



IMPROVING ACCESS TO CARDIOVASCULAR CARE

A White Paper from the **Physicians Cardiovascular Disease Working Group**

CONTENTS

1. The Promise of New Treatments

- Newfound Success in Stopping Heart Failure
- New Hope for Curbing High Cholesterol

2. Barriers to Access

- PCSK9 Inhibitors: A Case Study of Patient Barriers
- The Burden of High Cost Sharing
- Step Therapy: Why "Fail First" is Failing Patients
- The Pain of Prior Authorization
- Taking Heart: Forging the Way Forward

Hearth health has long been on the minds of Americans. About 85.6 million people in this country are living with some form of cardiovascular disease (CVD) or the after-effects of stroke.¹ Worldwide, CVD is the cause of 17.3 million deaths per year, a number that is expected to grow.

Cardiovascular disease touches most U.S. households in some way. The great equalizer, it cuts across all ethnicities and income levels as the leading cause of death, claiming the lives of 2,150 Americans daily. That's more deadly than all forms of cancer combined.²

The scope of cardiovascular disease's cost, both financial and in human suffering, should not be underestimated. Heart disease costs the United States an estimated \$30.7 billion per year. And the situation is only going to grow worse: The American Heart Association projects that 40.5 percent of the U.S. population will have some form of CVD by the year 2030.

The good news is that cardiovascular disease sits at the apex of priorities for the U.S. healthcare system. As a result, patients and physicians have access to a range of effective and time-tested treatments, such as statins, beta blockers and ACE inhibitors, as well as life-changing devices, such as pacemakers. Over the past few years, treatment

options have expanded further to include significant new therapies that can help more patients gain better control over their symptoms, experience fewer side effects, and live longer lives with conditions like heart failure, high cholesterol and high blood pressure.

But obstacles threaten patients' access to both new options and old, dissuading or outright preventing them from obtaining the best therapy or device. That's because healthcare concerns are trumped by decisions based on short-term benefits. But by carefully advocating long-term solutions backed by experts—the physicians and providers on the front lines treating cardiovascular disease—we can radically improve the heart health of our nation.

THE PROMISE OF NEW TREATMENTS

Newfound Success in Stopping Heart Failure

When the heart can't pump enough blood to provide oxygen to support other organs, heart failure occurs. The condition affects more than 5 million adults.³

But after the largest study ever of a heart failure treatment, in 2015 the U.S. Food and Drug Administration (FDA) approved a revolutionary new drug combination, sacubitril/valsartan. This treatment enhances

the heart's protective systems while suppressing the chemicals that decrease the heart's function. In the clinical trial the treatment reduced the rate of cardiovascular death by 20 percent and the rate of hospitalization by 21 percent.

Signaling its recognition of the potential importance of this medication, the FDA granted sacubitril/valsartan fast track designation, used by the agency to expedite the review of drugs that fill an "unmet medical need."⁴ The FDA ended the study early based on finding an "overwhelming benefit" to the drug.⁵

New Hope for Curbing High Cholesterol

Lowering high cholesterol is a permanent goal of cardiovascular professionals and those suffering with CVD. Yet until now, the predominant treatment was to use a class of drugs called statins in conjunction with diet and lifestyle modifications. While clearly proven effective in lowering LDL cholesterol and reducing cardiovascular events, the use of statins alone is not enough for some patients.

In 2003, a protein called PCSK9 was discovered. PCSK9 regulates the lifespan of the receptors in liver cells that clear cholesterol from the blood. This discovery led to rapid and innovative pharmaceutical development. In 2015, the FDA approved the first ever PCSK9 inhibitor drugs: alirocumab and

evolocumab, which dramatically reduce the amount of LDL cholesterol in the bloodstream.

Both drugs were approved for patients with known cardiovascular disease or familial hypercholesterolemia (FH) who are on maximally tolerated statin therapy and yet still require additional lowering of LDL cholesterol. FH is a genetic disorder that causes severe, lifelong elevations of LDL cholesterol and dramatically increases the risk of CVD.

