Asthma and Allergy Foundation of America

February 28, 2025

Stephanie Carlton
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services Hubert H. Humphrey Building,
Room 445–G
200 Independence Avenue,
SW Washington, DC 20201

RE: Medicare Drug Price Negotiation Program Public Submission

Dear Acting Administrator Carlton:

I am writing on behalf of the Asthma and Allergy Foundation of America (AAFA), the leading patient organization advocating for people with asthma and allergies and the oldest asthma and allergy patient group in the world. AAFA enthusiastically supports the goals of the Medicare Drug Price Negotiation Program. We also urge CMS to provide strong oversight of the program to avoid unintended consequences that could jeopardize access to medications for Medicare beneficiaries.

AAFA's mission is to save lives and reduce the burden of disease for people with asthma and allergies through support, advocacy, education and research. Asthma is a chronic lung disease that causes airways to become inflamed, making it hard to breathe. There is no cure for asthma, but many people can live to their fullest potential if their asthma is properly managed and controlled. Asthma is one of the most prevalent diseases in the United States, affecting some 28 million Americans and killing more than 10 every day. It is also very expensive, exacting a toll of more than $82 billion on the U.S. economy each year.[1]

AAFA believes that people with asthma and food allergies need access to affordable health insurance and to affordable medications and devices. Currently, people with allergies and asthma can face large financial barriers to drugs that hinder optimal treatment. For example, as detailed in AAFA's "My Life with Asthma" report, in a national survey regarding adult asthma, less than a quarter of respondents always

[1] Nurmagambetov, T., Kuwahara, R., & Garbe, P. (2018). The economic burden of asthma in the United States, 2008-2013. *Annals of the American Thoracic Society, 15*(3), 348-356. https://doi.org/10.1513/AnnalsATS.201703-259OC

used their asthma treatments as prescribed.[2] The top three reported reasons for not using treatments were related to cost: inability to afford treatment, treatment was too expensive, and lack of insurance coverage for the treatment. High out-of-pocket costs hinder adherence, threaten the health of patients, and exacerbate disparities in health status.

The Medicare Drug Price Negotiation Program

The rising cost of prescription drugs has long been a concern for patients and for the financial health of the Medicare program. The 2022 Inflation Reduction Act includes several provisions to lower prescription drug costs for people with Medicare and to reduce drug spending by the federal government. One of the law's primary drug-related provisions is a requirement for the Secretary of Health and Human Services to negotiate prices with drug companies for certain drugs covered under Medicare Part D (starting in 2026) and Part B (starting in 2028).

Price negotiations for the first set of 10 drugs are complete.[3] On January 17, 2025, CMS announced the selection of 15 additional drugs for price negotiations for 2027.[4] This list includes two drugs with indications for asthma. The negotiations with participating drug companies for these 15 drugs will occur in 2025, and any negotiated prices will become effective in 2027.

AAFA applauds the goal of making prescription drugs more affordable for Medicare enrollees and for the Medicare program through price negotiation. In addition, because of the complex web of factors affecting drug pricing, coverage, and access, unintended consequences could result from the drug price negotiations process. As a result, we urge CMS to implement appropriate oversight and regulatory mechanisms.

The Asthma Community's Experience With Flovent

Our concern is informed in part by a recent experience related to unintended barriers to medication in the asthma community.

Flovent (fluticasone propionate) was a branded corticosteroid inhaler used as an asthma controller medicine. In 2023, the company's manufacturer, GSK, opted to

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[2] Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). Available at https://aafa.org/asthma-allergy-research/our-research/my-life-with-asthma-report/

take the branded version of Flovent off the market entirely in favor of an authorized generic version.

The authorized generic could have served the same patients who relied on the branded version. However, following the withdrawal of branded Flovent from the market, thousands of people discovered that their insurers would not cover a generic version. In some cases, this may be because different drugs in the same class were cheaper than generic Flovent. Meanwhile, pharmacy benefit managers (PBMs) that negotiate drug plans for issuers were often applying burdensome and time-consuming prior authorization requirements for patients to switch to new drugs.

As a result of this complex interplay of policy, industry decisions, and problematic incentives, many people who had relied on Flovent to control their asthma had to either pay for it out of pocket or scramble to find medically appropriate, affordable alternatives. This was not just an inconvenience but a threat to people's health: different kinds of inhalers work better for some people than others, and continuity of care is paramount for asthma control, particularly for children.

GSK discontinued Flovent on January 1, 2024, and within six months there was a jump in emergency room visits, hospital admissions, and ICU admissions among people prescribed Flovent.[5] Asthma-related hospitalizations increased by 17.5% within three months and 23.1% in the following three to six months among people who had been using Flovent. Asthma-related ICU admissions increased by 17.4% in the first quarter of 2024, and by 21.3% in the second quarter of the year.

Monitoring Medicare Price Negotiations

In the context of the Medicare price negotiations, we urge proactive steps to ensure that similar unintended lapses in patient access are prevented or, if they occur, are swiftly addressed.

Because Medicare plans have significant flexibility in how they cover most drugs, they could respond to changes in pricing in various ways. In some cases, these changes could lead to reduced access for enrollees.

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[5] Alban, C., Deckert, J., Carrico, N., & Edwards, G. (2024, October 17). Asthma visits more common after Flovent no longer manufactured. *Epic Research*. https://www.epicresearch.org/articles/asthma-visits-more-common-after-flovent-no-longer-manufactured

For example, pharmacy benefit managers (PBMs) negotiate rebates with pharmaceutical companies, and in exchange, the PBMs may design drug benefits in a way that steers patients towards a particular company's products, rather than a competitor's products. If plans anticipate lower rebates from a drug because the price has declined, they might discourage use by assigning the drug to a higher tier with more cost sharing.

Insurers may also employ prior authorization requirements and other types of utilization management to review treatment decisions made by doctors and patients—and even deny coverage for medications if not deemed necessary or cost-effective. However, different asthma medications work better for some people than others. Utilization management could make it more difficult for patients to obtain the medications they and their doctors think are best. These new barriers could lead to ineffective or delayed treatment for people with asthma or apply more restrictive utilization management requirements.

CMS has admitted that these threats exist.[6] To help Medicare enrollees benefit from cost savings without unintended loss of access, AAFA strongly encourages CMS to closely monitor any proposed formulary changes from prescription drug plan sponsors. For example, CMS could specify to issuers what changes in formulary design or UM would be considered problematic; conduct specific reviews with regard to price-negotiated drugs when reviewing annual formulary submissions and create a portal for Medicare enrollees to report changes in access or UM requirements.[7]

Conclusion

The Medicare drug price negotiation program represents an important step in lowering drug prices for patients and for our healthcare system, and AAFA supports this endeavor. However, Flovent's example shows how attempting to address prices in America's drug marketplace can make medicines less accessible if appropriate

[6] Department of Health & Human Services, Centers for Medicare & Medicaid Services. (2023, June 30). *Medicare drug price negotiation program: Revised guidance, implementation of sections 1191–1198 of the Social Security Act for initial price applicability year 2026*. (p. 82, 84)

[7] Adina Lasser, "Drug Price Negotiation Requires Oversight To Protect Older Americans," Health Affairs Forefront, January 14, 2025. Available at https://www.healthaffairs.org/content/forefront/drug-price-negotiation-requires-oversight-protect-older-americans

oversight is not provided. We urge CMS to work proactively to prevent similar unintended consequences in the Medicare program.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America