MJ Cushman M et al., M Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*, 2015. 131(e29).

ago, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*, published by the Institute of Medicine³ (IOM), highlighted existing disparities in care. In particular, the report identified the lower rate of necessary cardiovascular procedures – up to 50% lower – performed on black compared to white patients. The IOM findings led to a greater focus on addressing racial and ethnic disparities, and initiated more aggressive funding and programming by both public and private organizations.⁴ The quality of cardiovascular care for both blacks and whites has since improved; from 2004 to 2014, CVD-attributable death rates for all adults dropped by 25.3% and the actual number of CVD deaths decreased 6.7%.⁵ Along with this decline in mortality, there has been a tightening in the gap between white and black patients on some CVD clinical outcomes, particularly the rates of death attributable to CVD.^{6,7}

However, significant disparities continue to be evident. Cardiovascular-related mortality, specifically related to heart disease and stroke, has dropped more slowly for black individuals than for whites, with the overall rate of decline decelerating significantly after 2011 for all races. In the 2000-2011 period, among non-Hispanic blacks, the annual rate of decline was 3.71%; this fell to 1.29% in 2011-2014.⁸ The decline was not as significant for the non-Hispanic white population.

The continued gap in life expectancy between black and white patients can be largely attributed to cardiovascular-related mortality.^{5,9} This is particularly salient when considering the changing demographics in the US. The Census Bureau reports that close to 38 percent of the current population belongs to minority groups, with blacks and Hispanics making up the largest proportions. Census data project that these minority populations will continue to grow and predominate by 2045.¹⁰ It is increasingly critical to focus delivery of care to these populations with CVD.

³Nelson A, Unequal treatment: confronting racial and ethnic disparities in health care. *Journal of the National Medical Association*, 2002. 94(8).

⁴Lewey J Choudhry NK., The current state of ethnic and racial disparities in cardiovascular care: lessons from the past and opportunities for the future. *Current cardiology reports*, 2014. 16(10).

⁵Benjamin EJ Blaha MJ Chiuve SE Cushman M Das SR Deo R Floyd J Fornage M Gillespie C Isasi CR Jiménez MC., Heart disease and stroke statistics-2017 update: a report from the American Heart Association. *Circulation*, 2017. 135(10): p. e146.

⁶ Agency for Healthcare Research and Quality, National Healthcare Disparities Report 2012. AHRQ Publication No. 13-0003. 2013: Rockville MD.

⁷Go AS Mozaffarian D Roger VL Benjamin EJ Berry JD Blaha MJ et al., Heart disease and stroke statistics—2014 update: a report from the American Heart Association. *Circulation*, 2014. 129(3): p. e28-e292.

⁸Sidney S Quesenberry C Jr Jaffe M Sorel M Mai N Nguyen-Huynh M Kushi L Go A Rana J, Recent Trends in Cardiovascular Mortality in the United States and Public Health Goals. *JAMA Cardiology*, 2016. 1(5): p. 594-9.

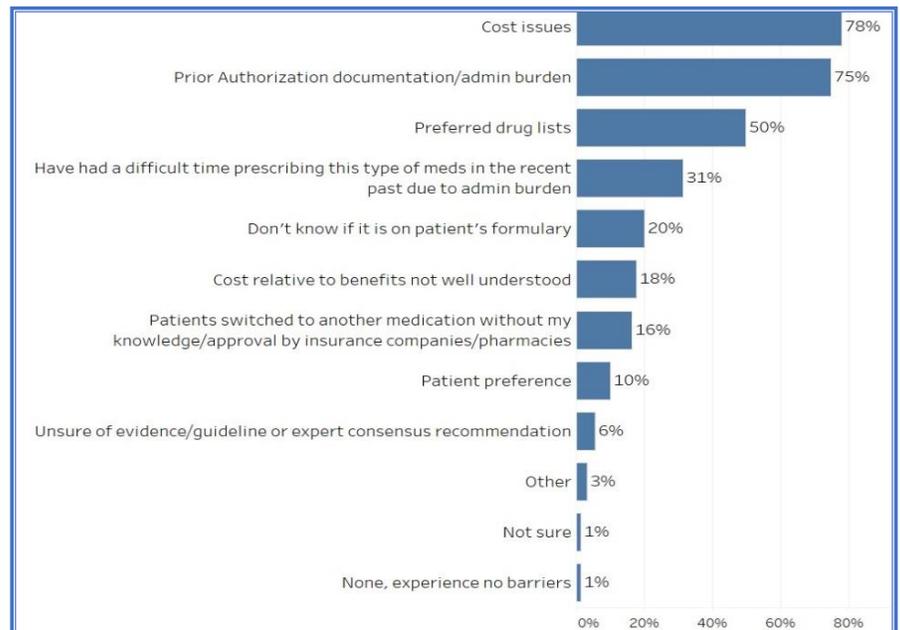
⁹Macinko J Elo IT, Black-white differences in avoidable mortality in the USA, 1980–2005. *J Epidemiol Community Health*, 2009. 63(9): p. 715-21.

