April 15, 2020

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

Dear Ms. Verma and Mr. Kouzoukas:

The National Minority Quality Forum (NMQF) is a 501(c)(3) not-for-profit, non-partisan, independent research and education organization that was founded in 1998 to address the critical need to enable evidence-based, data-driven initiatives to eliminate inequities in morbidity and mortality for all populations, with particular focus on those that were underserved, and underrepresented in clinical research.

Overview of the Issue
Following President Trump’s declaration of a national emergency concerning the novel coronavirus disease (COVID-19) outbreak,¹ it became clear that the coronavirus pandemic presents unparalleled challenges to the U.S. healthcare system, and threatens the health and sustainability of communities nationwide. Moreover, 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, including adults aged 65 years and older, African Americans, and individuals with underlying chronic health conditions such as, diabetes, heart disease, and lung disease. These alarming facts (this alarming reality) lead President Trump to acknowledge that the virus appears to be infecting and killing African Americans at a disproportionately higher rate and committing the Administration to address this health disparity.

In support of President Trump’s commitment, we urge you to require all Medicare plans, including Medicare Advantage (MA) and Part D prescription drug plans, to temporarily suspend prior authorization or step-therapy requirements for Medicare Part B and Part D medications to help assure that Medicare beneficiaries adequately protected should they become infected with Coronavirus or contract COVID-19.

It is our understanding that the Centers for Medicare and Medicaid Services (CMS) can use the emergency authority afforded to the Agency under Section 1135 of the Social Security Act (SSA)² to require that Medicare Advantage (MA) and Part D plans waive all prior authorization and step therapy restrictions for Medicare Part B and Part D medicines during the Coronavirus/COVID-19 emergency.

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Doing so will better protect these beneficiaries by increasing the likelihood that these beneficiaries’ underlying health conditions remain under control should they contract COVID-19.

**Disproportionate Impact of COVID-19 on High-Risk and Minority Populations**  
Although no one is immune to the spread of Coronavirus or COVID-19, certain populations are more vulnerable than others to serious complications as a result of a coronavirus infection. The Centers for Disease Control and Prevention (CDC) identifies people aged 65 years and older (i.e., the Medicare population) as particularly vulnerable to serious COVID-19 illness.\(^3\) That risk is heightened if the person has any underlying medical condition, including a range of specified chronic diseases.\(^4\) Moreover, as COVID-19 sweeps across the United States, it appears to be infecting and killing African Americans and other minority populations at a disproportionately higher rate. On April 8, 2020, the CDC released data that examined approximately 1,500 patients hospitalized due to the coronavirus across 14 different states. Although the CDC only had race data for 580 of the 1,500 patients, the data indicate that African Americans are being disproportionately impacted by COVID-19 as African Americans accounted for 33 percent of patients hospitalized even though they only make up 18 percent of the U.S. population\(^5\). Moreover, the analysis below depicts available data and census demographics regarding the regions nationwide that have a majority of African American citizens have three times the rate of COVID-19 infections, and almost six times the rate of deaths as regions where Caucasian citizens are in the majority\(^6\).

To that end, Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases, described the disproportionate effects of the coronavirus on the African American community as an “exacerbation of a health disparity.” The same conditions that are far too prevalent in African American communities also “lead to a bad outcome with the coronavirus,” Dr. Fauci said\(^7\).

Unfortunately, treatments for chronic disease and other underlying conditions often include drug therapy and other treatment regimens that are frequently subjected to prior authorization and step therapy requirements by health insurance plans. Therefore, in light of the heightened Coronavirus/COVID-19 risk to minority populations with underlying medical conditions, it is more important than ever that such individuals have access to medical treatments needed to stabilize their underlying conditions.

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\(^3\) CDC, Coronavirus Diseases 2019 (COVID-19). People who are at higher risk for severe illness.  

\(^4\) Id.

\(^5\) ABC News. CDC releases new data as debate grows over racial disparities in coronavirus deaths. Available at:  


\(^7\) Id.
Dangers of Prior Authorization and Step Therapy Requirements

As stated above, the National Minority Quality Forum strongly recommends that CMS use its emergency authority under Section 1135 of the Social Security Act (SSA) to require Medicare plans, including Medicare Advantage and Part D plans, to offer beneficiaries unrestricted access to their Part B and Part D drugs by removing all prior authorization and/or step therapy criteria associated with any drug regimens for the duration of the Coronavirus/COVID-19 public health emergency. Doing so, will help ensure that vulnerable patients, including elderly and minority patients, are in stable condition if they contract the coronavirus and maximize their ability to successfully combat the virus.

