Ryan Gough, Executive Director
Partnership to Advance Cardiovascular Health
2020 K Street NW
Suite 505
Washington, DC 20006

December 2, 2021

Troyen Brennan, MD, Chief Medical Officer
CVS Health
One CVS Drive
Woonsocket, RI 02895

Dear Dr. Brennan,

The Partnership to Advance Cardiovascular Health (PACH) is a non-profit cardiovascular stakeholder coalition of patient, provider and advocacy organizations dedicated to advancing public policies and practices that accelerate innovation and improve cardiovascular health for patients. As a platform for patients and providers, PACH advocates at the federal, state and health plan levels for reforms that increase access and personalized care for patients with cardiovascular and related conditions.

**Concerning Changes to CVS's Commercial Formulary**

We write today to express concern about CVS's recent decision to remove all but one direct oral anticoagulant (DOAC) from its commercial pharmacy benefit plan.

As you know, DOACs are used to treat and prevent blood clots and to prevent stroke in people with nonvalvular atrial fibrillation. DOACs are also the mainstay treatment for deep vein thrombosis (DVT) and pulmonary embolism (PE), collectively referred to as venous thromboembolism (VTE). The removal of all but one DOAC option from formulary means that stable patients who are at high risk of stroke and other cardiovascular events will be forced to switch their anticoagulation therapy in the 2022 plan year. It also appears that there is no option for current, stable patients to be grandfathered into the new plan year on their previously covered DOAC therapy.

This abrupt change will be dangerously disruptive for patients currently on therapy and reliant upon a previously covered DOAC to manage their cardiovascular risk.

## How Non-Medical Switching Endangers Patients

Sudden and disruptive formulary changes that upset care for stable patients pose a growing challenge, so much so that they assumed the name "non-medical switching."

Non-medical switching, such as the change that CVS is instituting, occurs when a managed care plan changes its formulary or cost-sharing requirements in a way that forces stable patients off their prescribed medication. Non-medical switching is problematic for both patients and providers because it actively discourages adherence to therapy and increases the paperwork burden for clinicians and their staff.

In a national poll of patients – including those with cardiovascular disease – nearly 40% who had their medication regimen switched stopped taking their medicine altogether.[1] Nearly 60% noted one or more complications due to a non-medical switch, including re-emergence of previously controlled symptoms, side effects or adverse interaction with other medications. Additionally, 40% of switched patients reported increased frequency of visits to their clinician, and 1 in 10 required hospitalization after being switched. Visits like these lead to an increased burden for patients but also increased costs to the health care system.

For patients on anticoagulant therapy in particular, nonadherence can be debilitating, even deadly.

Atrial fibrillation (AF) is the most common cardiac arrythmia in the United States, and patients with AF are five times more likely to experience an ischemic stroke. In fact, patients who abandon anticoagulant therapy have a risk of ischemic stroke that is 2-3 times higher than those who continue therapy.[2] Venous thromboembolism is the third most common life-threatening cardiovascular disease in the United States. And for some PE patients, risk of a recurrent VTE is 10% in the first year after stopping anticoagulation and 5% per year after.[3] Any utilization management protocol that discourages adherence – as non-medical switching does – only invites disaster for patients.

Furthermore, this switch will disproportionately affect historically disadvantaged patients, making it only more difficult for them to navigate an already complicated healthcare system. As a result, patients who can least afford the change will be left with limited options and are likely to give up on the medication regimen prescribed by their doctor. This will unquestionably exacerbate health equity concerns that exist in cardiovascular care.

## Non-Medical Switching Compounds Grim Cardiovascular Trends

Policies like this one could not come at a worse time for cardiovascular patients. America's progress in decreasing the rates of death from heart disease and stroke has stalled. 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.[4]

Particularly alarming, certain age and demographic groups are seeing increases in the rate of cardiovascular-related death. Tactics like non-medical switching only exacerbate these trends.

**Course Correction Can Protect At-Risk Patients**

Given the risks posed by non-medical switching, we urge you to allow patients who have been successfully managing their atrial fibrillation and other symptoms with a specific DOAC therapy to maintain their current treatment. As you know, patients on anticoagulation therapy are managing a complex disease and often several comorbidities that increase stroke risk. Many undertook years of trial and error before becoming stable.

Given the work patients and providers have undertaken, as well as the daily risk these patients face, we strongly urge CVS to continue coverage for patients who are already established on a specific DOAC medication.

Doing so would encourage adherence, honor the decisions made by patients and their providers, and clearly prioritize the health and well-being of patients who face cardiovascular risk.

Thank you for your consideration, and we look forward to continued dialogue at rgough@advancecardiohealth.org or at (202) 964-2644.

Sincerely,

Ryan Gough
Executive Director, PACH
rgough@advancecardiohealth.org
(202) 964-2644

cc: Superintendent Elizabeth Kelleher Dwyer

AIMED ALLIANCE
AfPA Alliance for Patient Access
ASPC
ABC Association of Black Cardiologists, Inc. Saving the Hearts & Minds of a Diverse America
GHLF
Mended Hearts
NHMA National Hispanic Medical Association
Partnership to Advance Cardiovascular Health
Anticoagulation FORUM Always Learning. Forever Leading.
National Minority Cardiovascular Alliance
National Blood Clot Alliance Stop The Clot®
PCNA Preventive Cardiovascular Nurses Association
StopAfib.org
WOMENHEART The National Coalition for Women with Heart Disease

[1] A Study of the Qualitative Impact of Non-Medical Switching. *Alliance for Patient Access.* February 2019.

[2] García R, L., Cea SL, Munk H, et al. Discontinuation of oral anticoagulation in atrial fibrillation and risk of ischaemic stroke. *Heart* 2021; 107(7): 542-548.

[3] Kearon C, Akl EA, Ornelas J, et al. Antithrombotic Therapy for VTE Disease: CHEST Guideline and Expert Panel Report. *Chest* 2016;149:315-352.

[4] Mckay B. Heart Attack at 49 – America's Biggest Killer Makes a Deadly Comeback. *The Wall Street Journal.* June 21, 2019.