AIMEDALLIANCE

January 5, 2024

Hon. Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: 2025 Medicare Proposed Rule File Code: CMS-4205-P

Dear Secretary Becerra and Administrator Brooks-LaSure:

Aimed Alliance is a non-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We appreciate the opportunity to comment on the *Medicare Program: Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Plan Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications* under file code *CMS-4205-P.*

We are writing to express our concerns regarding the recent decision by CMS to permit plans to switch consumers from a biologic to a biosimilar, regardless of the drug's interchangeability designation. Additionally, we would like to share our concerns regarding the widespread adoption of double-step fail-first policies within Medicare Advantage plans. Furthermore, we want to affirm our support of CMS's commitment to increase transparency within the Utilization Management committee.

I. Biologic and Biosimilar Interchangeability

Biological products are treatments and medications formulated from living entities, including cells and tissues. They are often used to treat patients with complex chronic conditions, such as cancer, arthritis, and bowel diseases.[1] Currently, Medicare Advantage Part D plans must receive approval from CMS to make ***midyear formulary*** changes that involve replacing a reference biologic with a biosimilar product. This approval process, however, is not mandated for the substitution of a reference biologic with an ***interchangeable biosimilar*** product. Under the current rule, patients undergoing treatment with a biologic that is removed from the formulary can continue accessing the removed medication for the remainder of the plan year.

The Food and Drug Administration (FDA) has consistently recognized that not all biosimilars are interchangeable.[2] The FDA created the interchangeable biosimilar designation to allow

[1] FDA, *What Are "Biologics" Questions and Answers,* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers; FDA, *Biosimilars,* https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers.

[2] The state must have an applicable interchangeability law; FDA, *Interchangeable Biological Products,* https://www.fda.gov/media/151094/download#:~:text=Interchangeable%20Biosimilars,-%E2%80%A2&text=An%20interchangeable%20biosimilar%20may%20be,substituted%20for%20brand%2Dname%20drugs.&text=Not%20all%20biosimilars%20are%20interchangeable.

pharmacists to automatically exchange a biosimilar for the biologic reference product at the pharmacy without the healthcare provider's permission.

In October 2023, the FDA affirmed its long-standing position on the differences between biosimilars, interchangeable biosimilars, and biologics.[3] The FDA's updated guidance stated that biosimilars and interchangeable biosimilars have the "high standard of similarity . . . and both are as safe and effective as the reference product."[4] However, this clarification did not change the interchangeability designation or permit non-interchangeable biosimilars to be automatically substituted at the pharmacy.

Under the 2025 proposed rule, Medicare Advantage Part D plans would be permitted to make midyear formulary changes to replace a reference product for a biosimilar, irrespective of its interchangeability designation. Furthermore, the proposed rule introduces the possibility for plans to require all beneficiaries to switch to the new biosimilar, subject to a 30-day notice requirement.

The proposed rule is inconsistent with the FDA's recent clarification. According to the FDA, pharmacy substitutions are deemed appropriate exclusively for biosimilars that have received the interchangeability designation. Yet, under the proposed rule, all biosimilars could be substituted at the pharmacy for a reference product, regardless of the drug's interchangeability designation. Aimed Alliance encourages CMS to reconsider this policy and align Medicare Advantage plans with the FDA's established interchangeability standards and pharmacy substitution requirements.

Moreover, Aimed Alliance is concerned that this proposed rule will lead to patients undergoing non-medical switches from their biologic to a biosimilar. Non-medical switching occurs when patients are compelled to switch medications due to payer mandated reasons rather than medical necessity.[5] Imposing such switches can disrupt a patient's medication stability, potentially exposing the individual to preventable negative health outcomes and increased costs for both the plan and the individual.[6] Forcing patients switch treatments overlooks the fact that while some consumers can seamlessly transition between a biologic and a biosimilar, others may not. Consequently, the decision to switch should be a collaborative one made by the individual and their healthcare provider, rather than being mandated by the plan upon the availability of a biosimilar. Additionally, implementing mid-year formulary changes are unfair to consumers who enroll in a plan at the start of the year with the expectation of accessing their prescribed medication for the entirety of the plan year. Changing plan terms mid-year undermines the careful research and selection process many consumers undergo when selecting a plan.