¹⁰Mozaffarian D Benjamin EJ Go AS Arnett DK Blaha MJ Cushman M et al., M Heart disease and stroke statistics—2015 update: a report from the American Heart Association. *Circulation*, 2015. 131(e29).

Data indicate that barriers to new medications continue to be prevalent for all patients.

A survey conducted by the Association of Black Cardiologists (ABC) and the American College of Cardiology (ACC) in February 2018 asked physicians about barriers encountered in prescribing the newest evidence-based therapy for cardiovascular care.¹¹

Almost all physicians (98%) reported experiencing a barrier when prescribing new evidence-based therapy, with the most prevalent being cost issues (78%) and prior authorization documentation / administrative burden (75%). This data are consistent with a previous survey conducted by ACC in 2016.¹²



When considering health care disparities within this context however, an outstanding question is whether certain groups of patients – underserved and minorities – have a more difficult time accessing new or novel medications. Using the recently approved medication for hyperlipidemia as an example – proprotein convertase subtilisin/kexin type 9 or PCSK9 inhibitors – the ABC Work Group has not found evidence in any published data that addressed or confirmed a differential rate at which particular groups within the population have been rejected from receiving the medication. However, data did indicate that a very small proportion of blacks (less than 1%), far less than the prevalence of blacks with hyperlipidemia in the population, ever received a script for a PCSK9i.¹³

The ABC Work Group has hypothesized that lower resource levels at cardiology practices with large minority and underserved patient populations may result in unique barriers to responding to PA needs, thereby exacerbating treatment disparities for these populations. Our objective is to further explore and articulate the gap in understanding the unintended consequences of PA, how this impacts care for underserved and minority populations, and why additional data and information are required.

¹¹American College of Cardiology. Eliminating Barriers and Reducing Disparities. January - February 2018 Survey.

¹²American College of Cardiology. Cardiologist Perceptions of Access to New Therapies. October 2016. CardioSurve.

¹³Symphony Health Solutions, (PCSK-9 inhibitor claims analysis), [or the period: 7/30/2015-7/21/2016], commercial, managed Medicaid, Medicaid, cash-paying, and assistance claims are all included in analysis.

Background/Problem to be Addressed

Reducing the use and cost of prescription drugs through formulary restrictions has been found to be effective.¹⁴ Requirements for PA, however, extend to virtually all

- **29.1 average total PAs per physician per week***
- **Average of 14.6 hours (approximately 2 business days) spent each week by the physician/staff to complete this PA workload**
- **34% of physicians have staff who work exclusively on PA**

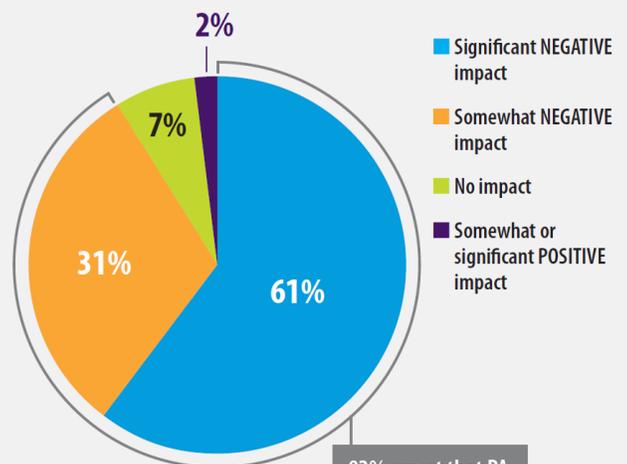
therapeutic areas, and provider dissatisfaction with the process is widespread. A 2017 survey conducted by the American Medical Association (AMA) reported that 84 percent of physicians perceive the burden associated with PA to be “high” or “extremely high,” with the average time dedicated to addressing PA per practice shown to the left. In addition, 86

