January 25, 2019

Alex Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Ave. SW
Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses – Docket CMS-4180-P

Dear Secretary Azar and Administrator Verma:

Aimed Alliance is a 501(c)(3) non-profit organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for providing us with the opportunity to comment on Docket CMS-4180-P, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses*. This proposed rule lays out significant changes to Medicare Advantage and Medicare Parts B and D. We are concerned that some of these changes may limit the ability for Medicare beneficiaries to afford and access their medications.

I. Providing Plan Flexibility to Manage Protected Classes

As the Centers for Medicare and Medicaid Services ("CMS") acknowledges in the Six Protected Classes policy, in some cases, Medicare beneficiaries may require access to multiple medications within a therapeutic class.[1] As such, Medicare Part D plans must cover "all or substantially all drugs" within each Protected Class.[2] However, the proposed rule from CMS could limit beneficiaries' access to a number of those treatments, including by expanding step therapy and prior authorization and by creating additional instances in which medications could be excluded from coverage.[3]

A. Utilization Management and Indication-Based Formulary Design

Currently, Part D sponsors are prohibited from implementing prior authorization or step therapy requirements for beneficiaries presently on a medication within a Protected Class.[4] The proposed rule would reverse this policy, thereby allowing Part D plan sponsors to use step therapy and prior authorization for all Protected Class medications. CMS anticipates that this authority could be used to determine whether the medication is being used for a protected class

[1] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
[2] https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
[3] https://www.regulations.gov/document?D=CMS-2018-0149-0002
[4] https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

indication, promote the use of preferred formulary alternatives, and verify that a medication is medically necessary and not separately covered under Medicare Parts A or B.[5]

We oppose this proposed rule because step therapy and prior authorization can cause significant delays in treatment, and in some instances, denials of treatment altogether. Approximately 92 percent of physicians responding to a 2018 American Medical Association ("AMA") survey reported that prior authorization delays patients' access to necessary care,[6] and step therapy is known to have the same effect.[7] These delays can be particularly harmful for individuals with serious conditions, such as cancer, who need access to specific treatments within the Six Protected Classes. These delays can be particularly harmful for individuals with serious conditions, such as cancer, who need access to specific treatments within the Six Protected Classes. According to the American Society for Clinical Oncology, step therapy policies are generally inappropriate in oncology due to the individualized nature of modern cancer treatment and the general lack of interchangeable clinical options."[8] Furthermore, delays and denials of treatment can cause increased symptom severity, relapse, disease progression, and even death.[9] For example, patients with breast cancer whose treatment was delayed by three months or more had a 12 percent lower five-year survival rate than those with a zero to three month delay.[10]

Part D plan sponsors already possess tools to adequately manage costs, including step therapy and prior authorization for most new medication starts, tiered formularies, and coinsurance requirements.[11] These existing tools adequately steer patients toward less expensive generic medications. According to a 2018 study by Avalere, although only 35 percent of covered medications within the Six Protected Classes were generic, 91 percent of prescriptions filled were for generic products.[12] Another study found that only one percent of prescriptions filled for medications across the Six Protected Classes were for products placed on the highest tiers.[13]

Furthermore, step therapy and prior authorization may result in increased costs to the health system. Studies have shown that although step therapy may reduce insurers' short-term pharmacy benefit costs, it can "hinder patient health and indirectly cause increased long-term costs."[14] Likewise, according to the 2018 AMA survey, nearly 90 percent of physicians reported experiencing increased administrative waste directly related to prior authorization over the past five years.[15] Therefore, CMS should maintain its current policies rather than allowing step

---

[5] https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf?1543499121
[6] https://www.ama-assn.org/practice-management/sustainability/prior-authorization-major-practice-burden-how-do-you-compare
[7] https://www.healthaffairs.org/do/10.1377/hblog20160602.055116/full/
[8] https://patientengagementhit.com/news/how-does-step-therapy-impact-patient-care-access-costs
[9] https://www.healthaffairs.org/do/10.1377/hblog20160602.055116/full/
[10] https://www.healthaffairs.org/do/10.1377/hblog20160602.055116/full/
[11] https://www.regulations.gov/document?D=CMS-2018-0149-0002
[12] https://avalere.com/insights/patients-use-generics-more-frequently-than-brands-in-medicares-protected-drug-classes
[13] http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf
[14] https://patientengagementhit.com/news/how-does-step-therapy-impact-patient-care-access-costs
[15] https://www.ama-assn.org/practice-management/sustainability/prior-authorization-major-practice-burden-how-do-you-compare

therapy and prior authorization for stable Medicare beneficiaries who require a Protected Class treatment.

