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**Via Electronic Communication**

Re: Double-Step Fail-First Policies Impacting Medicare Advantage Plan Beneficiaries

Dear Ms. Medosch and Ms. Petrone:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of health care consumers and providers. We are reaching out to express our concerns regarding the use of burdensome step-therapy policies in Medicare Advantage plans.

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 Medicare-eligible persons opting for Medicare Advantage over Original Medicare coverage.<sup>1</sup> Medicare Advantage plans are also more likely to have enrollees over the age of 75 compared to Original Medicare.<sup>2</sup> With these statistics in mind, we are increasingly concerned with 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.<sup>3</sup> Such 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 plan utilization management tactics provide a feasible and meaningful way to avoid the step-therapy policy when medically appropriate.<sup>4</sup> Generally, these laws prohibit health plans from imposing step therapy when the patient (1) has already tried and failed on the required drug; (2) will experience irreversible consequence if they have a delay in access to the appropriate treatment; (3) would be harmed by trying and failing on an alternative drug; (4) would be prohibited from working or fulfilling daily activities; and (5) if they are already stable on their current treatment.<sup>5</sup>

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<sup>1</sup> 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..>

<sup>2</sup> America’s Health Insurance Plans, *Medicare Advantage Demographics*, <https://www.ahip.org/resources/medicare-advantage-demographics>.

<sup>3</sup> Aimed Alliance, *Step Therapy*, <https://aimedalliance.org/step-therapy/>

<sup>4</sup> 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/>.

<sup>5</sup> See generally, National Psoriasis Foundation, *Step Therapy*, <https://steptherapy.com/step-therapy-legislation-by-state/>.

Some laws also prohibit step-therapy policies from requiring patients to try and fail on off-label treatments.<sup>6</sup>

While states have implemented a number of step-therapy protections for consumers, these protections do not extend to Medicare Advantage plans. In addition, the federal government has not imposed step-therapy guardrails for Medicare Advantage plans, leaving consumers subject to a variety of egregious step-therapy policies.

In 2023, Aimed Alliance has sent letters to Aetna, United HealthCare, and WellCare regarding their use of step therapy in Medicare Advantage plans. Collectively, these plans cover 17.5 million Medicare Advantage lives.<sup>7</sup> In each of these plans, Aimed Alliance identified a step-therapy policy that required patients to try and fail on more than one medication, with some policies requiring patients step through off-label treatments, before being able to access the originally prescribed treatments. These policies were also often inconsistent with clinical practice guidelines. Requiring patients to try-and-fail on two treatments can lead to patients experiencing irreversible disease progression, development of additional co-occurring conditions, and other negative and serious health consequences.

Aimed Alliance attempted to engage these companies to discuss the impacts their policies were having on plan beneficiaries but did not receive a response from any of them. Therefore, we are asking to meet with CMS to discuss our concerns surrounding the widespread use of step-therapy policies within Medicare Advantage plans, and the actions CMS could take to ensure consumers are provided reasonable guardrails around step therapy. We would greatly appreciate an opportunity to meet with your team to discuss our concerns in more detail. Please contact us at [avantrees@aimedalliance.org](mailto:avantrees@aimedalliance.org) if you have any questions. We look forward to your response.

Sincerely,

Ashira Vantrees  
Counsel

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<sup>6</sup> 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.

<sup>7</sup> 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-plans-2024#:~:text=As%20the%20only%20company%20to,Medicare%20Advantage%2C%20Medicare%20Part%20D%20C>.