percent report PA burdens have increased over the past five years. According to the survey, every week, a medical practice completes an average of 29.1 prior authorization related tasks per physician, which takes an average of 14.6 hours to process, or nearly 2 business days. In order to overcome the excessive demands of the administrative burden, about a third of physicians (34%) rely on staff members who work exclusively on the data entry and other manual tasks needed for prior authorization. This puts a substantial obligation – both in terms of staff time and money – on physician practices.

Most important to note however, is the associated impact on patient care. Over 90 percent (92%) of physicians report delays to necessary care for patients whose treatment required a PA, and about three-quarters (78%) indicate that PA can (at least sometimes) lead to patients abandoning their treatment. This is

Impact of PA on clinical outcomes

Q: For those patients whose treatment requires PA, what is your perception of the overall impact of this process on patient clinical outcomes?



92% report that PA can have a negative impact on patient clinical outcomes

Total does not equal 100% due to rounding.

¹⁴Shoemaker S, Pozniak A, Subramanian R, Mauch D. Effect of 6 managed care pharmacy tools: a review of the literature. J Manag Care Pharm. 2010;16(6 Suppl A):S3-20.

consistent with a recent ACC Journal publication that suggested suboptimal access can also lead to medication non-adherence, which is connected to 125,000 preventable deaths annually.¹⁵ A negative impact on patient clinical outcomes by PA is reported by 92 percent of physicians.

A recent systematic literature review on the effect of formulary restrictions on patient and payer outcomes¹⁶ demonstrated that some level of unintended consequences may result from formulary restrictions, such as PA, in a number of different areas, including medication adherence, clinical outcomes, treatment satisfaction, drug utilization, health care resource utilization, and economic outcomes. In addition, the analysis suggested that, although drug utilization and costs were reduced through formulary restrictions, costs savings could be mitigated by an increase in resource utilization and medical costs.

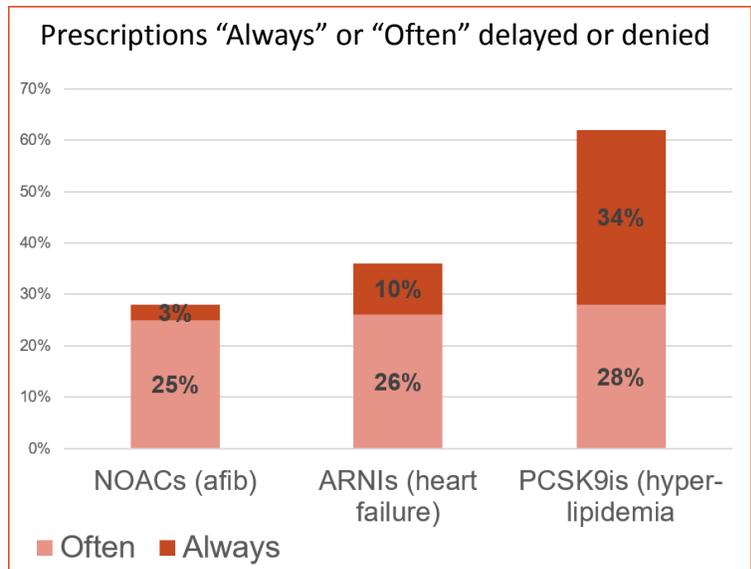
The 2018 ABC/ACC survey “*Eliminating Barriers and Reducing Disparities in Care*”¹⁷ supports the claim that PA requirements impact patient care. This survey, by design, included physicians who have a fairly high proportion of underserved and minority patients (about 40 percent) in their practice. Approximately two thirds (67%) indicated that PA requirements take time away from their focus on patients and over 60 percent (61%) cite interruptions in patient treatment. Importantly, 75 percent (75%) of physicians say that formulary restrictions lead to disparities in care, as well as patient confusion (51%) and increased medication discontinuation (51%), highlighting the negative impact on underserved and minority patients. This is exacerbated by the fact that over 40 percent (43%) of physicians say they do not have appropriate employee resources in place to properly manage PAs. To further complete the picture, practices that have more minority patients have a higher percentage of lower socioeconomic status patients, are in urban areas, and are more likely to report a lack of resources to properly manage prior authorization documentation, submissions, and appeals.

