August 4, 2025

Juliet Hodgkins
Acting Inspector General
Office of Inspector General
US Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201
(sent electronically)

RE: Request for HHS OIG Study on the Impacts of Step Therapy Requirements

Dear Inspector General Hodgkins,

The undersigned organizations, representing millions of Medicare beneficiaries with life-threatening, complex, chronic conditions and the physicians who care for them, are reaching out to the Health and Human Services Office of the Inspector General (HHS OIG) to express our appreciation for the agency's continuous focus on Medicare Advantage (MA) plans' use of prior authorization. We also would like to share our concerns, similar to those which inspired the OIG's reports on prior authorization, regarding MA plans continuing and expanding use of step therapy requirements for Part B drugs. For the reasons outlined below, **we encourage HHS OIG to conduct a study and report on the impacts on Medicare beneficiary access to medically necessary care created by MA plans' use of step therapy for Part B drugs.**

The undersigned organizations thank HHS OIG for its thoroughly researched reports on MA plan prior authorization practices. The agency's publications proved to be pivotal to our efforts, along with other interested stakeholders, to generate public awareness of the significant challenges prior authorization requirements impose on physicians and MA enrollees' ability to access medically necessary care in a timely manner. The reports were an essential tool in securing landmark regulations which reformed MA plans' use of prior authorization for utilization management: the *CY 2024 Policy & Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs;* the *Advancing Interoperability and Improving Prior Authorization Processes*. Similarly, the undersigned organizations seek to advance greater patient protections and strengthen the physician-patient relationship by ensuring step therapy requirements do not interfere with access to medically necessary physician administered therapeutics.

Background – CMS Reversal of Longstanding Ban on Part B Step Therapy

Step therapy and prior authorization are both forms of utilization management. Step therapy, also known as "fail first" therapy, requires patients' care to default to a drug preferred by a health plan, interfering with the physician-patient relationship. Providers are only permitted to prescribe and administer alternatives to a preferred drug under specific limited circumstances dictated by the health plan. Step therapy can create barriers for Medicare beneficiaries trying to access Part B and Part D covered drugs, including lower-cost biosimilar medications. We are focusing this request on Part B drugs because these are medications administered by a physician and are typically needed by at-risk, medically vulnerable Medicare patients.

While multiple drugs or therapies may sometimes be generally considered appropriate for a condition, individual patient concerns—the presence of comorbidities, potential drug interactions, or patient intolerances—can necessitate the treating physician's selection of a specific drug as the first course of treatment. Step therapy requirements typically fail to

consider such factors, resulting in delays in getting patients the right treatment at the right time. Those delays can have negative—even devastating—consequences for patient outcomes.

The Centers for Medicare and Medicaid Services (CMS) previously imposed a prohibition on mandatory step therapy for Part B drugs and services (unless also required through Original Medicare) through its September 2012 Health Plan Management System memo: *Prohibition on Imposing Mandatory Step Therapy for Access to Part B Drugs and Services*. On August 7, 2018, the agency issued the memo, *Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage*, which allowed MA plans to enact step therapy protocols for Part B drugs as of January 1, 2019. Later in 2019, CMS finalized regulations similar to the memo in the *Medicare Advantage and Part D Drug Pricing Final Rule* (CMS-4180-F).

Unfortunately, the use of step therapy has increased significantly since the guidance from CMS went into effect in 2019, with 84% of surveyed providers reporting an increase in step therapy requirements in the last five years.[1] CMS' memo recognized that MA plans may apply step therapy to control the utilization of services but not create undue access barriers for beneficiaries. However, there is very little research available to assess the actual impact of CMS' guidance. As MA enrollment has now surpassed Medicare fee-for-service enrollment,[2] it is important to evaluate whether step therapy protocols are leading to disparate access to covered Part B drugs. There is a need to ensure the policy is working as CMS intended and that any negative impacts on MA enrollee access and safety are appropriately mitigated. **To that end, the undersigned organizations urge the HHS OIG to study and publicly report the impacts on beneficiary access to medically necessary care imposed by MA plans' use of step therapy requirements for Part B drugs.**

Examples of Misuse of MA Part B Drug Step Therapy Requirements

Over the last year, the undersigned organizations have increasingly received reports from patients and physicians about regional and national MA plans adopting new or expanded step therapy requirements which threaten patient outcomes and/or fail to align with clinical guidelines widely regarded as the standard of care for applicable health conditions.