B. Indication-based Formulary Design

Historically, if a Part D plan offers coverage for a medication, it must offer coverage for every indication for which it has received approval from the U.S. Food and Drug Administration ("FDA"). CMS proposes to allow indication-based formulary designs for Protected Class medications beginning in 2020. These formulary designs would allow plan sponsors to restrict coverage of a medication to specific indications rather than covering all FDA-approved indications.[16]

Indication-based formulary designs may be discriminatory because coverage is granted or denied based solely on which health condition the beneficiary has, even though the medication was FDA-approved for multiple conditions.[17] In attempts to meet anti-discrimination requirements, the proposed rule requires plan sponsors to cover an alternative treatment if a medication is excluded for a particular indication.[18] However, even though two medications that are both approved for a particular indication may be in the same therapeutic class, they are not necessarily interchangeable. For example, patients with HIV who receive an inappropriate medication for their individualized needs are at risk of "developing resistance to an entire class of drugs and potential side effects."[19]

This proposed rule could also interfere with off-label coverage for medications in Part D. Some patients have come to rely on using off-label medications to manage their health, especially those with certain forms of cancer for which no FDA-approved medication to treat their particular indication exists.[20] According to the National Cancer Institute, "Frequently, the standard of care for a particular type or stage of cancer involves the off-label use of one or more drugs."[21] It is unclear whether these individuals will lose access to their treatments once an indication-based formulary design is adopted. For these reasons, indication-based formulary design should not be implemented for medications within the Six Protected Classes.

C. New Formulations of Existing Medications

CMS proposes to exclude new formulations of existing medications from the Six Protected Classes, which could harm patients. The proposed rule states that new formulations

---

[16] https://www.cms.gov/newsroom/fact-sheets/indication-based-formulary-design-beginning-contract-year-cy-2020
[17] https://www.cms.gov/newsroom/fact-sheets/indication-based-formulary-design-beginning-contract-year-cy-2020
[18] *See* https://www.cms.gov/newsroom/fact-sheets/indication-based-formulary-design-beginning-contract-year-cy-2020, which implements a similar policy and states "If a Medicare Part D plan sponsor chooses to tailor on-formulary coverage of drugs to certain indications, it must ensure that there is another therapeutically similar drug on the formulary for the non-covered indication in order to meet the anti-discrimination requirements. . . ."
[19] https://www.modernhealthcare.com/article/20181126/TRANSFORMATION04/181129962#
[20] https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/off-label-drug-use.html
[21] https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/chemotherapy/off-label-drug-use.html

can be excluded "even if the older formulation is removed from the market."[22] Patients may have no covered options if they need access to a specific treatment within the Six Protected Classes, the older formulation has been taken off the market, and the plan sponsor chooses to exclude the new formulation from coverage as well. In these circumstances, the patient may experience nonmedical switching. Nonmedical switching is the practice in which a third-party payer disrupts a stable patient's continuity of care by forcing them to switch to a different medication for cost-driven reasons. This practice can result in adverse events and increased health care utilization.[23] For example, medications used to treat HIV can rarely be substituted for one another, and different patients will have unique reactions to each medication. Causing these patients to switch to a non-preferred medication could result in a loss of disease control, intolerable side effects, and hospitalization.[24] In the context of HIV, loss of disease control could also result in unintended disease transmission to another person. This could increase spending by Medicare Part A, Part B, and state Medicaid programs, which would defeat the purpose of this policy change.[25]

Additionally, there may be clinical differences between medication formulations that make one option or the other a better fit for a given patient. Specifically, formulations could differ by dosage and frequency of administration.[26] The complexity of a drug regimen and frequency of administration can impact medication adherence.[27] One study showed that 79 percent of patients who had to take their medication once daily were compliant whereas compliance rates dropped down to 38 percent for individuals who had to take their medication three times per day.[28] Therefore, CMS should not allow plan sponsors to exclude new formulations of medications within the Six Protected Classes, especially if older formulations have been removed from the market.

D. Exclusions Based on Price Increases

CMS notes in the proposed rule that the prices of Protected Class medications have historically risen more than non-Protected Class medications. To reverse this trend, CMS proposes to allow Part D plan sponsors to exclude coverage for any single-source or biologic Protected Class medication if the price for that medication increases beyond a threshold within a lookback period. Yet, removing a medication from the Protected Class designation could prevent Medicare beneficiaries from accessing that medication altogether. It punishes patients for something they cannot control.