In clinical trials, when added to statin therapy, PCSK9 inhibitors resulted in an average reduction in LDL cholesterol that ranged from 36 to 59 percent, compared to treatment with statin plus placebo. By anyone's estimation, a treatment that can lead to a nearly 60 percent reduction in LDL cholesterol on top of maximally tolerated statin therapy is game-changing.

BARRIERS TO ACCESS

PCSK9 Inhibitors: A Case Study of Patient Barriers

Few treatments demonstrate the access challenges associated with breakthrough treatments like PCSK9 inhibitors do. Despite the revolutionary nature of the treatment, insurers still will not reimburse for this new medication for nearly three out of every four patients for whom it has been prescribed.⁶ In the nine months following the launch of PCSK9



“Physicians can cite guidelines and label indications; we can be meticulous in our descriptions of the specifics, the statins that patients have taken previously and their doses, as well as pertinent side effects. But still you get these capricious denials from insurance companies.”

Laurence Sperling, MD

drugs, between 75 and 90 percent of all patients—both those using private insurance and those on Medicare—were not able to fill their prescriptions, according to Symphony Health Solutions, a healthcare analytics firm.⁷

Appropriate prescribing of PCSK9 inhibitors is important. Yet physicians who treat CVD and FH were shocked to find that health plans block even those patients who fit FDA-approved uses from getting the medication.

For example, insurers may require patients to go through the extra step of seeing a specialist such as a cardiologist or endocrinologist in addition to their primary care physician. This could deter patients by requiring additional time and an extra copay.

Cardiac healthcare providers already recognize their responsibility to avoid overprescribing PCSK9 inhibitors and to prescribe according to current indications for treatment. “But blanket rejections by health plans mean that high-risk patients for whom the therapy is FDA approved are denied access to these important medications,” says Pamela Morris, MD, director of the Seinsheimer Cardiovascular Health Program and co-director of Women’s Heart Care at the Medical University of South Carolina.

PCSK9 inhibitors provide a window into the overall issues of CVD treatment access. Other treatments, such as the heart failure medication mentioned above, are also out of reach for many patients, and the barriers seem to favor short-term considerations over long-term cost savings. Here’s why.

The Burden of High Cost Sharing

A medication can help only if a patient can afford to take it as



“If providers prescribe the PCSK9 inhibitors in accordance with the FDA-approved indications,

patients should have access to the treatment.”

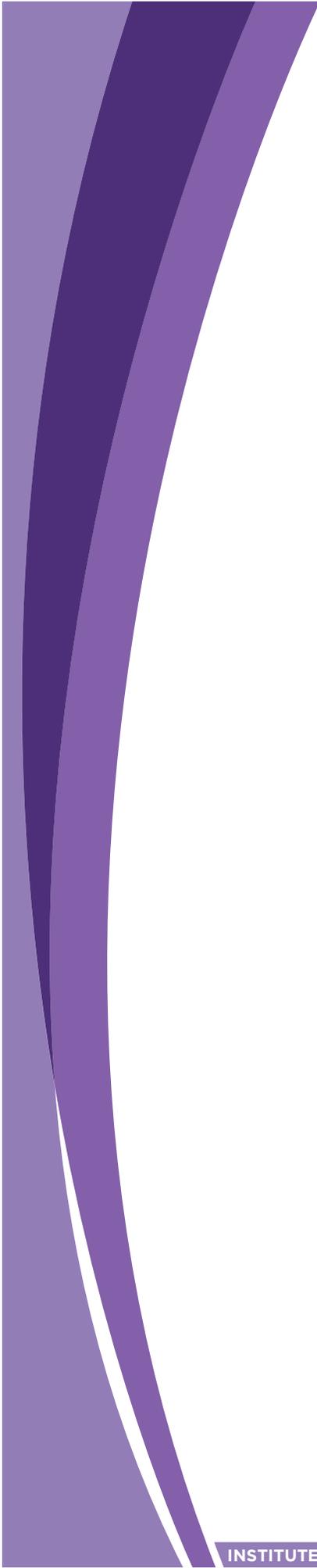
Pamela Morris, MD

prescribed. Even if a patient can get authorization for the best drug to treat his or her symptoms, high copays and deductibles can create yet another barrier.

