DISCLOSURES

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ICER Can Do Better for Patients

Kenneth Mendez, MBA

COMMENTARY

The Asthma and Allergy Foundation of America (AAFA), 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 saving lives and

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reducing the burden of disease for people with asthma and allergic diseases through support, advocacy, education, and research. While we appreciate the review by the Institute for Clinical and Economic Review (ICER) of biologic therapies for asthma and its effort to include patient perspective in the analysis, ICER's analysis falls short of adequately addressing certain factors related to health and quality of life for people living with asthma, particularly those with severe, uncontrolled asthma.

TABLE 1 Treatment Responder Scenario Incremental CE Ratio Cost per QALY Gained Including Modified Societal Perspective (vs. SoC)

	Omalizumab	Mepolizumab	Reslizumab	Benralizumab	Dupilumab
Treatment responder scenario CE cost ratio (Table 4.21 ^a), \$	213,000	214,000	222,000	199,000	218,000
Incremental QALY from modified societal perspective (Table 4.20 ^a)	1.73	1.63	1.48	1.41	1.63
Adjusted incremental CE ratio including societal perspective, \$	123,121	131,288	150,000	141,135	133,742

Note: Data were based on internal analyses conducted by AAFA.

^aFor tables, please see the ICER asthma final evidence report.⁷

AAFA = Asthma and Allergy Foundation of American; CE = cost-effectiveness; QALY = quality-adjusted life-year; SoC = standard of care.

Asthma is an episodic yet chronic disease that places great burden on patients, their families, and the health care system. In the United States, approximately 6 million children and 20 million adults currently have asthma.¹ Deemed a significant public health and medical issue, asthma often requires the use of emergency care and is responsible for a high number of missed school and/or work days.² According to the Centers for Disease Control and Prevention, asthma costs the United States \$56 billion each year.³ A growing body of knowledge regarding the pathophysiology and environmental factors leading to the development of the disease has resulted in the proliferation of targeted biological and small molecule therapies that aim to achieve disease control while minimizing morbidity.⁴

To estimate the cost-effectiveness of the biologic therapies, ICER used a Markov model that included 3 primary health states: (1) an asthma nonexacerbation state (i.e., day-to-day asthma symptoms); (2) an asthma exacerbation state (including 3 mutually exclusive subcategories: asthma-related event that requires an oral corticosteroid burst without emergency department (ED) or inpatient care, asthma-related ED visit, or asthma-related hospitalization); and (3) death (including asthma-related mortality and other cause mortality). While ICER's efforts in developing a model framework and approach to estimating the cost-effectiveness of biologic therapies seek to include the patient voice, the asthma review falls well short of this goal. ICER's analysis yields only a partial view of the effect of biologics, missing information on real-life patient, provider, and insurer experiences and decision making. For example, ICER's calculations of cost-effectiveness and budget impact were based on the population for which biologics are approved: patients aged 6 years and older with moderate to severe uncontrolled asthma. However, this is an extremely heterogeneous group, and only some patients are considered candidates for biologics, either based on their providers' assessments or their insurance policy's restrictions. Data confirm that in the real world, biologics are used by a far smaller proportion of patients with severe asthma than the 27% ultimately assumed in ICER's budget impact analysis.

In our comment letter on the draft report,⁵ AAFA suggested that ICER develop an approach using real-world data to more

accurately reflect comorbidities, incremental adverse events from chronic steroid use, and the intrinsic biologic variability of the inputs associated with asthma. We noted that claims and enrollment datasets from the Centers for Medicare & Medicaid Services, IBM Watson Health, and other sources are available that could offer a real-world view regarding various asthma disease and treatment questions. Such data could, for example, be used to compare the rate of asthma exacerbations in patients using biologics to those not using biologics. Without such real-world information, cost-effectiveness analyses reflect a merely theoretical view of the effectiveness of medications for real people with asthma.

Similarly, we are concerned that ICER's analysis did not accurately reflect the patient-reported effect of asthma. For example, adults living with uncontrolled asthma often miss days of work, and parents of children with asthma miss work to care for them. AAFA's "My Life with Asthma" survey found a level of lost work productivity that was higher than the figure used by ICER. Without meaningfully reflecting the health and social costs of asthma, a cost-effectiveness analysis is incomplete.

As noted by ICER and many other organizations, the high price of asthma medications contributes heavily to health care costs.⁶ AAFA appreciates that ICER is calling attention to cost issues and is using an economic framework to do so.

However, we are not persuaded that the assumptions ICER made in its economic analyses meaningfully reflects the actual experience of asthma patients using biologics or any subpopulations of this group. We developed estimates demonstrating that small changes to the cost and utility assumptions in ICER's analysis could lead to a significant difference in cost per quality-adjusted life-year. These overlaid analyses more meaningfully reflect the real world and patient experience. With these minor changes, the cost effectiveness figure were at or below ICER's target of \$150,000 (Table 1).

Ultimately, for AAFA, our priority is that patients with asthma receive the medication and health care services that are right for them at an affordable cost. We understand that cost-effectiveness is an important factor for payers and appreciate ICER's focused attention to this category of asthma drugs, which holds important promise for improving—and

sometimes saving—lives. Our hope is that moving forward, ICER can evolve and improve its analyses to incorporate the real-life data and patient-reported quality of life information that meaningfully reflects the value of this set of medications to those who could benefit from them.

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