Our organizations regularly contact health plans directly with such concerns, achieving limited success in advancing step therapy policy revisions. The increasing adoption of step therapy requirements, and accompanying patient care issues, make evaluation of the policy a logical and imperative next step. These concerning recent permutations of step therapy requirements include:

- Plans requiring patients to fail *multiple* treatments (two, or even three) before being approved for the drug their physician believes would most effectively treat their condition.
- Plans adding medical necessity criteria to step therapy requirements, despite no such criteria on the U.S. Food and Drug Administration (FDA) label.

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1 Gustafson, K., Frazier, L., Sullivan, M., Potter, A., & Leonard, M. (2025, June 4). White Paper: Provider Survey on Part B Step Therapy in Medicare Advantage. Avalere Health. https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-step-therapy-in-medicare-advantage

[2] Freed, M., Fuglesten Biniek, J., Damico, A., & Neuman, T. (2024, August 8). *Medicare Advantage in 2024: Enrollment update and key trends*. KFF. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/

- Plans including drugs in 'step' regimens which have not been tested for the indicated treatment, thereby *forcing* off-label use. For example, requiring the use of biosimilar drugs that have not been approved by the FDA for intra-ocular administration (i.e., Alymsys, Mvasi, Zirabev, Vegzelma).
- Plans requiring new enrollees, and even existing patients, with preexisting disease and in-effect treatment plans to 'step down' or switch to another drug, despite a prescribed drug already successfully managing the patient's condition. This directly contradicts CMS' guidance that step therapy should not disrupt ongoing Part B drug therapies for enrollees and may only be applied to new prescriptions of Part B drugs for enrollees that are not actively receiving the affected medication.
- Plans mandating the use of a preferred biosimilar in the step therapy protocol, even when its physician's acquisition cost exceeds the reimbursement rate, which may prevent enrollees from accessing alternative therapies (e.g., a more affordable biosimilar or the reference biologic) in a timely way. If physicians cannot afford to purchase and administer the mandated biosimilar, patients must be referred to another site of care, typically a hospital, which significantly increases patient costs and poses additional risks for immune-compromised patients. As hospitals also face reimbursement shortfalls for these medications, they may refuse to treat the patient, leaving enrollees without access to therapy.

Interference with the Physician-Patient Relationship

Step therapy protocols may prohibit safe and clinically appropriate medication recommended in physician-directed treatment plans resulting in delayed or suboptimal treatment, increased disease activity, disability, and in some cases irreversible disease progression.

Such interference with physicians' clinical decision-making is concerning when it disrupts continuity of care, forcing patients with demonstrated success on a drug to instead experiment with another therapeutic due only to a change in their health plan. In a recent provider survey on Part B step therapy in MA, 94% of physicians reported that step therapy limits their ability to prescribe the Part B drug that is most clinically appropriate for their patient, and 74% of respondents reported that step therapy protocols for Part B drugs were not consistently based on established clinical guidelines.[3] Furthermore, stopping and restarting certain medicines may cause the treatments to fail due to immunogenicity or cause dangerous reactions when the medication is re-initiated. The decision to start, change, or stop a medication is best left to the expert judgment of physicians directly entrusted by patients with disease management. Across medical specialties, there have been numerous cases of patient harm due to payors' interference in the physician-patient relationship via step therapy protocols:

- **American Academy of Ophthalmology:** *AAO has a member ophthalmologist in Tennessee who shared "BlueCross BlueShield required [my patient] to use a treatment I consider less optimal for her needs and show no improvement first before "stepping up" to a treatment better for her specific condition. This does not happen without consequences. Her vision continued to deteriorate, and she's now left blind in both eyes, unable to do most activities in her daily life without assistance.*

[3] Gustafson, K., Frazier, L., Sullivan, M., Potter, A., & Leonard, M. (2025, June 4). White Paper: Provider Survey on Part B Step Therapy in Medicare Advantage. Avalere Health. https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-step-therapy-in-medicare-advantage

Unfortunately, for my patient, step therapy does not consider each individual's circumstances and often leaves patients having to endure worsening health for months—or even longer."

