Asthma and Allergy Foundation of America

September 12, 2016

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

RE: ICER National Call for Proposed Improvements to Value Assessment Framework

Dear Dr. Pearson,

The Asthma and Allergy Foundation of America (AAFA) is pleased to provide input on the 2017 update to Institute for Clinical and Economic Review (ICER)'s Value Assessment Framework. AAFA (www.aafa.org), a not-for-profit organization founded in 1953, is the leading patient organization for people with asthma and allergies, and the oldest asthma and allergy patient group in the world. AAFA is dedicated to improving the quality of life for people with asthma and allergic diseases through education, advocacy and research.

As noted by ICER and many other organizations, rising health care costs, as well as changing benefit designs, place increased pressure on care access and affordability. In this environment, it is more important than ever to address the issue of value, and to make sure these efforts are centered on care and outcomes that matter most to individuals, their families and caregivers.

One important element of this is making sure that patients, providers and other decision-makers have sound information and decision-support tools available to them. Understanding and defining the value of health care treatments and interventions is a national priority. AAFA is eager to take part in the value discussion. Patient perspectives on value often integrate considerations beyond clinical outcomes and cost, such as a treatment's ability to help patients achieve personal goals.

AAFA recognizes ICER's recent efforts to engage the patient community by, for example, appointing a patient representative to the governance board and by outlining a plan for gathering patient input in the scoping documents that inform ICER's reviews. However, we urge ICER to adopt a more open and collaborative process for identifying and appointing additional patient representation as well as create other opportunities for patient engagement.

Patients are critical members of the health care, drug development and innovation, research and policy making teams, and they must be given the opportunity to work side by side as equal partners with clinicians, researchers, payers, and policymakers in order to achieve the outcomes that are most important to them. Solving the challenges and problems of living with chronic diseases such as allergies and asthma requires active engagement of patients, families, and caregivers, in all issues relating to clinical discoveries and interventions, clinical trials, medical devices, regulation of drugs and devices, and their uses. Value

methodologies should consider diverse patient perspectives based on their unique circumstances, needs, treatments and life goals.

AAFA offers comments in the four areas ICER has identified as the highest priorities for potential revision to the framework.

1. ***Methods to integrate patient and clinician perspectives on the value of interventions that might not be adequately reflected in the scientific literature, elements of value intended to fall in the current value framework within "additional benefits or disadvantages" and "contextual considerations"***

We commend ICER for recognizing the importance of integrating patient perspectives as a high-priority area to improve ICER's value assessment framework. AAFA believes that there is a significant gap in appropriate, validated methods to integrate patient and clinician perspectives into value assessments and appreciates ICER's effort to solicit more input in this area. AAFA is concerned, however, that the scope of this priority as articulated in the call for comments is too narrow and assumes that relevant patient-centered data is widely available for assessment. Specifically, the current scientific literature does not adequately incorporate patients' perspectives, which underscores the need for a paradigm shift in how research is designed, conducted and evaluated. To imply that the current literature in any way includes appropriate incorporation of patient perspectives misrepresents the state of the field and, unfortunately, downplays the underlying need for gathering and considering these perspectives and the potential impact their inclusion can have on value assessments.

Therefore, AAFA encourages ICER to partner and collaborate directly with patients and patient advocacy groups and incorporate the patient voice in its value assessment process. We encourage ICER to acknowledge the fundamental deficiencies, gaps, and challenges in capturing and recognizing patient perspectives of value. We urge ICER to develop a more robust, systematic process for incorporating the patient perspective into its reviews and to make the process transparent and understandable to patients. Doing so will greatly improve and lead to greater credibility of ICER's work.

AAFA recommends that ICER develop a more formalized patient-engagement process as part of its value assessment framework to ensure that the process and results are informed by patients, their families and caregivers. AAFA recommends that as part of each assessment, ICER describe how patient input and preferences were considered and incorporated to ensure accountability to patients, demonstrate responsiveness to patient input, and help patients better understand the information ICER uses.