Adherence to a medication regimen is essential for keeping disease at bay. According to the CDC, improving adherence is paramount to reducing CVD in the United States. Yet cardiovascular patients are falling behind in adherence. A 2015 CDC study of patients with high cholesterol and high blood pressure found that less than half of those diagnosed with hypertension have it controlled at recommended levels and 33 percent of U.S. adults with high LDL cholesterol did not have it controlled at recommended levels.⁸

Healthcare providers find that high drug cost often correlates with low adherence. For the heart failure drug sacubitril/valsartan, the drug manufacturer had said sales of the medication didn’t meet expectations. Early estimates were that 60 percent of Medicare patients would have access to the drug but almost half would have copays of \$100 or higher because the drug is typically listed on the lowest reimbursement tier.⁹

An analysis of PCSK9 inhibitors in late 2015 proposed that the drugs would have to cost \$2,400



per year to be cost effective for patients. In the United States, the PCSK9 inhibitor drugs alirocumab and evolocumab have list prices over \$14,100 per year.¹⁰ This broad cost assessment may have made a critical, and possibly misleading assumption: That everyone who could take PCSK9s would, perhaps indefinitely. This premise led to inflated cost projections and insurance plans skittish to cover a class of drugs that could have significant benefit to patients.

High cost sharing has real consequences for patients, including being priced out of access or forced to ration treatments, and taking reduced doses or delaying refills. We can't allow patients, particularly senior citizens on fixed incomes, to choose between everyday necessities and medication.

Step Therapy: Why "Fail First" is Failing Patients

Disease treatment is an important decision, informed by evidenced-based guidelines and managed by a healthcare provider who carefully considers patient preferences and values. When the provider and patient determine an appropriate course of treatment, the system should support prompt evidence-based therapy and allow patients to improve their health as efficiently as possible. Patients should not be forced to suffer needlessly. And health plan officials should not undermine the physician-patient relationship.

Step therapy, sometimes referred to as "fail first," is a way insurance companies control costs by preferring drugs that have been on the marketplace longer, and therefore are cheaper and have a longer safety record (step-1 drugs). Only when a step-1 drug fails is a patient qualified to move to step-2 drugs.

In reality, though, the best medicines are not always the least expensive. Even if a doctor prescribes a superior, yet higher cost drug, step therapy requires patients to try a cheaper alternative first. The use of step therapy is rising fast; 27 percent of plans used it in 2005 as compared to 67 percent in 2013.¹¹ This restricts a patient's access to evidence-based treatment and values cost considerations over the medical decisions made between patients and doctors.

Insurers' unrestricted ability to force step therapy signals an inappropriate reversal, putting health plans' formulary decisions ahead of doctors' judgement. This approach, which happens in both private and Medicare Part D plans, also represents a misuse of clinical guidelines. Although guidelines may recommend using one drug before another, guidelines are not meant to be interpreted inflexibly. When guidelines are distorted into step therapy mandates, patients can face burdensome and potentially dangerous treatment requirements.

Step therapy also creates unnecessary confusion and complications for high-risk patients. The situation is never starker than when a CVD or FH patient switches insurers—and is forced to re-start step therapy. Patients could simply change jobs, or their health plan could decide to exit the health insurance marketplace. Either scenario can force changes in treatments. A patient's health may suffer if an effective therapy is stopped, particularly if the payer requires initial therapy with a medication that has already proven ineffective or is poorly tolerated.

Additionally, insurance formularies can themselves change year to year, further complicating a patient's

ability to get prescribed treatments. These unpredictable changes add to patient anxiety about what becomes an uncertain path to a prescribed course of treatment.

This is a problem, and not just for new, cutting-edge drugs. Step therapy can apply to traditional treatments such as statins, too.

The Pain of Prior Authorization

For insurers, prior authorization is a set of checks conducted before a plan will agree to pay for a procedure or treatment. For healthcare providers and patients, prior authorization is burdensome, time-consuming paperwork to prove that a doctor's prescribed course of treatment is necessary. Requirements for prior authorizations vary widely between insurers and oftentimes, despite laborious work, claims are still denied.

