

March 31, 2020

[Address Block]

Re: Improving Access to Care for Individuals with High-Risk Conditions

Dear Governor [Name]:

Aimed Alliance is a 501(c)(3) non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are writing on behalf of the undersigned organizations. As you know, the COVID-19 outbreak was declared a national emergency on March 13, 2020. The Centers for Disease Control and Prevention (CDC) has identified a number of patient populations that are at a heightened risk for severe illness and death if they contract COVID-19. To protect these high-risk patients, Aimed Alliance asks you to 1) prevent health insurers from imposing prior authorization requirements and 2) require insurers to approve health practitioners' step therapy exemption requests for these patients' treatment for the duration of the public health emergency. Doing so will create a greater likelihood that these patients' underlying health conditions remain under control should they contract COVID-19.

A. High-Risk Patient Populations

According to the CDC, older adults and people of any age who have serious underlying medical conditions might be at higher risk for severe illness from COVID-19.² In particular, CDC has noted that such high-risk individuals could include those who are immunocompromised; those who are pregnant; and those with chronic lung disease, moderate-to-severe asthma, serious heart conditions, severe obesity, diabetes, renal failure, or liver disease.³ The CDC has stated that these individuals are most vulnerable to severe acute respiratory infection secondary to COVID-19, which can result in death. Immunocompromised or immunosuppressed individuals – individuals with cancer, autoimmune diseases (e.g., rheumatoid arthritis, lupus, multiple sclerosis, and inflammatory bowel disease), and HIV – also have a diminished ability to fight off infection and heal due to compromised immune systems.⁵ Patients with cardiac conditions, such as coronary artery disease, heart failure, and hypertension, are at an increased risk of acute coronary syndromes associated with severe inflammatory response to the infection; myocardial depression leading to heart failure; and under-recognized risk of arrhythmias related to acute inflammation.⁶

A study of 1,590 patients in China found that people infected with the coronavirus who were already coping with a chronic condition were 1.8 times more likely to have a "poor outcome," such as being put on a ventilator or dying, than those with no underlying conditions. As such,

¹ https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novelcoronavirus-disease-covid-19-outbreak/

² https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/people-at-higher-risk.html

³ https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/people-at-higher-risk.html

⁴ https://www.nursingcenter.com/ncblog/march-2020/covid-19-highest-risk

⁵ https://www.nursingcenter.com/ncblog/march-2020/covid-19-highest-risk

⁶ https://www.nursingcenter.com/ncblog/march-2020/covid-19-highest-risk

⁷ https://www.nytimes.com/2020/03/12/health/coronavirus-midlife-conditions.html

patients with one or more of these conditions need access to treatments and services to successfully manage their health and reduce their chances of developing severe COVID-19 symptoms, which present the greatest risk of mortality.⁸

B. Prior Authorization and Step Therapy

Aimed Alliance recommends that you require state-regulated health plans to offer coverage for treatment for these high-risk conditions for the duration of the public health emergency. These services should be covered without step therapy if a patient's health care provider deems the treatment medically necessary and without prior authorization.

Step therapy policies require insured individuals to try and fail on alternative treatments specified by a health plan, sometimes with adverse effects, before the health plan will cover the prescribed treatment. Due to rising health care costs, health plans often use step therapy as a cost-containment technique. When step therapy is used appropriately, it can steer patients towards less risky and lower cost treatments as first-line treatment options. However, some step therapy policies are inconsistent with sound scientific and clinical evidence, require patients to try and fail on the same treatment multiple times, and do not have adequate exceptions processes in which a practitioner can submit a request to the health plan to override the step therapy protocol. In such instances, step therapy can interfere with the professional-patient relationship, cause care delays that interrupt disease stability, and result in disease progression and relapse thereby increasing health care utilization. To ensure that patients have appropriate access to treatment during this public health emergency, insurers should be required to automatically approve any health care practitioner's request for a step therapy exemption if the patient has a high-risk condition.