¹⁵ Ferdinand, Keith et al (2017) Improving Medication Adherence in Cardiometabolic Disease. Journal of the American College of Cardiology Jan 2017, 69 (4) 437-451; DOI: 10.1016/j.jacc.2016.11.034 Retrieved from <http://www.onlinejacc.org/content/69/4/437?rss=1>.

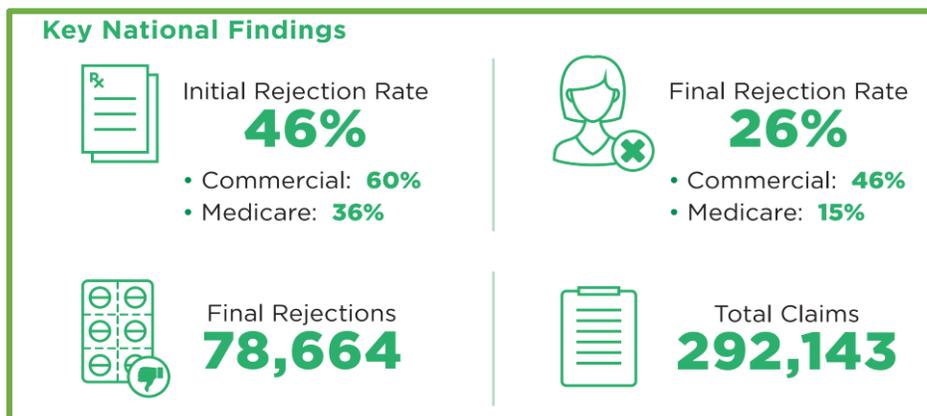
¹⁶ Park, Yujin et al (2017) The Effect of Formulary Restrictions on Patient and Payer Outcomes: A Systematic Literature Review. J Manag Care Spec Pharm. 2017;23(8):893-901.

¹⁷American College of Cardiology. Eliminating Barriers and Reducing Disparities. January - February 2018 Survey.

The ABC/ACC survey showed that PA requirements made it difficult for 42% of physicians to get access to new pharmacologic therapies for their patients. More specifically, about one-quarter to two-thirds of physicians, depending upon the drug requested, said they experience delays or denials. This is most prevalent for the PCSK9 inhibitors prescribed for hyperlipidemia (62%), followed by angiotensin receptor-neprilysin inhibitors (ARNIs) for heart failure (36%), and novel oral anticoagulants (NOACs) for atrial fibrillation (28%). When coverage is denied, particularly for PCSK9 inhibitors, about 60 percent (61%) of physicians file appeals, further drawing on resources already considered insufficient. Around 60 percent of physicians indicate they would be more likely to prescribe these medications if they did not experience delays or denials (64%-PCSK9i; 61%-ARNi; 59%-NOAC).¹⁸



Evaluating ‘real-word’ data, a national data supplier reviewed PCSK9 inhibitor claims for Medicare, Medicaid, Medicaid managed care, and commercial managed care organizations across the nation from January through December 2017.¹⁹



Medicare, Medicaid, Medicaid managed care, and commercial managed care organizations across the nation from January through December 2017.¹⁹ Of the 292,143 total claims, there was an initial rejection rate of

46 percent and a final rejection rate of 26 percent. Those with commercial plans specifically, experienced a 60 percent initial rejection rate and a 46 percent final rejection rate.

¹⁸American College of Cardiology. Eliminating Barriers and Reducing Disparities. January - February 2018 Survey.

¹⁹Institute for Patient Access: National Statistics Report Card.

http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2018/03/IfPA_CV-National-Report-Card_2018.pdf.

