



August 9, 2023

Brian Kane
Executive Vice President & President of Aetna
Aetna Inc.
ExecutiveResponseTeam@aetna.com

Via Electronic Communication

Re: Double Step Fail First Policies Harm Health Care Consumers

Dear Mr. Kane:

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 Aetna’s recent decision to require a two-step requirement for patients with ophthalmic disorders. Step therapy policies that require patients to try and fail on multiple medications before accessing their originally prescribed treatment force patients to endure ongoing symptoms without relief and can result in irreversible disease progression.

The leading causes of blindness and low vision in the United States are age-related macular degeneration, cataract, diabetic retinopathy, and glaucoma.¹ Nearly 2.1 million individuals in the United States over the age of 50 are affected by age-related macular degeneration,² and an additional 7.7 million individuals are living with diabetic retinopathy.³ Left untreated, both age-related macular degeneration and diabetic retinopathy can lead to irreversible vision loss and long-term disability.⁴

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.⁵ Such policies can be unethical and inconsistent with standards of care, interfering with the patient-provider relationship and compromising patient health outcomes. The American Academy of Ophthalmology has explicitly voiced concerns about the use of step-therapy for ophthalmologic conditions. In a 2021 letter to the Centers for Medicaid and Medicare Services, the Academy highlighted that the use of step-therapy in Medicare Advantage plans has caused “clear instances of patient harm [including] patients becoming

¹ Center for Disease Control, *Common Eye Disorders and Diseases*, <https://www.cdc.gov/visionhealth/basics/ced/index.html>.

² American Academy of Ophthalmology, *Eye Health Statistics*, <https://www.aao.org/newsroom/eye-health-statistics>

³ *Id.*

⁴ National Institute of Health, *At a glance: AMD*, nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/age-related-macular-degeneration

⁵ Aimed Alliance, *Step Therapy*, <https://aimedalliance.org/step-therapy/>



legally blind or experiencing long term hospitalizations, infections, increased disease activity, and disability.”⁶

Aetna’s recently announced policy change, set to take effect September 1, 2023, will require patients with ophthalmic disorders to try and fail on both Avastin and Byooviz before the plan will cover several other preferred treatments.⁷ Avastin’s Food and Drug Administration (FDA) approved label is limited to treating metastatic colorectal cancer, non-squamous non-small cell lung cancer, glioblastoma, cervical cancer, metastatic renal cell, and carcinoma; it does not include ophthalmic conditions.⁸ As such, the use of Avastin to treat an ophthalmologic condition is an off-label use of the drug. 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. Furthermore, requiring patients to try-and-fail on two treatments could lead to patients experiencing irreversible disease progression, decreased vision, and, in some cases, blindness.

Therefore, Aimed Alliance urges Aetna to revise its double-step fail-first policy and remove the two-step requirement for patients with ophthalmic disorders. Please contact us at policy@aimedalliance.org if you would like to discuss any of our concerns.

Sincerely,

Ashira Vantrees
Counsel

⁶ American Academy of Ophthalmology, *Step Therapy: Clinicians’ Concerns and Challenges*, <https://www.aao.org/eyenet/article/step-therapy-clinicians-concerns-and-challenges#:~:text=The%20letter%20reiterated%20that%20step.from%20an%20Academy%2Dled%20meeting>

⁷ Aetna, *Part B Step-Therapy*, [https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/Aetna-Medicare-Advantage-\(MA\)-2023-Part-B-Preferred-Drug-List.pdf](https://www.aetna.com/content/dam/aetna/pdfs/aetnacom/health-care-professionals/Aetna-Medicare-Advantage-(MA)-2023-Part-B-Preferred-Drug-List.pdf)

⁸ FDA, *Avastin Label*, https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125085s301lbl.pdf