Prior authorization requirements, including step therapy or “fail first” requirements, are health plan restrictions that limit enrollees’ ability to obtain coverage for specified items and services by requiring that the plan approve coverage for an individual before the treatment can be covered. Although all prior authorization requirements can cause treatment delays and adverse health outcomes, step therapy protocols are particularly problematic. The American Medical Association (AMA) has raised concerns that step therapy requirements can undercut the physician-patient decision-making process, and can harm patients by causing treatment delays and unnecessary complications. These treatment delays can result

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8 See, e.g., Letter from AMA et al. to CMS Administrator Verma re: Memo of August 7th Regarding Prior Authorization and Step Therapy Requirements for Part B Drugs in Medicare Advantage (September 7, 2018),
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in disease progression and relapse, which, in turn, can result in increased health care utilization, putting further burden on our significantly strained health care delivery system. In fact, CMS acknowledged in its April 6, 2020 “Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies” that lack of processes to quickly review and approve requests for medically necessary tests, services and supplies can impact access to needed patient care.

Even when a patient is ultimately successful in obtaining the plan’s prior approval for a treatment, the process of obtaining approval burdens the patient’s provider and delays treatment. At present, MA and Part D plans impose rigid prior authorization requirements on many treatments (even though by law MA plans are required to provide the same benefits as Original Medicare, which does not impose prior authorization requirements on beneficiaries). Although procedures exist for enrollees and their providers to seek exceptions to prior authorization requirements, the procedures for seeking such an exception from an MA or Part D plan are onerous and time consuming, both for enrollees and their providers. For example, plans have up to three full days to make a standard initial determination on an enrollee’s request for an “organization determination” concerning an exception to a step therapy policy for a Part B drug, and 14 days to make a decision on a standard request for coverage of other items or services. Prior authorization requirements always impose a burden on patients and prescribers, but these burdens are exacerbated by the Coronavirus/COVID-19 crisis.

Overall, prior authorization and step therapy requirements can cause grave, undue and avoidable harm to vulnerable patients. During this Coronavirus/COVID-19 emergency, time is of the essence, and delays in treatment could have particularly catastrophic consequences for vulnerable patient populations. The consequences of prior authorization and step therapy requirements will only increase the magnitude of the danger.

**Recommended CMS Action**

Since President Trump’s declaration of the national emergency, the Administration and CMS have taken swift, decisive action to ensure that providers and patients are afforded necessary flexibilities to deliver and receive any care patients need during this tumultuous time. We highly commend the actions CMS has taken to-date to ensure continuity of care for beneficiaries and also strongly urge CMS to take measures to protect the most vulnerable beneficiaries to ensure they are in stable condition should they contract the coronavirus by requiring MA and Part D plans to remove all prior authorization and step therapy restrictions for Part B and Part D medicines.

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9 [https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/485447](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/485447).


11 By acknowledging the existence of MA plan step therapy restrictions and asking CMS to require an end to these restrictions during the COVID-19 emergency, we do not mean to imply that these restrictions are consistent with the Medicare Advantage statute; they are not, and we hope that CMS will recognize this (as it did before it reversed its prior position in August 2018).

12 See, e.g., 42 C.F.R § 422.560 et seq.; see also 42 C.F.R. 423.558 et seq.

13 42 C.F.R. § 422.568(b)(2) (timeframe for obtaining a decision on a request for an exception to an MA plan’s step therapy protocol for Part B drugs).

14 42 C.F.R. § 422.568(b)(1).
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NMQF believes that CMS has the appropriate authority to require that MA and Part D plans eliminate prior authorization restrictions for the duration of the COVID-19 emergency. In fact, in the circumstances here, CMS can provide the relief needed under SSA § 1135, “Authority to Waive requirements During National Emergencies,” as it expressly empowers CMS to waive or modify Medicare, Medicaid or CHIP prior authorization provisions in an emergency. As CMS stated in a March 16, 2020 § 1135 waiver granted to Florida which waived, among other things, prior authorization requirements in its State Medicaid plan:

“We interpret prior authorization requirements to be a type of pre-approval requirement for which waiver and modification authority under section 1135(b)(1)(C) of the Act is available. . . . CMS is using the flexibilities afforded under section 1135(b)(1)(C) of the Act that allow for waiver or modification of pre-approval requirements to permit services provided on or after March 1, 2020 through [a specified period] for beneficiaries with a permanent residence in the geographic area of the [COVID-19] public health emergency declared by the Secretary.”

In Closing
In response to the information presented above, the National Minority Quality Forum believes that CMS has sufficient legal authority and justification to suspend step therapy and prior authorization requirements for all Medicare beneficiaries to ensure that this population and their healthcare providers are spared the heightened burdens and compromised healthcare outcomes that these requirements would otherwise cause during the Coronavirus/COVID-19 pandemic.

Improved access to these treatments will assist high-risk, minority 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. Implementing this policy could save the lives of many high-risk, minority Medicare beneficiaries. 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. If you require additional information or would like to discuss this issue further, please contact Gretchen C. Wartman, NMQF Vice President for Policy and Program, at 202-223-7563 or gwartman@nmqf.org.

Sincerely,

Gary A. Puckrein, PhD
President and Chief Executive Officer

15 March 16, 2020 CMS Response to the State of Florida’s Section 1135 Waiver Requests (emphasis added).
16 https://www.aarp.org/health/conditions-treatments/info-2020/chronic-conditions-coronavirus.html