AAFA recommends that ICER consider ongoing work that addresses the need for capturing the patent perspective including work undertaken by the National Health Council (NHC) and

the Partnership to Improve Patient Care (PIPC)[1]. The NHC, with stakeholder input, has created a Value Model Rubric to help evaluate the patient centeredness of value models and to guide value model developers on the meaningful incorporation of patient engagement throughout their processes. [2] PIPC held a roundtable discussion about value assessments with organizations representing diverse patients and people with chronic conditions and disabilities. The PIPC roundtable report elicits and captures diverse perspectives on patient-centeredness in value assessment. AAFA participated in these activities and shares the concerns noted in the PIPC report and supports ICER's use of the NHC's Patient-Centered Value Model Rubric.

2. ***Incremental cost-effectiveness ratios: appropriate thresholds, best practice in capturing health outcomes through the QALY or other measures***

AAFA recognizes the importance of evaluating treatments and services to understand their comparative clinical and cost effectiveness. However, we stress that the appropriateness of outcomes selected is critical to the relevance and accuracy of determining value to patients. ICER should better reflect patient-centered outcomes. Quantifying value in a way that is useful and meaningful to individuals, their families and caregivers requires a basic understanding of their values and preferences. Doing so will benefit the patient and other stakeholders as they identify and integrate the appropriate patient-centered criteria in assessing the value of treatments for a particular condition. ICER's assessments should not conflate value considerations at the population level with value considerations experienced at the individual level, where real-world personal, clinical, outcomes and financial considerations differ from population-based models.

Again, input from the appropriate patient group for identification of outcomes that are important to them is critical to support a value assessment approach that is meaningful and has utility for individuals, their families and caregivers.

3. ***Methods to estimate the market uptake and "potential" short-term budget impact of new interventions as part of judging whether the introduction of a new intervention may raise affordability concerns without heightened medical management, lower prices, or other measures.***

We are concerned that this ICER priority appears to focus solely on identifying methods that would help assess short-term affordability from the payer perspective and results in restricted access to care and treatments as an unintended consequence for patients. AAFA

[1] PIPC ROUNDTABLE SUMMARY: ASSESSING VALUE TO THE PATIENT June 17, 2016 http://www.pipcpatients.org/pipc-admin/pdf/a19d1a_PIPC%20Roundtable%20Summary%20-%20Value%20to%20the%20Patient.pdf

[2] The Patient Voice in Value: The NHC Patient-Centered Value Model Rubric http://www.nationalhealthcouncil.org/value

urges ICER to also consider long-term outcomes and impacts from the patients' perspective. While interventions may have notable short-term budget impacts, they may not only greatly improve patient outcomes but can reduce the costs for a patient and the health care system over a longer period of time by reducing the likelihood of more costly interventions and/or poorer outcomes such as frequent emergency department visits, hospitalizations and/or surgeries.

Focusing on short-term (5 years or less) budget impacts in isolation, de-coupled from approaches that consider longer-term impacts over a person's lifetime, is not an appropriate or meaningful patient-centered approach to assessing the impact and value of interventions and services. As currently described, ICER's priority appears to focus too narrowly on the short-term impact for payers on siloed costs.

4. ***Methods to set a threshold for potential short-term budget impact that can serve as a useful "alarm bell" for policymakers to signal consideration of whether affordability may need to be addressed through various measures in order to improve the impact of new interventions on overall health system value.***

AAFA has concerns with ICER's focus on short-term budget impact models. We urge ICER to acknowledge that the measure of value to patients inherently extends beyond the short-term perspective that payers and other stakeholders often adopt. We are concerned that emphasizing the budget impact of treatments using assumptions and arbitrary thresholds for short-term budget impact will be and is used as a rationale to restrict patient access to evidenced based care and treatment, particularly when they are established without the context of any offsetting long-term benefits that are important to individuals, their families, and caregivers. Chronic conditions such as asthma and allergies impact individuals throughout their lives. Furthermore, we offer the following suggested revision for your consideration to the above wording: *Methods to set a threshold for potential short-term budget impact that can serve as a useful tool for policymakers to consider when affordability may need to be addressed through various measures in order to improve the impact of new interventions on overall health system value.*

AAFA is eager to assist in any way that we can, to help further inform ICER's discussions. If you require additional information or clarification, please do not hesitate to contact me at csennett@aafa.org or Meryl Bloomrosen, AAFA's Senior Vice President Policy, Advocacy, and Research at mbloomrosen@aafa.org.

Regards,

Cary Sennett, MD, PhD
President and CEO