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January 27, 2025

Administrator

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

**Re: CY 2026 Policy and Technical Changes to the Medicare Advantage
and Medicare Prescription Drug Benefit Programs Proposed Rule
(CMS-4192-P)**

Dear CMS Administrator:

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,700 members in the United States, Canada and 72 other countries. This membership includes allergist/immunologists (A/I), other medical specialists, allied health and related healthcare professionals—all with a special interest in the research and treatment of patients with allergic and immunologic diseases. In the paragraphs that follow, we provide feedback on key proposals and policies in the aforementioned rule.

Utilization Management

The AAAAI has consistently raised concerns regarding the detrimental impact of utilization management (UM) practices, including prior authorization (PA) and step therapy, on patients with complex conditions. These practices disproportionately impact underserved populations, which is a significant proportion of our patients given allergic and immunologic diseases are more prevalent in those communities¹. We applaud CMS's proposals to revise the metrics used in the required annual health equity analyses of PA practices. To further ensure equitable access to care, AAAAI recommends 1) ensuring these analyses apply to physician- and self-administered drugs, and 2) incorporating step therapy and non-medical switching into these health equity metrics.

In addition, we urge CMS to expand its electronic PA standards to include both physician- and self-administered drugs in order to streamline processes, reduce administrative burdens on providers, and ensure timely access to therapies.

¹ https://www.jacionline.org/article/S0091-6749%2821%2900365-1/fulltext?utm_source=chatgpt.com

Finally, the AAAAI reiterates our strong opposition to the continued allowance of step therapy for Part B medications. CMS's 2018 memorandum permitting step therapy has led to significant disruptions in care, resulting in patients suffering harm caused by payer barriers to their prescribed care, based on the individual patient's needs. This is particularly problematic for vulnerable immunodeficient patients. Such interference should be considered the practice of medicine, and payers should be held accountable when patients suffer harms from interruptions in established, effective, prescribed care. We urge CMS to rescind this policy. At a minimum, we ask that CMS apply protections for continuity of care for new MA enrollees who are actively receiving affected therapies, by making them exempt from step therapy requirements.

Formulary Inclusion and Placement of Biosimilars

The AAAAI commends CMS for its focus on improving access to generics, biosimilars, and other lower-cost therapies. These medications are vital for treating asthma, allergy and immunodeficiency diseases, yet current formulary structures often disadvantage these cost-effective alternatives due to tier placement and rebate-driven incentives. We support CMS's proposed review of Part D formularies to ensure they provide broad access to generics and biosimilars and place these drugs on lower-cost tiers.

Plan Marketing

The AAAAI strongly supports CMS's proposed updates to improve the transparency and accountability of Medicare Advantage (MA) and Part D plan marketing practices. Misleading marketing by agents and brokers has long caused confusion for beneficiaries, resulting in inappropriate plan selections that hinder access to care. The proposed requirements, such as including low-income subsidy (LIS) eligibility criteria and resources for Medicare Savings Programs in pre-enrollment discussions, address key information gaps that will promote informed choice. We particularly support requiring agents and brokers to explain the 12-month guaranteed issue (GI) rights period for disenrolling from an MA plan and returning to traditional Medicare with Medigap coverage.

In addition, AAAAI recommends CMS strengthen its enforcement mechanisms by imposing financial penalties or program termination on MA and Part D plans found to engage in deceptive marketing practices.

Star Ratings and Health Equity

As we have shared before, the AAAAI urges CMS to establish additional measures capturing physicians' experiences with MA plans, including metrics related to PA burdens and step therapy challenges and capturing data on harm caused to patients. Such measures would provide critical insights into systemic barriers affecting both providers and patients.

We appreciate the opportunity to provide comments on the aforementioned issues of importance to our members. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul Williams MD". The signature is fluid and cursive, with a large, stylized "S" at the end.

Paul Williams, MD FAAAAI
President, American Academy of Allergy, Asthma & Immunology