



Steven D. Pearson, MD, MSc
President, Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, Massachusetts 02109

October 14, 2021

Dear Dr. Pearson,

I am writing on behalf of the Asthma and Allergy Foundation of America (AAFA) to comment on your recent draft evidence report, “Tezepelumab for Severe Asthma,” which found that “tezepelumab reduces exacerbations in patients with severe asthma, including in some types of asthma for which other biologic therapies are not effective.”¹ We are encouraged by this finding and hopeful that this new monoclonal antibody might be effective for certain patients.

Concerns

Despite the overall positive conclusion about tezepelumab’s effectiveness, we are concerned that the draft report reflects inaccurate assumptions about potential use, undervaluing quality of life and overestimating potential uptake. As we noted in 2018 comments on ICER’s review of biologic therapies for asthma,² only a relatively small proportion of patients with moderate to severe asthma receive biologics, and typically only for a short duration. Furthermore, it is important not to underestimate the value of biologics that can address exacerbations that may lead to death.

ICER’s review also seems to understate the importance of the new possibilities tezepelumab raises for treatment. It appears likely that tezepelumab will not have a phenotype restriction, making it effective for asthma with either allergic or eosinophilic phenotypes, or mixed phenotypes. It would also be the only biologic therapy for T2-low asthma (i.e. non-allergic and

¹ Tezepelumab for Severe Asthma, Draft Evidence Report, Institute for Clinical and Economic Review, at ES2.

² AAFA letter to ICER on Draft Report “Biologic Therapies for Treatment of Asthma Associated with Type 2 Inflammation” (Oct. 22, 2018). <https://www.aafa.org/media/2398/aafa-comment-letter-icer-draft-report-biologic-therapies.pdf>



non-eosinophilic). AAFA considers the emergence of treatments for patients with no similar options to be particularly important for our community.

AAFA is also concerned that the draft report seems to reach a conclusion regarding cost effectiveness of the product despite unknown pricing information. The report acknowledges that “[p]ricing for tezepelumab is not yet known but at anticipated prices the treatment will not reach traditional thresholds considered cost-effective in the US market.”³ Basing this conclusion on “anticipated prices” is premature. As we stated regarding ICER’s review of peanut allergy treatments in 2019,^{4,5} conducting a review prematurely risks limiting access – or creating fears about limited access among people who could potentially benefit from this drug – when adequate information is not yet available. We urge caution in this area until additional information about pricing can be determined and analyzed.

We also recommend that ICER modify the Questions for Deliberation and Voting so “yes” and “no” are not the only responses available for a committee vote. Given the early review of this therapy by ICER but before FDA review and long-term data availability, ICER should reflect this nuance in the voting questions for example by adding “NA” for not applicable or another selection that does not force the committee into binary voting choices.

Moving toward reflecting equity in ICER analyses

We do appreciate that, consistent with our earlier recommendation, the draft report notes that most clinical trials, including those for asthma drugs, disproportionately enroll white participants, even though asthma is more prevalent and has more serious effects among Black Americans and other ethnic minority groups. We encourage ICER in future reports and analysis to continue to, at a minimum, strive to detail the representativeness, or lack thereof, of clinical trial data, and discuss how any lack of representation may impact the analysis.

³ *Id* at ES3.

⁴ AAFA statement, “Asthma and Allergy Foundation of America Elevates Patient Voice in ICER Review of New Peanut Allergy Treatments” (June 14, 2019). <https://www.aafa.org/media/2436/aafa-letter-icer-review-treatments-peanut-allergy.pdf>

⁵ AAFA statement, “Asthma and Allergy Foundation of America Responds to Premature ICER Review of New Peanut Allergy Treatments” (July 11, 2019). <https://www.aafa.org/media/2439/aafa-statement-on-icer-final-report-for-peanut-allergy-therapies.pdf>



The draft also makes clear that a treatment that benefits people with asthma will be particularly impactful for those minority populations that are most impacted. As noted in our earlier correspondence with ICER, AAFA is deeply concerned about racial and ethnic disparities in asthma, rooted in a broad range of social determinants that affect individual and community risk.⁶ The most affected communities are, in many ways, most in need of effective treatments, and we urge ICER to continue to note where such impacts may occur.

Conclusion

Our goal is for all patients with asthma to be able to access the medication they need, through reasonable pricing and adequate insurance coverage. We look forward to continuing to provide input on ICER's work in this area. Thank you for your time and attention.

Sincerely,

Kenneth Mendez
President & CEO
Asthma and Allergy Foundation of America

⁶ Asthma and Allergy Foundation of America, "Asthma Disparities in America" (2020). Available at <https://www.aafa.org/asthma-disparities-burden-on-minorities.aspx#pdf>