Overall, physicians believe that underserved and minority patients face challenges to care. When asked for their level of agreement with a number of statements related to quality of care, a substantial proportion of respondents to the ABC/ACC Survey indicated they were in agreement with the following:

Whites with heart disease are more likely than some minorities with heart disease to get the newest medicines and treatments	73%
Across the US, minority patients generally receive lower quality care than white patients	71%
Some minorities with heart disease are less likely than whites with heart disease to get specialized medical procedures and surgery	70%
In health care, in general, clinically similar patients receive different care on the basis of race/ethnicity	58%
In my hospital or clinic, clinically similar patients receive different care on the basis of race/ethnicity	24%

Physicians note that they would like to see ABC play a role in reducing the administrative burden of access to innovative new evidence-based therapies.

²⁰American College of Cardiology. Eliminating Barriers and Reducing Disparities. January - February 2018 Survey.

Solutions

To address this critical issue of access, ABC convened thought leaders for the ***Improving Health Care Access for Minority and High-Risk Populations Roundtable***. This unique Roundtable consisted of experts in various key cardiovascular areas, as well as from an array of health care sectors. Roundtable participants discussed barriers and then identified consensus-driven solutions that can enhance access and positively impact minority and high-risk populations; one such solution was to standardize and centralize the prior authorization process.



The Roundtable was conducted in November of 2016, and the participants represented areas of cardiovascular care, such as heart failure, stroke, hyperlipidemia, familial hypercholesterolemia, and other disease

categories adversely impacting minority populations. The health care sectors that had a presence at the Roundtable included government, advocacy organizations, health plans, providers, academia, and industry. Participants assembled with the objective of addressing the issues related to patient access among minority and high-risk populations in a solutions-oriented manner.

A Work Group comprising members from multiple sectors began meeting to advance the program ideas in support of standardizing and centralizing the prior authorization process in late spring 2017. A number of activities have been outlined that include:

1	White paper to identify the gap in literature and understanding regarding the hypothesis that lower resource levels at cardiology practices with large underserved and minority patient populations may pose a unique barrier to responding to PA needs for these populations, further fostering existing treatment disparities
2	Survey to fill the gaps in information related to the above
3	Regional meetings to bring together physicians and payers to discuss the challenges and potential solutions

Conclusion/Call to Action

The ABC is committed to reducing the cardiovascular disease disparity gap by 20% by 2025. In order to meet this aggressive goal, identifying the myriad of factors that lead to disparities and developing programming directed toward high-priority issues for which a solution is in its perview. Addressing prior authorization and its unintended consequences in the realm of underserved and minority health care is one such factor.

Physicians who participated in the ABC/ACC survey “*Eliminating Barriers and Reducing Disparities in Care*” provided a number of comments that underscore the importance of this issue.

- *“Regarding denials of meds from insurance companies: the reasons given are absurd and not supported by literature. I let all my patients know of this game, the illogical reason for denial, and why the payer is wrong, so they know I’m not the one withholding best practices. Occasionally, the drug then gets covered.”*
- *“Wealthy, highly-educated professionals receive better quality care, irrespective of race. Similarly, poor, uneducated, unemployed, socially marginalized patients receive worse quality of care.”*
- *“Many physicians lack knowledge about the social determinants of health and, by doing so, miss targeted treatment options on a grand scale.”*
- *“The main limitation for patients of all race/ethnicity for optimal medical therapy is affordability/cost and formulary restrictions.”*
- *More often than not, coverage is denied, or at a higher tier, pushing more of the cost burden on patients who do not have the means to afford these new medications.”*

The ABC Work Group asks that a priority be placed on understanding the consequences of PA, and that you will support the ABC in its efforts by responding to the survey that will follow and lending your voice to progress this conversation.

About the Association of Black Cardiologists

The Association of Black Cardiologists (ABC) is a nonprofit organization with an international membership of over 1,700 health professionals, community health advocates, corporate and institutional members, all dedicated to eliminating the disparities related to cardiovascular disease in all people of color. The association's aggressive goal is to reduce the cardiovascular disease disparity gap by 20% by 2025.

More information about the ABC Access to Care Initiative, the Prior Authorization Workgroup, the Workgroup participants, and the other access solutions in development can be found on the ABC website:

www.abcadio.org

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