PARTNERSHIP TO ADVANCE
Cardiovascular
Health

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Stephen Robertson
311 W. Washington Street
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Indianapolis, IN 46204

RE: Progress for cardiovascular patients in Indiana

Dear Commissioner Robertson:

The Partnership to Advance Cardiovascular Health (PACH) is a 501(c)(4) nonprofit advocacy coalition of stakeholder groups that represent patients, patient advocates, health care providers and medical researchers in the cardiovascular space. On behalf of its members, PACH advocates for patient access to FDA-approved therapies and promotes innovation in cardiovascular health care for the millions of Americans who are at high risk for heart disease.

We believe that insurance commissioners have a unique regulatory role to ensure fairness in a market so that consumers may receive the life saving therapies their clinicians prescribe and for which they have paid for in their premiums, and we want to provide you with critical information about systemic challenges cardiovascular patients face.

Stalled Progress on Reducing Cardiovascular Deaths

Given PACH's commitment to heart health, you can understand the alarm our organization's members feel about emerging trends in cardiovascular health. America's progress in decreasing the rates of death from heart disease and stroke has stalled, as reported by the *Wall Street Journal* on June 21. The death rate for cardiovascular disease, including heart disease and strokes, has fallen just 4% since 2011. That's after dropping more than 70% over the six decades prior. Particularly alarming is that certain age and demographic groups are actually seeing increases in the rate of cardiovascular related death.[1] Cardiovascular disease accounts for approximately one in three deaths in America each year.[2]

The latest data available from the American Heart Association for the state of Indiana shows that 14445 people died of heart disease, making it the number number 1 killer in the state. 3150 people died from stroke in the state in 2017, making it the number number 5 killer in Indiana.[3]

These numbers are striking when you consider that scientists' understanding of cardiovascular disease, and the options for medications and devices to treat heart conditions, have never been greater. However, we increasingly hear from patients and providers that access to therapies are systemically denied, switched or are otherwise out of reach for the most vulnerable heart patients.

PCSK9 Inhibitors & Access to Preventive Treatment

One of the most egregious examples where market access has been systemically restricted for consumers is the PCSK9 inhibitor (PCSK9i) drug class, and it provides a strong example for what cardiovascular patients increasingly face today across cardiovascular medication classes, devices and even diagnostic testing.

PCSK9 inhibitors are medications that have come to market in the last five years that have proven to significantly reduce the rates of heart attack, stroke and even death. These therapies are appropriate for patients with high lipids that have not responded to traditional statin therapy and are particularly effective for those who have familial hypercholesterolemia (FH), among other patient groups.

PACH has heard from patients and providers across the country that access to these therapies has been restricted at an unprecedented level. Last year, the Institute for Patient Access found that nearly 60% of patients with commercial insurance plans were denied access to a PCSK9 inhibitor.[4] In some states, nearly every claim was denied. This data is publicly available on our website, where you can find data for your state broken down by demographics and risk factors.

Cost is clearly an issue, but even where list prices have been lowered by 60%, patients are not achieving access to these therapies. Further, it is our understanding that both commercial plans and Medicare alike have failed to adopt the lower list prices, forcing patients to pay co-insurance based on the higher list price—or in some cases, abandon their medication at the pharmacy counter, with tragic outcomes.[5] Data released in July from the FH Foundation shows that those who are rejected or abandon their medication are *16% more likely to suffer a cardiovascular event*.[6] This issue has had such an impact that the Congressional Heart and Stroke Coalition expressed concern to Secretary Alex Azar at Health and Human Services. That letter is enclosed here for your reference.

PCSK9i access challenges are partly caused by onerous prior authorization requirements. A recent Penn Medicine study published in *Circulation* found that "prior authorization requirements for PCSK9 inhibitors were substantially more burdensome than those for the comparator drugs, involving three to 11 times the number of required items to be filled out on the prior authorization

form and more frequent demand to justify responses to individual items with medical record submissions."[7]

PACH has identified one potential solution that would help ease the paperwork burden experienced by providers: The American Society for Preventive Cardiology has created a 1-page uniform prior authorization form (enclosed) that would help ameliorate the clerical reasons for denial. We recommend it to insurers in your state.

PACH as a Resource

Again, PCSK9i therapy serves only as an example for what cardiovascular patients in your state are facing today. Many medications, devices and even diagnostic tests in the cardiovascular space are facing unprecedented utilization management barriers, and studies now show that these access restrictions contribute to increased cardiovascular events. In your critical regulatory role ensuring appropriate market access, we write today to offer our organization as a resource to your office. We will also look forward to outreaching to state legislators and health plans so that together we can work to prevent cardiovascular events by promoting patient-centered care. I can be reached at rgough@advancecardiohealth.org.

Sincerely,

Ryan Gough
Executive Director
Partnership to Advance Cardiovascular Health

Enclosures

1. Mackay, Betsy. “Heart Attack at 49—America’s Biggest Killer Makes a Deadly Comeback.” *Wall Street Journal* , 21 June 2019, www.wsj.com/articles/after-decades-of-progress-america-backslides-on-heart-disease-11561129106?mod=searchresults&page=1&pos=15.
2. *Heart Disease and Stroke Statistics-2019 At-a-Glance*. American Heart Association, 2019, professional.heart.org/idc/groups/ahamah-public/@wcm/@sop/@smd/documents/downloadable/ucm_503396.pdf.
3. “Quality Systems of Care Across the U.S.” Www.heart.org, American Heart Association, www.heart.org/en/about-us/policy-research/quality-systems-of-care-across-the-us.
4. *National Statistics: PCSK9 Inhibitors*. Institute for Patient Access, 2019, *National Statistics: PCSK9 Inhibitors*, instituteforpatientaccess.org/wp-content/uploads/2019/03/IfPA_National-Report-Card_PCSK9-Access_March-2019.pdf.
5. Wilkerson, John. “PBMs Reluctant To Place Repatha On Lower Tiers Despite List-Price Cut.” *Inside Health Policy*, 26 Feb. 2019, insidehealthpolicy.com/inside-drug-pricing-daily-news/pbms-reluctant-place-repatha-lower-tiers-despite-list-price-cut.
6. Myers, Kelly, et al. “Effect of Access to Prescribed PCSK9 Inhibitors on Cardiovascular Outcomes.” Circulation: Cardiovascular Quality and Outcomes, American Heart Association, 23 July 2019, www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.118.005404.
7. Doshi, Jalpa, et al. “Prior Authorization Requirements for Proprotein Convertase Subtilisin/Kexin Type 9 Inhibitors Across US Private and Public Payers.” *Circulation: Cardiovascular Quality and Outcomes*, 11 Jan. 2018, www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.117.003939.