National Eczema Association

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Steven D. Pearson, MD, MSc
President, Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
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Dear Dr. Pearson:

Thank you for the opportunity as a Key Stakeholder Organization for the 2021 evaluation of *JAK Inhibitors and Monoclonal Antibodies for the Treatment of Atopic Dermatitis* to engage in the recent webinar as well as a follow-up meeting with the ICER team to discuss the proposed model supporting this effort. We would like to submit the following feedback for consideration as you finalize the framework for analysis.

1. **Calculation of life-years and equal value life-years gained**
    - We understand and agree with the model assumption that treatment will have no impact on mortality. As such, we are concerned that calculation of life-years and equal value life-years gained (evLYG) for 'completeness' could have an unintended consequence of de-valuing the analyzed treatments. We suggest it would be appropriate to either not report these as analysis outcomes or present this information in a separate table apart from the main model results so that it may be appropriately qualified.

2. **Inclusion of anxiety and depression in the cost consequence analyses**
    - We applaud ICER for including outcome improvements related to itch and sleep in the cost consequence analyses. However, as we have shared previously, many atopic dermatitis patients, and especially those with moderate to severe disease, suffer from anxiety and depression stemming largely from the uncontrolled and unpredictable nature of their disease, which can also detrimentally affect work/school.[1-3] We strongly recommend these impacts be additional included in the cost consequence analyses. There are now published clinical trial data from at least two of the drugs to be evaluated[4,5] on this important consideration that contributes to disease and quality of life improvement as well as the overall cost of care.

3. **Importance of the pediatric/adolescent model**
    - We noted the intention to evaluate the effect of therapies on the pediatric population as a <u>potential</u> scenario analysis given the more limited information for this population across all treatments to be included in this report. However, as completed, and ongoing clinical trials for abrocitinib[6-8], upadacitinib[9-11], and

tralokinumab[12] have included ages 12 and up, as well as the potential for off-label usage, we recommend this scenario be included and emphasis given to help give the panel a clearer picture of the value in this population. As part of this proposed analysis, we also reiterate the importance of factoring into the assessment the impact on caregivers for this population. Numerous reports have indicated the caregiver burdens associated with atopic dermatitis[2,13-14], including a recent publication highlighting societal impacts that have potential cost implications.[15]

4. **Access, affordability, and out-of-pocket considerations**
    - While the "average" eczema patient experiences substantial financial difficulties due to the well documented economic burden of this disease, patients of lower socioeconomic status are particularly vulnerable.[16-18] Without explicit consideration for health plan polices that place therapies on tiers with high out-of-pocket cost-sharing, lower socioeconomic status patients could be impacted more than those with more expendable income. A recent NEA survey has shown that patients with lower household income and/or Medicaid insurance are more likely to report a greater negative financial impact due to out-of-pocket costs for atopic dermatitis disease management.[19] We suggest the ICER team expand on this either in the scenario analyses and/or be more explicit in the contextual considerations section of the report about this important consideration.

5. **Modified societal perspective**
    - We note the model indicates that the modified societal perspective will be included as a co-base case only "if the societal costs of atopic dermatitis are found to be large relative to the direct health care costs". As the trigger for undertaking this analysis remains unclear, we reiterate the value of this assessment from the patient and caregiver perspective and agree with ICER's plan to include components such as productivity and caregiver burden when it is undertaken.
    - We are unsure of the inclusion of "criminal justice and incarceration" in the modified societal perspective as we are unaware of any publications focusing on atopic dermatitis in this population. If included, it may warrant more explanation as to why these items were specifically identified in the model plan.

We hope that these comments are helpful as you finalize your assessment plan, and we thank you for willingness to engage with our organization and our patient community.

Sincerely,

Julie Block
NEA President and CEO

Lawrence F Eichenfield, MD
Chair, NEA Scientific & Medical Advisory Council

With Support From:

Kenneth Mendez
President and CEO
Asthma and Allergy Foundation of America

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