AIMED ALLIANCE

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Demetrios Kouzoukas,
Principal Deputy Administrator for Medicare and Director
The Centers for Medicare and Medicaid Services
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Re: Medicare Coverage During the Coronavirus Pandemic

Dear Ms. Verma and Mr. Kouzoukas:

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. As you know, the COVID-19 outbreak was declared a national emergency on March 13, 2020.[1] Aimed Alliance is writing on behalf of the undersigned patient advocacy groups.

The Centers for Disease Control and Prevention (CDC) continues to identify a number of patient populations that are at a heightened risk for severe illness and death if they contract COVID-19. To protect high-risk beneficiaries, the undersigned organizations ask the Centers for Medicare and Medicaid Services (CMS) to levy its emergency authority under Section 1135 of the Social Security Act (SSA) by issuing a blanket waiver of certain prior authorization and step therapy requirements in Medicare Advantage (MA) and Part D plans for the duration of the public health emergency.[2] More specifically, the waiver would permit health care providers to administer or prescribe Part B or Part D medications to treat high-risk beneficiaries, and would allow for the coverage and payment of such medications, without having to comply with the plans' prior authorization and step therapy requirements. A beneficiary would be considered high risk if he or she has a serious underlying medical condition as determined by the CDC or by his or her health care provider. Granting such a waiver will create a greater likelihood that these beneficiaries' underlying health conditions remain under control should they contract COVID-19.

A. High-Risk Patient Populations

According to the CDC, adults who are 65 years and older are at higher risk for severe illness from COVID-19.[3] In fact, eight out of 10 deaths reported in the U.S. have been in adults 65 years old and older. That risk is heightened if the person has a serious underlying medical condition.[4] The CDC has identified the following list as examples of serious underlying medical

[1] https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/
[2] 42 U.S.C. § 1320b-5.
[3] https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/people-at-higher-risk.html
[4] https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/people-at-higher-risk.html

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conditions: chronic lung disease, moderate-to-severe asthma, serious heart conditions, conditions causing a person to be immunocompromised (e.g., cancer, autoimmune conditions, and HIV), obesity, diabetes, chronic kidney disease, and liver disease.[5] The list has continued to grow as health experts and scientists learn more about COVID-19. Additionally, health care practitioners can determine if their patients' medical conditions place them at high risk based on their medical judgement, even if that condition is not currently on the CDC list.

Data supports the supposition that Medicare beneficiaries who are both 1) 65 years or older; and 2) have underlying chronic medical conditions, are even more at risk. A study of 1,590 patients in China found that while just 1.3 percent of patients with COVID-19 in their 50s died, the death rate rose with each additional decade of life, increasing to 3.6 percent for patients in their 60s, 8 percent for patients in their 70s, and 15 percent for those in their 80s or older.[6] Additionally, people infected with COVID-19 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.[7] As such, older patients with one or more underlying 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]

In light of the heightened COVID-19 risk to persons with certain underlying medical conditions, it is important that high-risk individuals have access to medical treatments needed to stabilize their underlying conditions. Unfortunately, medications used to treat many serious underlying medical conditions are frequently subjected to prior authorization and step therapy requirements by health plans.

B. Prior Authorization and Step Therapy

The undersigned organizations recommend that CMS use its emergency authority under Section 1135 of SSA to waive certain prior authorization and step therapy requirements in MA and Part D plans for the duration of the public health emergency.[9] The waiver would permit health care providers to administer or prescribe Part B or Part D medications to treat high-risk beneficiaries, and would allow for the coverage and payment of such medications, without having to comply with the plans' prior authorization and step therapy requirements. A Medicare beneficiary should be deemed "high risk" if 1) he or she has a condition identified by the CDC as "a serious underlying medical condition"; or 2) the beneficiary's health care practitioner certifies that the beneficiary has a serious underlying medical condition that, in the practitioner's opinion, places the patient at high risk.

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

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[5] https://www.cdc.gov/coronavirus/2019-ncov/specific-groups/people-at-higher-risk.html
[6] 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
[7] https://www.nytimes.com/2020/03/12/health/coronavirus-midlife-conditions.html
[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
[9] 42 U.S.C. § 1320b-5.

service.[10] 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.[11] However, prior authorization standards can be inconsistent with medical standards of care.[12] 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.[13] 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.[14] These care delays can cause disease progression and relapse that can result in increased health care utilization.[15] A 2018 AMA physician survey found that 91% of physicians reported that prior authorization requirements can have a significant or somewhat negative impact on patient care and 28% of physicians report that prior authorization requirements have led to a patient experiencing a serious adverse health event (e.g., death, hospitalization, disability/permanent body damage, or other life threatening event), highlighting the concerning impact prior authorization requirements have on patient care.[16] To ensure that beneficiaries have appropriate and timely access to treatment during this public health emergency, Medicare plans should be prohibited from using prior authorization for therapies that treat high-risk beneficiaries.

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.[17] When step therapy is used appropriately, it can steer patients towards less risky and lower cost treatments as first-line treatment options.[18] However, some step therapy policies are inconsistent with sound scientific and clinical evidence and require patients to try and fail on the same treatment multiple times.[19] The American Medical Association (AMA) and other medical organizations have raised concerns that step therapy requirements can undercut the provider-patient decision-making process, and can harm patients by causing treatment delays and unnecessary complications.[20] Such delays and complications can interrupt disease stability, result in disease progression, and thereby increase health care utilization.[21] While step therapy requirements can be burdensome on patients and prescribers, these burdens are exacerbated by the COVID-19 crisis. As such, to ensure that beneficiaries have appropriate and timely access to treatment during this public health emergency, Medicare plans should be required to automatically waive step-therapy requirements for high-risk beneficiaries.