Moreover, the inflation threshold does not give the pharmaceutical manufacturer an opportunity to justify the price increase, which could provide helpful context for CMS to make a more informed decision regarding the Protected Class designation. For example, unforeseeable events beyond the manufacturer's control could cause the production costs of a Protected Class

---

[22] https://www.regulations.gov/document?D=CMS-2018-0149-0002
[23] http://www.keepmyrx.org/wp-content/uploads/2017/02/ProtectingPatientsFromNMS.pdf
[24] https://patientsrising.org/florida-health-insurance-bait-and-switch/
[25] http://www.partdpartnership.org/uploads/8/4/2/1/8421729/partnership_for_part_d_report_2018.pdf
[26] https://pdfs.semanticscholar.org/305b/42ea67d70ed62afe6889ae6b89216db03756.pdf
[27] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3191684/
[28] https://www.ncbi.nlm.nih.gov/pubmed/9314626

medication to increase beyond inflation, which would not be accounted for in the proposed rule.[29] We recommend that an additional decision-point be inserted into this determination to allow the pharmaceutical manufacturer to justify the price increase and for CMS to make a decision based on all of the relevant facts.

II. E-Prescribing and The Part D Prescription Drug Program, Updating Part D E-Prescribing Standards

CMS proposes requiring Part D plan sponsors to implement an electronic real-time benefit tool that can integrate with existing electronic prescribing and health record systems. This program is intended to improve the cost-effectiveness of the Part D program by making beneficiary-specific cost and coverage information available to prescribers before a prescription is written.

We support this change because it will enable patients and providers to have meaningful conversations about medication coverage and costs at the point-of-prescribing. As a result, patients may make more informed health care decisions and the Medicare program may experience cost-savings.

III. Medicare Advantage and Step Therapy for Part B Drugs

In the proposed rule, CMS reinterprets a past policy as permitting Medicare Advantage ("MA") plans to impose step therapy protocols on Part B medications, including by requiring patients to fail on a Part D medication before they can access a Part B medication. CMS anticipates that this will provide MA plans with greater leverage when negotiating prices with manufacturers. To protect patients, CMS proposes to require MA plans to administer the existing exception and appeals processes under a new proposed timeframe similar to that for Part D coverage determinations and to allow enrollees to request an exception to the process or an appeal. Both exceptions and appeals would be monitored by CMS to ensure that they are appropriately evaluated and processed. CMS would also require MA plans to use a P&T committee to implement the step therapy protocol, which is the same requirement under Part D.

As discussed above, step therapy can result in one-size-fits-all treatment of patients that may need individualized care. It may also result in harmful delays or denials of treatment. While appropriate exception and appeals processes would allow for individualized care and appropriate access to treatment, the current exception and appeals process has not provided Medicare beneficiaries with a sufficient avenue to achieve these goals. In 2017, only a small fraction of Medicare Advantage beneficiaries filed a reconsideration appeal, and of the 3,498 cases that were decided, only 10 percent of beneficiaries received decisions that were fully or partially in their favor.[30] Therefore, this proposed rule should not be implemented until the step therapy exception and appeals process is streamlined.

Additionally, the proposal to use step therapy with Part D medications to restrict access to Part B medications could create difficulties for providers who specialize in administering Part

---

[29] https://www.regulations.gov/document?D=CMS-2018-0149-0002

[30] https://khn.org/news/new-medicare-advantage-tool-to-lower-drug-prices-puts-crimp-in-patients-choices/

B medications and rely on reimbursements for those services to keep their businesses open. Losing access to an infusion center could force patients to receive their infusions in a hospital setting, which is often much more expensive for the patient.[31] Therefore, we oppose CMS's proposal to allow Medicare Advantage plans to use step therapy to restrict access to Part B medications.

IV. Educational Materials

While many of CMS's proposed changes could result in delays or denials of access, Medicare beneficiaries could request an exception or appeal an adverse determination. However, as stated above, many Medicare beneficiaries do not utilize the exception and appeals processes. This low utilization could be due to a general lack of awareness and understanding of the exception and appeals process. Therefore, to ensure that Medicare beneficiaries who require access to a particular treatment impacted by this proposed rule are able to obtain such medication, CMS should create simple and clear materials explaining the exceptions and appeals process. CMS should require plan sponsors to provide these materials to beneficiaries annually.

V. Conclusion

Thank you for providing us with the opportunity to comment on this matter. We hope that you will consider our recommendations as you continue developing this proposed rule.

Sincerely,

John Wylam
Staff Attorney

[31] https://www.communityoncology.org/pdfs/avalere-cost-of-cancer-care-study.pdf