- **American Academy of Neurology shared:** *Plans requiring patients that are being treated for Multiple Sclerosis to step through lower efficacy, older treatments, before covering higher efficacy treatments. In the months it takes to step through multiple drugs to the provider preferred option, many patients with this progressive disease have lost mobility or other functions they cannot gain back through starting treatment on the higher efficacy drug.*
- **The Coalition of State Rheumatology Organizations (CSRO) shared:** *Manufacturers use rebates to secure preferred formulary placement, effectively ensuring their product is the only option available under step therapy protocols. This practice, separate from the clinical considerations of treatment selection, exacerbates access issues and must be addressed to ensure that step therapy decisions prioritize patient health rather than financial incentives. As a result, plans are restricting access to the highest-rebated biosimilar, preventing patients from receiving alternative therapies, including other biosimilars or the reference biologic, even when their rheumatologist determines another therapy would be as or more effective for their condition. For patients with rheumatoid arthritis and other autoimmune diseases, delays in accessing the right treatment can lead to irreversible joint damage, loss of mobility, and long-term disability. A recent study also found that patients subject to step therapy face increased missed work, higher out-of-pocket costs, and a greater decline in quality of life—both physically and emotionally—compared to those not required to undergo step therapy.*[4]
- **Oncology Nursing Society shared:** *Plans are increasingly mandating step therapy for provider-administered cancer treatments. For example, several medications used in lung cancer are now subject to step therapy protocols in Medicare Advantage plans, delaying enrollee access to the clinician-recommended treatment—such as targeted therapies—where timing and precision are critical.*
- **American Society for Gastrointestinal Endoscopy shared**: *Plans are requiring a "fail first" approach based on outdated clinical practice. For example, mandating a "fail first" with steroids for treatment of IBD before a patient can access biologics, which delays effective care, prolongs patient suffering, and often results in irreversible damage. Steroids, while effective in the short term, are associated with significant long-term side effects, including osteoporosis, diabetes, hypertension, cataracts, and increased risk of infection. These risks accumulate quickly, especially with prolonged use.*
- **American Academy of Allergy, Asthma, and Immunology shared:** *Plans increasingly apply step therapy to medications used to treat complex conditions like asthma and immune deficiency, resulting in delays that compromise patient care. In asthma, step therapy can limit timely access to the biologic most appropriate for an enrollee's specific disease characteristics. Because response to biologics is highly individualized, requiring failure on a preferred medication may result in prolonged symptoms, preventable exacerbations, and avoidable use of emergency services. For enrollees with primary immunodeficiency disease (PIDD), step therapy applied to immune globulin (IVIG) may force the use of alternatives that are less effective or*

[4] Snow, J., Feldman, M. A., & Kappel, J. (2019). *The impact of step-therapy policies on patients*. Xcenda. https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/impact-of-step-therapy-on-patients_final_1019.pdf

poorly tolerated, delaying symptom control and increasing the risk of adverse outcomes.

Further, multiple and inconsistent step therapy requirements among carriers are administratively burdensome on physicians and their staff as they help patients navigate complicated and often opaque coverage determination processes. Payor exemption and appeals processes are often complicated and lengthy, making them onerous for busy physician practices and patients awaiting treatment. In a recent study on utilization management and physician burnout, 79% of surveyed physicians indicated that step therapy is a major or significant barrier to their clinical and patient care, and more than half the physicians reported spending 6 to 21 or more hours per week on paperwork related to health insurance utilization management.[5] Another study on prior authorization requests for anti-vascular endothelial growth factor medications found that nearly 60% of approved prior authorization requests resulted in a delay in care greater than 24 hours, and each prior authorization request required a median of 100 minutes of clinical staff time.[6] Management of step therapy protocols takes physicians and clinical staff efforts away from direct patient care.

Concerns for Vulnerable and Rural Patients

There have been numerous cases of patient harm due to the utilization of step therapy protocols, as detailed above. Beneficiaries receiving Part B covered drugs include some of the most vulnerable and high-needs patients in the program. Further, Medicare fee-for-service program beneficiaries are largely not subject to Part B step therapy restrictions, creating disparate access to treatment for patients in the MA program.