That's because insurers can make authorization paperwork more complex for the treatments for which they'd prefer not to reimburse. This practice delays a patient's access to treatment. Moreover, the stamina involved in filling out lengthy forms and dealing with rejections and appeals may dissuade a patient from pursuing the treatment altogether.

Working group members report that prior authorization paperwork sometimes requires a nearly impossible level of detail and becomes a time-consuming exercise in futility that takes valuable time and resources away from patient

care. For example, if a doctor is asked by insurers to list every statin a patient has taken, it may be impossible to track down the

information if the patient has switched healthcare plans, jobs, pharmacies or providers. In the future, electronic medical records may help to allow such continuity, but the system isn't comprehensive enough to fill the gap yet.

In some states, prior authorizations may impose an added burden. One North Carolina health insurance plan now requires physicians to pay \$250 to file a second appeal of an adverse insurer decision. This fee may discourage physicians from continuing to fight for their patients' access to necessary treatment.

National surveys confirm that the current application of prior authorization is a substantial burden on healthcare providers, costing the U.S. healthcare system between \$23 and \$31 billion each year, or about \$83,000 to \$85,000 per physician. The American Medical Association acknowledges the problem and has called for standardizing prior authorization.¹²

Some physicians have identified creative ways to prove the medical effectiveness that insurance companies require. Physicians can, for example, give samples of cardiac drugs to patients for a month or two, document improvements, and then submit the information to healthcare plans. The approach will not help patients and physicians in academic medical centers, however, where physicians are prohibited from accepting medical samples.



“Even when we overwhelm health plans with data, the patient’s treatment can still be denied coverage.”

Seth Baum, MD



“Health plans are not only limiting access to novel therapies based on their aversion to increased cost, but also limiting access to providers—especially those who have the autonomy to act as the best patient advocates.”

Daniel J. Humiston, MD

One physician noted that reauthorization of PCSK9 inhibitors may be denied if a patient’s health is “too good” on the treatment.

As with high copays, the result of lengthy prior authorizations for new medications is delay in initiation of therapy, lack of adherence to a treatment regimen, more hospital visits and higher long-term costs to the healthcare system.¹³

Taking Heart: Forging the Way Forward

The American Heart Association has stated that prevention strategies are essential to limiting the growing burden of cardiovascular disease on the healthcare system. Rising healthcare costs means that all stakeholders—patients, healthcare providers, policymakers and the public alike—must decide how to best use public funds to encourage public health.

Insurers’ efforts to cut spending alone will not solve the problem because payers have structured their reimbursement protocols on short-term considerations versus long-term outcomes. Regulators and policymakers need to steer a path that will help. And the physician’s voice must inform healthcare policies, helping to shape how plans get new treatments to patients. Following the passage of the Affordable Care Act, there has been an increase in physicians elected

to state legislatures as healthcare professionals recognize they must be involved to change the system.

State legislatures, in turn, are becoming a laboratory for laws that tackle prior authorization and step therapy. For example, Maryland passed a law in 2013 that requires certain insurers to accept the prior authorization of another insurer. And during the 2015-2016 session, several states passed legislation that limits “fail first,” including New York, Illinois, Indiana and Missouri. Some bills create a route for physicians and patients to bypass step therapy altogether.

Although cost-conscious healthcare decisions are important to the stability of our system, price considerations shouldn’t come between the decisions made at the bedside between patients and doctors. By following the example of states working to overcome barriers to access, we as a nation can achieve better outcomes for long-term cardiovascular health and ensure the doctor-patient relationship remains the cornerstone of our healthcare model.

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Please note that the views expressed in this document do not necessarily reflect those of the institutions with which working group members are affiliated.

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Formed in 2016, the Physicians Cardiovascular Disease Working Group is a home for physicians interested in public policy issues relating to access to therapies for cardiovascular conditions. Working group members collaborate in the development of educational resources and participate in advocacy initiatives that promote informed policymaking. To learn more, visit www.AllianceforPatientAccess.org.



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