September 24, 2021

PUBLIC COMMENT FOR REVIEW OF SEVERE ASTHMA TREATMENT

As President of the American Association for Respiratory Care (AARC), I am writing to express concerns over the potential for the Institute for Clinical and Economic Review (ICER) to limit access to *tezepelumab*, the first biologic to have shown consistent and significant reductions in exacerbations in a broad population of severe asthma patients.

The AARC is a national professional organization of 40,000 members and whose organizational activities impact over 190,000 practicing respiratory therapists across the country. Respiratory therapists are medical professionals who specialize in all aspects of pulmonary medicine and treat patients who suffer from chronic respiratory conditions like chronic obstructive pulmonary disease (COPD), asthma, pneumonia, lung trauma and other respiratory-related diagnoses such as COVID-19.

Tezepelumab has been granted Priority Review by the U.S. Food and Drug Administration. because it believes the biologic, if approved, would offer significant improvements in the safety or effectiveness for the treatment of severe asthma when compared to standard applications. Of concern to the AARC, and respiratory therapists who treat the disease, is the fact that patients with severe asthma are commonly prescribed the same treatment modalities as those who suffer mild or moderate asthma, although severe asthma imposes more life-threatening symptoms. That is why unfettered access to this new and promising biologic is mandatory for patients with severe asthma who face twice the risk of emergency visits to the hospital and an increased risk of mortality.

It is also important to note that asthma compounds health disparities, especially among Black Americans and those living below poverty levels and exposed to environmental triggers. Access to a new biologic with promising results of significant improvements over current treatments offers the option to give patients of all backgrounds and races a better chance of managing severe asthma.

As we understand the process, ICER uses a "health economics" approach in determining whether a new drug is worth the cost. While clinical trials data and available pricing information are taken into consideration, we are concerned that an analysis that relies too heavily on quantitative data does not account for the quality of life that matters most to patients, such as the ability to work, attend social functions, and enjoy time with family and friends. Treatment modalities can't be a "one size fits all" compromise. People living with severe asthma, along with their

family and caregivers, are daily burdened, even frightened, by the persistent and often unpredictable impact of symptoms.

ICER has a chance to make a difference and provide clinicians and patients suffering from severe asthma a new targeted treatment that could provide unprecedented relief and an improved quality of life. Because each patient's experience with severe asthma is not exacerbated by the same triggers, different drugs offer different benefits. Now is the time to give those patients with several asthma a chance for a new, promising treatment that can make a difference in their lives.

Sincerely,

Sheri Tooley

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