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[3] FDA, *Updated FDA Labeling Recommendations for Biosimilar and Interchangeable Biosimilar Products,* https://www.fda.gov/drugs/our-perspective/updated-fda-labeling-recommendations-biosimilar-and-interchangeable-biosimilar-products .
[4] *Id.*
[5] Aimed Alliance, *Non-Medical Switching,* https://aimedalliance.org/nonmedical-switching-enacted-laws/ .
[6] *Id.*

Ultimately, while Aimed Alliance supports initiatives to lower consumer costs and increase access to innovative treatments and biosimilars, these efforts should not interfere with a patient's ability to access the treatment initially prescribed by their health care provider.

II. Annual Health Equity Analysis of Utilization Management Policies and Procedures

Benefit utilization management policies are cost-management strategies implemented by health plans to lower health plan spending. These policies can include measures such as step-therapy, non-medical switching, adverse tiering, and prior authorization.[7] However, the implementation of these policies can contribute to provider administrative burnout and impose barriers that prevent consumers from accessing their prescribed treatments. For instance, prior authorization requires an individual to obtain approval from the insurer or pharmacy benefit manager before the plan will cover the cost of a healthcare product or service.

Without proper guardrails, prior authorization policies can perpetuate health disparities and create additional barriers for individuals trying to access to necessary treatments. A 2023 survey found that nearly one in four individuals with Medicaid encountered healthcare access challenges related to prior authorization, while nearly 11 percent of Medicare-enrolled individuals experienced similar obstacles.[8] Furthermore, the survey indicated that 26 percent of individuals seeking mental health treatment reported access challenges due to prior authorizations.[9] Leading healthcare provider associations, including the American Academy of Family Physicians, have also voiced concerns that prior authorization policies can perpetuate health disparities, particularly amongst minority and underserved populations.[10]

In response to these concerns, the 2025 proposed rule would require the Utilization Management committee to include a health equity expert. This expert would assess how prior authorization policies impact low-income subsidy or dually eligible Medicare and Medicaid individuals, as well as individuals with disabilities. The proposed rule would also mandate that this information be publicly available on the company's website. Aimed Alliance supports CMS's efforts to improve transparency surrounding prior authorization practices to prevent these policies from perpetuating health disparities and causing delays in access to necessary treatments.

III. Step Therapy in Medicare Advantage

Medicare Advantage plans continue to represent an increasingly diverse percentage of the older population with 69 percent of Latino, 65 percent of Black, and 60 percent of Asian

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[7] Aimed Alliance, *Policy Priorities,* https://aimedalliance.org/policy-priorities/ .
[8] Kaiser Family Foundation, *Consumer Problems with Prior Authorization: Evidence from KDD Survey,* https://www.kff.org/health-reform/issue-brief/consumer-problems-with-prior-authorization-evidence-from-kff-survey/ .
[9] *Id.*
[10] American Academy of Family Physicians, *AAFP Calls for Comprehensive Prior Authorization Reform,* https://www.aafp.org/news/government-medicine/prior-authorization-reform-letter.html .

Medicare-eligible individuals opting for Medicare Advantage over original Medicare coverage.[11] Medicare Advantage plans are also more likely to have enrollees over the age of 75 compared to Original Medicare.[12] Given this demographic landscape, Aimed Alliance is increasingly concerned by the prevalence of double-step fail-first policies within Medicare Advantage plans.

