

May 8, 2019

Dr. Steven D. Pearson
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Dear Dr. Pearson,

On behalf of the Partnership to Improve Patient Care (PIPC), I am writing to provide comments on the Institute for Clinical Economic Review's (ICER) draft evidence report on treatments for peanut allergy. Our concerns are largely consistent with previous comments and we continue to urge ICER to evolve its methodology to be patient-centered and incorporate outcome measures that matter to patients and people with disabilities. Unfortunately, ICER's assessments continue to be conducted in a manner that, if used by insurers to make coverage and reimbursement decisions, would be dangerous to patient access and outcomes.

As you may know, researchers estimate that 32 million Americans have food allergies, including 5.6 million children under the age of 18. Caring for children with food allergies costs U.S. families nearly \$25 billion annually. The prevalence of childhood nut allergy is estimated to have more than tripled between 1997 and 2008.¹ Peanut reactions can be unpredictable, and even small amounts of peanut contact can cause a severe and potentially life-threatening reaction.² Peanut allergy can be particularly anxiety-provoking, as there is no proven way to determine which patients are at risk for life-threatening anaphylaxis reactions.³

We would like to highlight the following concerns with ICER's draft evidence report:

ICER Overlooks Patient Input and Preferences in Favor of Discriminatory QALYs

Despite the availability of validated quality of life metrics specific to patients with peanut allergy, ICER chose not to incorporate these metrics and instead used quality-adjusted life years (QALYs) in its assessment.

Patients with peanut allergies and their caregivers overwhelmingly look for reduced complexity and reduced caregiver burden. For example, reduced complexity of lifestyle and treatment

¹ Food Allergy Research Network. Facts and Statistics. <https://www.foodallergy.org/life-with-food-allergies/food-allergy-101/facts-and-statistics>. Accessed April 18, 2019

² Food Allergy Research Network. Peanut Allergy. <https://www.foodallergy.org/common-allergens/peanut-allergy>. Accessed April 18, 2019.

³ Cianferoni A, Muraro A, Food induced anaphylaxis. *Immunol Allergy Clin North Am*. 2012; 32(1):165-195.

would be of huge benefit to the nearly 40% of individuals with peanut allergies who experience accidental exposure or reaction.⁴ The Allergy and Asthma Network highlighted this lack of patient-centricity in their comments to ICER, stating, “We implore the evaluators to consider patient-reported outcomes rather than simply QALYs. We advocate for appropriate use of these innovative treatments and believe that when the right treatment is selected for the right patient at the right time it inevitably saves the system and the individual patient.”

ICER Uses a Faulty Model that Does Not Account for Complexities of the Condition

In this study, ICER chose to use a patient-reported outcome (PRO) tool that is known to be insensitive to allergies.^{5, 6} Peer-reviewed literature is replete with examples of where the use of this particular tool, the EQ-5D, has underestimated treatment effect and differences.⁷ Yet, ICER continues to choose a PRO tool that is insensitive to the outcome of interest solely because it can easily be cross-walked into a QALY. Doing so is both illogical and deliberately discriminatory to those suffering from disabilities and serious health conditions. As the Asthma and Allergy Foundation of America (AAFA) stated in their comment letter related to ICER’s recent review of asthma biologics, “when real-world healthcare data is available, real-world healthcare data should be used to estimate the potential patient population and treatment effectiveness.”

An additional flaw in ICER’s model is the assumption that everyone begins treatment at seven years of age. The two trials each have broad age ranges, from four to eleven years of age and from four to seventeen years of age. Based on ICER’s own assessment, there is some evidence that the younger the treatment recipient, the more effective the intervention (page 16, para 2).⁸ With this information, assuming an older age of treatment, and selecting one age for the entire population, minimizes the observed benefits that could be captured if the assessment took a more realistic perspective. It is an overly simplistic choice to address just one single age archetype. Treating patients earlier in life may significantly improve patient quality of life and increase the effectiveness of both interventions, an essential consideration that is not incorporated into ICER’s model.

⁴ Panel N.I.-S.E., Boyce J.A. Assa’as A., et al. Guidelines for the diagnosis and management of food allergy in the United States; report of the NIAID-sponsored expert panel. *J. Allergy Clin Immunol.* 2010;126(6 Suppl):S1-58.

⁵ Marklund B, Ahlstedt S, Nordström G. Health-related quality of life among adolescents with allergy-like conditions—with emphasis on food hypersensitivity. *Health and quality of life outcomes.* 2004 Dec;2(1):65. Flokstra-de Blok BM, Dubois AE. Quality of life in food allergy: valid scales for children and adults. *Current opinion in allergy and clinical immunology.* 2009 Jun 1;9(3):214-21.

⁷ Flokstra-de Blok BM, Van der Velde JL, Vlieg-Boerstra BJ, Oude Elberink JN, DunnGalvin A, Hourihane JO, Duiverman EJ, Dubois AE. Health-related quality of life of food allergic patients measured with generic and disease-specific questionnaires. *Allergy.* 2010 Aug;65(8):1031-8.

⁸ Page 16, para 2 of draft evidence report

ICER Continues Concerning Pattern of Premature Studies

ICER's rush to judgment has significant real-life implications for allergy patients. Because of the very low mortality rates for those with peanut allergies, most of the benefit accrued from these interventions will be seen in improved quality of life. Yet, ongoing studies measuring health-related quality of life (HR-QOL) in these interventions have not been published yet, which ICER acknowledges.⁹ By ICER's own valuation of the available evidence for these therapies, evidence on their effectiveness is currently only marked as inconclusive due to a lack of both head-to-head studies and HR-QOL data.¹⁰ This raises the question of why this report is being undertaken at this time when waiting for HR-QOL data would allow for a much more complete, and potentially more accurate, analysis. By conducting the assessment at this time, payers that reference ICER's reports to make coverage decisions will not receive a comprehensive understanding of the treatment's value and could rely on incomplete information to make decisions detrimental to patients' access to care.

Conclusion

ICER continues to use one-size-fits-all models and limited data that do not capture the complexities of different patient populations in their assessments of innovative medical products. PIPC echoes the Asthma and Allergy Network, the Asthma and Allergy Foundation of America, and other patient advocacy groups that have implored ICER to acknowledge that patients are unique individuals with different preferences who respond differently to treatments. Publishing reports that make one-size-fits-all judgements of value is harmful to patients and the health care system as a whole.

Thank you for your consideration of our comments.

Sincerely,



Tony Coelho
Chairman, Partnership to Improve Patient Care

⁹ Page 21 of draft evidence report

¹⁰ Pages 22-23 of draft evidence report