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[10] https://www.verywellhealth.com/prior-authorization-1738770
[11] https://www.verywellhealth.com/prior-authorization-1738770
[12] https://www.everydayhealth.com/cancer/prior-authorization-requirements-delay-interfere-with-cancer-treatment/
[13] https://www.rheumatology.org/Portals/0/Files/Issue-Brief-Prior-Authorization-Process.pdf
[14] https://healthpayerintelligence.com/news/prior-authorization-issues-contribute-to-92-of-care-delays
[15] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/485447
[16] https://www.ama-assn.org/media/42426/download.
[17] https://www.goodrx.com/blog/what-is-step-therapy-how-to-get-insurance-to-pay-for-your-non-preferred-drug/
[18] https://www.goodrx.com/blog/what-is-step-therapy-how-to-get-insurance-to-pay-for-your-non-preferred-drug/
[19] 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/
[20] See, e.g., https://searchlf.ama-assn.org/undefined/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2018-9-10-Signed-on-Letter-to-Verma-re-Step-Therapy.pdf; https://www.asco.org/practice-policy/policy-issues-statements/asco-in-action/media-issue-brief-utilization-management
[21] https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments/

Additionally, we request that you clarify that these changes apply to medications under both Part B and Part D. 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 classifications of medication. Without such clarity, providers and payers are uncertain how to proceed.

C. Authority

CMS has the authority to issue a blanket waiver of MA and Part D plans' prior authorization and step therapy requirements for the duration of the COVID-19 emergency. SSA § 1135 permits CMS to waive or modify Medicare, Medicaid, and Children's Health Insurance Program (CHIP) requirements during an emergency period to ensure that health care items and services are sufficiently available to meet beneficiaries' needs.[22] Two requirements must be met before CMS may invoke waiver authority: 1) the President must declare a national emergency or disaster; and 2) the Secretary of HHS must declare a public health emergency.[23] Both of these prerequisites were met as of March 13, 2020.[24]

SSA § 1135 permits Medicare coverage and payment in circumstances where payment would otherwise be barred.[25] In particular, SSA § 1135 allows CMS to issue a temporary waiver of regulations pertaining to "pre-approval requirements" for items or services furnished by a health care provider in any emergency area during any portion of the emergency period.[26] CMS defines "prior authorization" as "approval that you must get from a Medicare drug plan before you fill your prescription in order for the prescription to be covered by your plan" – in other words, a pre-approval.[27] Additionally, CMS describes "step therapy" as "a type of prior authorization for drugs."[28] As such, CMS has the authority to issue a 1135 blanket waiver of prior authorization and step therapy requirements, thereby allowing for the coverage of and payment for medications for high-risk Medicare beneficiaries without requiring a health care practitioner to first obtain pre-approval from a Medicare plan.

CMS has already levied this authority in response to the COVID-19 public health emergency. For example, on March 16, 2020, CMS granted Florida a § 1135 waiver, which waived, among other things, prior authorization requirements in its state Medicaid plan.[29] As of April 13, 2020, CMS has granted waivers to 40 states to suspend fee-for-service prior authorization requirements.[30] CMS has also issued several 1135 blanket waivers for health care providers.[31] CMS could allow for similar changes to MA and Part D plans.

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[22] SSA § 1135(b)(1); https://www.medicaid.gov/resources-for-states/disaster-response-toolkit/section-1135-waiver-flexibilities/index.html.
[23] https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf
[24] https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf
[25] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c38.pdf
[26] SSA § 1135(b)(1)
[27] https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover/drug-plan-coverage-rules#
[28] https://www.cms.gov/newsroom/fact-sheets/medicare-advantage-prior-authorization-and-step-therapy-part-b-drugs
[29] https://www.medicaid.gov/state-resource-center/downloads/fl-section-1135-appvl.pdf
[30] https://www.kff.org/medicaid/issue-brief/medicaid-emergency-authority-tracker-approved-state-actions-to-address-covid-19/
[31] https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

Additionally, CMS has also set a precedent for removing both step-therapy and prior authorization requirements for much needed medications during the current public health emergency. On March 24, 2020, CMS released a memo entitled "FAQs on Prescription Drugs and the Coronavirus Disease 2019 (COVID-19) for Issuers Offering Health Insurance Coverage in the Individual and Small Group Markets."[32] In it, CMS stated that in addressing any potential drug shortage, insurers should "work with their enrollees and providers to provide coverage for therapeutically equivalent non-formulary drugs as prescribed by the enrollee's provider, and waive prior authorization or step therapy for therapeutically equivalent formulary drug products."[33]

Therefore, we believe CMS has sufficient legal authority to do the same thing for Medicare beneficiaries: suspend step therapy and prior authorization requirements to ensure that high-risk beneficiaries with serious underlying medical conditions and their health care providers are spared the heightened burdens that these requirements would otherwise cause during the COVID-19 public health emergency.

D. Conclusion

Improved access to these treatments will assist Medicare beneficiaries with underlying conditions in successfully managing their health. The risk for serious illness from a COVID-19 infection could be significantly reduced if the underlying condition is well managed.[34] Implementing this policy could save the lives of many Medicare beneficiaries and could reduce the overall need for hospitalization or admission to an intensive care unit, thereby reducing health care 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 Medicare beneficiaries and prevent unnecessary deaths. Thank you for considering our recommendations for addressing the threat of COVID-19 among Medicare beneficiaries. Please contact us at policy@aimedalliance.org to discuss this matter further.

Sincerely,

[organizations]

[32] https://www.cms.gov/files/document/faqs-rx-covid-19.pdf
[33] https://www.cms.gov/files/document/faqs-rx-covid-19.pdf
[34] https://www.aarp.org/health/conditions-treatments/info-2020/chronic-conditions-coronavirus.html