Step-therapy policies, often known as "fail first," require patients to try and fail on alternative treatments, sometimes causing adverse effects, before the plan will cover the originally prescribed treatment.[13] These policies can be unethical and inconsistent with standards of care, interfering with the patient-provider relationship and compromising patient health outcomes. Thirty-six states have recognized that step-therapy policies need reasonable guardrails to ensure that plan utilization management tactics provide a feasible and meaningful way to avoid a step-therapy policy when medically appropriate.[14] These laws generally prohibit health plans from imposing step therapy when the patient has already tried and failed on the required drug, will experience irreversible consequence if they experience a delay in accessing the appropriate treatment, would be harmed by trying and failing on an alternative drug, would be prohibited from working or fulfilling daily activities, and if they are already stable on their current treatment.[15] Some laws also explicitly prohibit step-therapy policies from requiring patients to try and fail on off-label treatments.[16]

Despite these protective measures at the state level, Medicare Advantage plans lack similar safeguards. Notably, the federal government has not imposed step-therapy guardrails for Medicare Advantage plans, leaving consumers vulnerable to a variety of egregious step-therapy policies.

In 2023, Aimed Alliance sent letters to Aetna, United HealthCare, and WellCare addressing concerns about the implementation of step therapy in their Medicare Advantage plans. Collectively, these plans provide coverage for 17.5 million Medicare Advantage lives.[17] In our

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[11] Better Medicare Alliance, *New Report: Black, Latino, and Asian Beneficiaries Choose Medicare Advantage Over Traditional Medicare,* https://bettermedicarealliance.org/news/new-report-black-latino-and-asian-beneficiaries-choose-medicare-advantage-over-traditional-medicare/#:~:text=Altogether%2C%2027%25%20of%20MA%20enrollees,Medicare%2C%20the%20new%20analysis%20finds.&text=impacts%20of%20climate%20change.

[12] America's Health Insurance Plans, *Medicare Advantage Demographics,* https://www.ahip.org/resources/medicare-advantage-demographics.

[13] Aimed Alliance, *Step Therapy,* https://aimedalliance.org/step-therapy/

[14] Rachel Zimmerman, *Need a new drug? You may be asked to "fail" an old drug first,* The Washington Post, https://www.washingtonpost.com/wellness/2023/02/06/prior-authorization-fail-first-step-therapy/.

[15] *See generally,* National Psoriasis Foundation, *Step Therapy,* https://steptherapy.com/step-therapy-legislation-by-state/.

[16] Maryland, *Insurance Article §15-142* (2023). Off-label is the use of an FDA approved drug that has not been approved for the condition being treated. While off-label treatment may be appropriate in certain cases, this decision should be left to the health care provider's professional judgement, not mandated by the plan.

[17] CVS Health, *Aetna 2023 Medicare plans put money back in members' pockets,* https://www.cvshealth.com/news/medicare/aetna-2023-medicare-plans-put-money-back-in-members-pockets.html; Forbes, *WellCare Medicare Advantage Review for 2024,* https://www.forbes.com/health/medicare/wellcare-medicare-advantage-review/; United Healthcare, *United Healthcare's 2024 Medicare Advantage Plans Offer Enhancements to Benefits that Matter Most to Members,* https://www.uhc.com/news-articles/newsroom/medicare-

evaluation of each of these plans, Aimed Alliance identified step-therapy policies mandating that patients try and fail on more than one medication. Additionally, some policies required patients to step through off-label treatments before gaining access to the originally prescribed treatments. Critically, these policies were often inconsistent with clinical practice guidelines. The identified step-therapy policies, particularly those requiring patients to try-and-fail on two treatments, present significant risks, including irreversible disease progression, the onset of additional co-occurring conditions, and various other serious health consequences.

Despite Aimed Alliance efforts to initiate a dialogue with these companies and discuss the repercussions of their policies on plan beneficiaries, no response was received. In light of this, Aimed Alliance strongly urges CMS to take proactive measures in developing clear guardrails for step therapy policies. This is crucial to protect Medicare Advantage individuals from harmful double-step fail-first policies that may disproportionality impact minorities and contribute to the perpetuation of health disparities.

IV. Conclusion

Thank you for providing us the opportunity to comment on *CMS-4205-P.* Please contact us at policy@aimedalliance.org if you have any questions regarding this comment.

Sincerely,

Ashira Vantrees
Counsel

plans-2024#:~:text=As%20the%20only%20company%20to,Medicare%20Advantage%2C%20Medicare%20Part%20D%2C.