



February 6, 2023

Steven D. Pearson, MD, MSc
Institute for Clinical and Economic Review
14 Beacon Street, Boston, MA 02108

Re: ICER's Assessment of Tezepelumab for Severe Asthma: 12-month follow-up

Dear Dr. Pearson,

Thank you for the opportunity to comment on ICER's Tezepelumab for Severe Asthma final report and policy recommendations.¹ We appreciate the opportunity to share examples of how our patient community has experienced serious challenges accessing this medication since its approval.

We are concerned about persistent and deep racial and ethnic disparities in asthma prevalence and access to services.² These disparities stem from factors like low incomes, access to healthcare services, medical mistrust, and environmental pollution, that are driven by systemic racism.³ These factors are not adequately addressed in ICER's final report. We urged ICER to take into account that the clinical trials informing its analyses were disproportionately based on white participants.⁴

We concur with some of the report's policy recommendations, particularly regarding healthcare stakeholders' responsibility to promote equitable and affordable access to the medication. ICER did, to some extent, respond to our concerns regarding equity by applying a "Health Improvement Distribution Index," to reflect asthma treatment health gains for Black Americans. However, it was not clear how this index results in more equitable access in the real world, especially given ICER's reliance on inherently discriminatory Quality-Adjusted Life Years (QALY).

Unfortunately, a year later, access to tezepelumab remains problematic. Coverage under Medicare Part B has been changing and confusing to patients.⁵ We have received reports from our patient community regarding various utilization management and cost sharing approaches that make the medication difficult or impossible to access. Consumers report copayments in the hundreds or thousands of dollars; rejections of coverage and exemption requests; frustrating appeals processes; and a plan requiring a patient to receive

¹ <https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-and-policy-recommendations-on-tezepelumab-for-severe-asthma/>

² Asthma and Allergy Foundation of America, "Asthma Disparities in America" (2020). Available at <https://www.aafa.org/asthma-disparities-burden-on-minorities.aspx#pdf>

³ Asthma and Allergy Foundation of America, "Asthma Disparities in America" (2020). Available at <https://www.aafa.org/asthma-disparities-burden-on-minorities.aspx#pdf>

⁴ Letter from AAFA, American Academy of Allergy, Asthma, and Immunology, and the Allergy and Asthma Network to ICER, May 21, 2021. Available at <https://aafa.org/wp-content/uploads/2022/08/aafa-comment-letter-tezepelumab-treatment-severe-asthma.pdf>

⁵ In June 2022, Four Medicare Administrative Contractors (MACs) proposed to require Medicare patients to self-administer Tezpire despite the fact that the FDA approved it as a physician administered treatment and the product is not packaged for self-administration. Advocacy from patient groups like AAFA and others was required to prevent the proposal.



the drug by mail order pharmacy and then physically visit the physician's office for administration. These access problems are serious and must be addressed.

The use of QALYs, devaluation of the modified societal perspective, and ICER's presumption of non-cost-effectiveness before a price for tezepelumab was even announced, raised concerning questions about the review. ICER's final report may have supported health plans' decisions to place procedural and financial barriers in the way of access. At least in the case of tezepelumab, ICER's goal of "Fair Pricing, Fair Access and Future Innovation" remains to be seen. We look forward to ICER developing non-discriminatory value assessments that address the access and pricing concerns shared by our patient community.

Sincerely,

A handwritten signature in black ink, appearing to read 'Melanie Carver'. The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Melanie Carver
Chief Mission Officer
Asthma and Allergy Foundation of America