Prior authorization policies require a health care provider or an insured individual to obtain approval from the health plan before the plan will cover the cost of a health care product or service. Prior authorization is often used by health plans as a cost-containment measure intended to prevent health care professionals from prescribing high-cost treatments and services that are not medically necessary. However, prior authorization standards can be inconsistent with medical standards of care. Additionally, health plans sometimes use outmoded methods of communication when accepting requests for prior authorization, such as fax or mail, which can be unreliable. Plans may also take several days, or even weeks, before responding to a prior authorization request. When prior authorization is used inappropriately, it can cause care delays that prevent patients from accessing medically necessary treatments and services when they are needed. These care delays can cause disease progression and relapse that can result in increased

⁸ See, e.g., https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/asthma.html; https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/get-ready.html

https://www.goodrx.com/blog/what-is-step-therapy-how-to-get-insurance-to-pay-for-your-non-preferred-drug/

¹⁰ https://www.goodrx.com/blog/what-is-step-therapy-how-to-get-insurance-to-pay-for-your-non-preferred-drug/

¹¹ https://scholarlycommons.law.case.edu/cgi/viewcontent.cgi?article=3009&context=faculty_publications; https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/

¹² https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/

¹³ https://www.verywellhealth.com/prior-authorization-1738770

¹⁴ https://www.verywellhealth.com/prior-authorization-1738770

¹⁵ https://www.everydayhealth.com/cancer/prior-authorization-requirements-delay-interfere-with-cancer-treatment/

¹⁶ https://www.rheumatology.org/Portals/0/Files/Issue-Brief-Prior-Authorization-Process.pdf

¹⁷ https://healthpayerintelligence.com/news/prior-authorization-issues-contribute-to-92-of-care-delays

health care utilization.¹⁸ To ensure that patients have appropriate access to treatment during this public health emergency, insurers should be prohibited from using prior authorization for therapies that treat high-risk conditions.

Additionally, we request that you clarify that these changes not only apply to medications purchased in retail settings, but also therapies that are only available through specialty pharmacies. Currently, many of the orders, regulations, and policies granting new access to care during the public health emergency do not explicitly state whether they apply to both medications purchased at a retail setting and through specialty pharmacies. Without such clarity, providers and payers are uncertain how to proceed.

Coverage of these treatments will assist patients with high-risk conditions in successfully managing their health. The risk for serious illness from a COVID-19 infection could be significantly reduced if the underlying high-risk condition is well managed.¹⁹ Implementing this policy could save the lives of many high-risk patients and could reduce the overall need for hospitalization or admission to an intensive care unit, thereby reducing healthcare utilization at a time when hospitals have already reached their capacity.

In the midst of an unprecedented public health crisis, we ask you to take these measures to successfully protect your residents and prevent unnecessary deaths. Thank you for considering our recommendations for addressing the threat of COVID-19 in your state. Please contact us at policy@aimedalliance.org to discuss this matter further.

Sincerely,

Aimed Alliance

American Autoimmune and Related Diseases Association

American Partnership for Eosinophilic Disorders

Bridge the Gap - SYNGAP Education and Research Foundation

Chronic Disease Coalition

Coalition of State Rheumatology Organizations

Conquer Myasthenia Gravis

Cured Foundation

Global Healthy Living Foundation

Headache and Migraine Policy Forum

International Foundation for Autoimmune & Autoinflammatory Arthritis

Lupus and Allied Diseases Association

Myostitis Association

National Infusion Center Association

Patients Rising Now

Platelet Disorder Support Association

The American Behcet's Disease Association

The American Brain Coalition

The Gluten Intolerance Group of North America

¹⁸ https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/485447

¹⁹ https://www.aarp.org/health/conditions-treatments/info-2020/chronic-conditions-coronavirus.html

The National Adrenal Diseases Foundation The Sjögren's Foundation The Vasculitis Foundation