A 2024 Kaiser Family Foundation (KFF) spotlight on MA enrollment illustrates the link between where a beneficiary lives and the number of options they have when choosing an MA plan. According to KFF's analysis, 4 percent of beneficiaries live in a county where one to three firms offered MA plans (528 counties) and there were 130 counties, most of which are rural counties, where only one firm offered MA plans in 2024.[7] These beneficiaries may have no other option than to choose an MA plan that restricts access to their medications through step therapy requirements, simply due to where they live. As enrollment in MA plans rapidly grows, including Special Needs Plans, the need to address this barrier to care becomes more urgent.

Conclusion

When MA plans misapply step therapy requirements, they interfere with clinical decision-making, disrupt continuity of care, and increase the risk of preventable disease progression for Medicare Advantage patients. Revoking access to a treatment that a patient is currently on and that is working for their disease can lead to irreversible health complications and increased total expenditure to the Medicare program. We believe physician decision-making enhances

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[5] Struthers, A., Chapman, M. A., Charles, P. D., Conschafter, A., Cooper, J., & Clingham, G (2024). Utilization Management and Physician Burnout. The American Journal of Managed Care, 30(11), 561–566. https://doi.org/10.37765/ajmc.2024.89626

[6] Dang, S., Parke, D. W., Sodhi, G. S., Eichenbaum, D., Nielsen, J., Danzig, C., Lalwani, G., Moinfar, N., London, N., Kimura, A., Jumper, J. M., Lord, K., Sheth, V., Pieramici, D., Orlin, A., Madson, A., Horton, M., Blim, J., Cao, J. A., … Shah, A. R. (2024). Anti-VEGF pharmaceutical prior authorization in retina practices. *JAMA Ophthalmology*, *142*(8), 716. https://doi.org/10.1001/jamaophthalmol.2024.2217

[7] Freed, M., Fuglesten Biniek, J., Damico, A., & Neuman, T. (2024, August 8). Medicare Advantage in 2024: Enrollment update and key trends. KFF. https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends

patients' disease management and promotes the best possible health outcomes for chronic and potentially terminal diseases.

We appreciate that CMS' 2018 guidance intended for step therapy to help lower drug prices, improve clinical decisions, and increase patient engagement. However, the increased use of step therapy since the guidance went into effect warrants an examination to ensure unintended consequences for patients, as described above, are addressed. **Based on these reports from our physician members and patients, the undersigned organizations urge HHS OIG to study and publicly report the impacts on beneficiary access to medically necessary care imposed by MA plans' use of step therapy requirements for Part B drugs.**

We appreciate the OIG's consideration of these comments and would be happy to discuss this in more detail at your convenience. If you have questions or need any additional information regarding any portion of these comments, please contact Brandy Keys, MPH, Director of Health Policy at bkeys@aao.org or via phone at 202-587-5815. We look forward to engaging in this important patient access issue.

Sincerely,

Alliance for Aging Research
Alliance for Patient Access
American Academy of Allergy, Asthma, and Immunology
American Academy of Dermatology Association
American Academy of Neurology
American Academy of Ophthalmology
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Allergy, Asthma and Immunology
American College of Gastroenterology
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Glaucoma Society
American Macular Degeneration Foundation
American Osteopathic Colleges of Ophthalmology & Otolaryngology-Head and Neck Surgery
American Society for Gastrointestinal Endoscopy
American Society of Ophthalmic Plastic and Reconstructive Surgery
American Society of Ophthalmic Trauma
American Society of Retina Specialists
American Urological Association
American Uveitis Society
Arthritis Foundation
Campaign Urging Research for Eosinophilic Disease (CURED)
Coalition of State Rheumatology Organizations
Community Oncology Alliance

Congress of Neurological Surgeons
Cornea Society
Crohn's & Colitis Foundation
Epilepsy Alliance America
Global Healthy Living Foundation
Headache & Migraine Policy Forum
Hereditary Angioedema Association
Hypersomnia Foundation
IBDMoms
Infusion Access Foundation
Lupus and Allied Diseases Association, Inc.
Macula Society
Medical Group Management Association
Multiple Sclerosis Foundation
National Comprehensive Cancer Network
National Infusion Center Association
North American Neuro-Ophthalmology Society
Ocular Microbiology and Immunology Group
Oncology Nursing Society
Partnership to Advance Cardiovascular Health
Prevent Blindness
Project Sleep
Pulmonary Hypertension Association
Restless Legs Syndrome Foundation
Society for Cardiovascular Angiography and Interventions
Spondylitis Association of America
The Retina Society
The US Oncology Network
U.S. Pain Foundation