Asthma and Allergy Foundation of America

March 1, 2026

Mehmet Oz, MD
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
Submitted via Public Submission Form

RE: Medicare Drug Price Negotiation Program Public Submission

Dear Administrator Oz:

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 and of Medicare formularies to ensure robust 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. AAFA applauds the goal of making prescription drugs more affordable for Medicare enrollees and for the Medicare program through price negotiation. Because of the complex web of factors affecting drug pricing, coverage, and access, we also urge CMS to implement appropriate oversight and regulatory mechanisms to review formularies and ensure that patient access increases and costs decline. Our concerns are outlined below.

The Medicare Drug Price Negotiation Program

AAFA shares the Administration's concern regarding the rising cost of prescription drugs and the impact on patients and the financial health of the Medicare program. Two asthma drugs were included in the 2027 price negotiations. We appreciated the opportunity to comment both in writing and via roundtable. We hope that these negotiations helped make those drugs more accessible to our community and we

look forward to working with you to understand how these negotiations have impacted our community.

Xolair

One of the drugs selected for the 2028 Drug Price Negotiation cycle is Xolair.[1] Xolair is an injectable biologic drug that is FDA-approved for multiple indications important to our patient community: moderate to severe persistent allergic asthma, IgE-mediated food allergy, chronic spontaneous hives (or urticaria), and chronic rhinosinusitis with nasal polyps.

For people living with moderate to severe asthma, Xolair is an important treatment option. It is part of a small new class of drugs that addresses the immunological pathway in asthma patients. Asthma is heterogenous, and different patients need different medications to effectively manage their disease. Barriers to specific drugs, including adverse tiering and corresponding high costs, can lead to worse disease management and more asthma attacks. Similarly, utilization management approaches such as step therapy or prior authorization can delay access to appropriate care and lead to more attacks and higher healthcare costs.

For people with IgE-mediated food allergies, Xolair is the only FDA-approved medication that reduces the risk of allergic reactions, including anaphylaxis, for multiple food allergies.

Monitoring the Impact of Medicare Price Negotiations

In the context of the Medicare price negotiations, we remain optimistic that negotiations will lead to lower prices for drugs that translate and better consumer access. We are particularly encouraged by a recent Kaiser Family Foundation analysis showing that the drug negotiation program increased access to covered drugs because of the law's requirements that all Part D plans cover the program drugs.[2] We also appreciate CMS's projection of expected out-of-pocket savings for

[1] CMS, "Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028" (January 2026). Available at https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf

[2] Juliette Cubanski and Nolan Sroczynski, Kaiser Family Foundation. "The IRA Has Improved Coverage of Drugs Selected for Medicare Price Negotiation" (Feb. 11, 2026). Available at https://www.kff.org/medicare/the-ira-has-improved-coverage-of-drugs-selected-for-medicare-price-negotiation/

consumers in addition to savings to the program,[3] and encourage CMS to release this information on a per-drug basis and based on real costs over time.

We urge CMS to make sure that there are no unintended consequences that restrict patient access. Because Medicare plans have significant flexibility in how they cover most drugs, they could respond to changes in pricing in various ways. For example, if plans anticipate lower rebates from a drug because the price has declined, they could discourage use by assigning the drug to a higher tier with more cost sharing, or apply more restrictive utilization management requirements. Due to unanticipated changes in coverage and access to Flovent, an asthma drug, in 2024,[4] AAFA and our patient community are acutely aware of the need to remain vigilant regarding the complex interplay between drug prices and access.

These potential unintended consequences should not stand in the way of working to address drug prices and access. But as noted in our 2025 letter, AAFA strongly encourages CMS to proactively monitor any proposed formulary changes from Medicare Part D plan sponsors to ensure that access is unhindered. 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.[5]

Background: Asthma and Allergies

Asthma is a chronic lung disease that causes airway inflammation and hinders breathing. Asthma is one of the most prevalent diseases in the United States, affecting nearly 28 million Americans and killing between 9 and 11 individuals every day. It is also very expensive, exacting a toll of more than $115 billion on the U.S.

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[3] CMS, "Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027" (November 2025). Available at https://www.cms.gov/files/document/fact-sheet-negotiated-prices-ipay-2027.pdf

[4] Asthma and Allergy Foundation of America, Letter to Acting Administrator Carlton (Feb. 28, 2025). Available at https://aafa.org/wp-content/uploads/2025/05/aafa-comment-letter-supporting-medicare-drug-price-negotations-program-28-feb-2025.pdf

[5] 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

economy each year. Proper care and disease management, including medication, can allow people with asthma to live healthy lives.

Food allergies represent another significant health burden in the U.S., impacting nearly 22 million people in the United States. Approximately one in sixteen children and adults in the U.S have food allergies.[6] Food allergies can result in a severe reaction called anaphylaxis that in rare cases can lead to death. Unfortunately, the prevalence and impact of food allergies in the U.S. are increasing; for example, the rate of emergency room visits for food-related anaphylaxis increased by 124% from 2005 through 2014.[7] Children with food allergies are also two to four times more likely to have asthma or other allergic diseases.[8]

People with asthma and food allergies need access to affordable health insurance and to affordable medications and devices. Unfortunately, people with allergies and asthma can face large financial barriers to optimal treatment. For example, as AAFA detailed in our "My Life with Asthma" report, our national survey of adults with asthma found that less than a quarter of respondents always used their asthma treatments as prescribed.[9] 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.

Conclusion

AAFA is pleased by the continued progress of the Medicare drug price negotiation program. We are committed to ensuring that lower prices result in lower out of pocket costs for consumers and improved access overall. We would be happy to work with CMS to address these challenges for the asthma and allergy community

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[6] Ng, A.E. & Boersma, P. (2023). NCHS Data Brief, no 460: Diagnosed allergic conditions in adults: United States, 2021. National Center for Health Statistics. https://dx.doi.org/10.15620/cdc:122809; Zablotsky, B., Black, L.I., & Akinbami, L.J.(2023). NCHS Data Brief, no 459: Diagnosed allergic conditions in children aged 0-17 years: United States, 2021. National Center for Health Statistics. https://dx.doi.org/10.15620/cdc:123250

[7] Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005-2014." J Allergy Clin Immunol Pract. 2017 Jan - Feb;5(1):171-175.

[8] Branum, A., & Lukacs, S. (2019). Food Allergy Among U.S. Children: Trends in Prevalence and Hospitalizations. Centers for Disease Control and Prevention; National Center for Health Statistics. https://www.cdc.gov/nchs/products/databriefs/db10.htm

[9] 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/

and Medicare. If you have any questions, please contact Jenna Riemenschneider at jennar@aafa.org.

Sincerely,

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