



June 5, 2018

Institute for Clinical and Economic Review
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Submitted electronically to publiccomments@icer-review.org

To Whom It May Concern:

I am writing on behalf of the Asthma and Allergy Foundation of America (AAFA) to comment on the Draft Scoping Document on Biologic Therapies for Treatment of Asthma Associated with Type 2 Inflammation. As the leading patient organization for people with asthma and allergies and the oldest asthma and allergy patient group in the world, AAFA appreciates the opportunity to offer insight into the experiences of patients with moderate to severe asthma. Our recent 2017 patient survey, “My Life With Asthma,”¹ a national, three-part study about asthma in the United States, offers qualitative insight on the benefits and harms not typically addressed with clinical evidence. What follows are our findings that we hope will provide greater insight as ICER does its assessment on biologic therapies for treatment associated with type 2 asthma.

Disease Experience: AAFA’s survey included a total of 804 adult respondents living with asthma. Of these, 185 had “severe uncontrolled” asthma.² Among those with severe uncontrolled asthma, more than half of respondents reported that they experienced asthma symptoms more than once a day.³ Over a quarter of other respondents have symptoms more than twice a week.⁴ Respondents with severe uncontrolled asthma frequently end up in the emergency room. Eighteen percent reported one visit to the ER in the past 12 months, and an additional 42 percent reported two or more ER visits over the same time period.⁵ Meanwhile, 28 percent of other respondents with asthma reported at least one ER visit in the past 12 months.⁶

Day-to-Day Life: The majority of those with severe uncontrolled asthma said they were scared and burdened by their condition.⁷ More than two-thirds said it prevents them from living the life they want to live and more than three quarters said their asthma is always in the back of their

¹ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). The full report is available at www.aafa.org/media/my-life-with-asthma-in-2017-survey-findings-report.pdf.

² These respondents reported experiencing symptoms of asthma such as chest tightness, cough, shortness of breath, or wheezing more than two times per week; waking up during the night because of coughing or other asthma symptoms more than once per week; using a quick-relief or “rescue” inhaler more than two times per week; or having at least two asthma attacks that required them to take oral corticosteroids in the past 12 months. In addition, these 185 respondents reported either that a doctor or nurse had told them they had severe asthma, and that they had used a combination inhaler, an anti-IgE biologic agent, or an anti-IL-5 biologic agent in the past 12 months for their asthma.

³ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 5.

⁴ *Ibid*

⁵ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 6.

⁶ *Ibid*

⁷ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 7.



mind.⁸ Close to half (44 percent) felt like asthma ruins their life.⁹ Other respondents were less likely to report similar day-to-day impacts of asthma on their lives, but significant portions were scared and burdened by their asthma, as well as prevented from living the life they want to live.¹⁰

Impact on Family and Caregivers: Sixty percent of those with severe uncontrolled asthma and 31 percent of others reported that their conditions scare their loved ones.¹¹ Almost half of respondents with severe uncontrolled asthma reported their condition was a burden to their family.¹² Among caregivers for those with severe asthma, 77% reported being scared by their charge's condition, as were 29 percent of the caregivers who care for others with asthma.¹³

Impact on Ability to Work, Exercise, Care for Family: Respondents with severe uncontrolled asthma were much more limited in their daily activities than others with asthma. Forty percent of respondents in the former category reported extreme limitations on their activities.¹⁴ Nearly three quarters of respondents with severe uncontrolled asthma and half of other respondents missed at least one day of work in the past 12 months, and severe uncontrolled asthma was likely to cause extended absences from work (41 percent missed over 10 days of work).¹⁵ When at work or school, a majority of respondents in both categories reported at least one day in the past 12 months when tasks were difficult to perform because of asthma.¹⁶

Treatments: Cost and Other Barriers: Respondents with severe uncontrolled asthma were generally less satisfied with current asthma medicines than other respondents. More than one in three in the former category reported being somewhat or very unsatisfied compared to only 14 percent of the latter.¹⁷ Both types of respondents said treatment effectiveness and cost were the most important factors.¹⁸

Compliance with asthma treatment was similar across both groups: around one in four respondents always used their asthma treatments as prescribed by their doctor or nurse.¹⁹ The top three reported reasons for not using treatments were related to cost: inability to afford treatment, treatment was too expensive, and lack of insurance coverage for the treatment.²⁰ Respondents with severe uncontrolled asthma were more likely to report that their asthma treatments were not covered by their insurance plan.²¹ Compliance was also impacted by effectiveness (or lack

⁸ *Ibid*

⁹ *Ibid*

¹⁰ *Ibid*

¹¹ *Ibid*

¹² *Ibid*

¹³ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 17.

¹⁴ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 12.

¹⁵ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 13.

¹⁶ *Ibid*

¹⁷ *Ibid*

¹⁸ Asthma and Allergy Foundation of America, "My Life With Asthma: Survey Overview (2017). 14.

¹⁹ *Ibid*

²⁰ *Ibid*

²¹ *Ibid*



thereof) among respondents with severe uncontrolled asthma; for other respondents, side effects of treatments were a major concern.²²

Responses from healthcare providers echo this theme: of the 215 providers surveyed,²³ 74 percent said cost and coverage of treatment are the biggest barriers to controlling moderate-to-severe asthma in adults.²⁴

Other Relevant Publications on Patient Experience: While not unpublished, AAFA would like to point towards several studies regarding the experiences of individuals with asthma. One comprehensive review of the literature found that patients with asthma prefer treatments that increase days without symptoms, but would be willing to sacrifice some treatment outcomes (specifically, symptomless days) for higher convenience and fewer side effects.²⁵ Additionally, research shows that there is underuse of asthma medication among racial and ethnic minorities in the United States, due in part to issues such as cost and whether or not they are insured; one study of adults aged 50-64 found that African American adults were significantly more likely to have uncontrolled asthma than Whites, and that adults in the age cohort with cost limitations were significantly more likely to have limitations of activity.^{26,27}

Biologics: In our survey, few respondents overall reported significant knowledge of these new treatments.²⁸ Yet biologic treatment can be life changing and greatly improve quality of life for patients with asthma.²⁹ AAFA testimonials from several patients who have used a biologic include words like “revolutionary” and “miraculous.” Quality of life has been greatly improved.³⁰ AAFA also supports the use of biologics because they are more targeted to different “types” of asthma than previous classes. Xolair (omalizumab), Nucala (mepolizumab), Dupixent (dupilumab), Cinqair (reslizumab), and Fasenra (benralizumab) have different indications and provide options for patients based on their specific kind of asthma. These treatments may also be an attractive alternative to frequent use of oral corticosteroids for patients with frequent exacerbations.

However, biologics are out of reach for many due to cost. AAFA receives requests every day for financial assistance because many patients fall into the gaps between insurance and patient assistance. AAFA also hears from patients expressing their frustration with the high cost of

²² Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 14.

²³ These included physicians, physician assistants, nurses, nurse practitioners, and respiratory therapists with primary specialties in allergy/immunology, pulmonology, primary care, family medicine, and internal medicine. Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 21.

²⁴ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 29.

²⁸ Asthma and Allergy Foundation of America, “My Life With Asthma: Survey Overview (2017). 15.

²⁹ McCracken, Jennifer, Julia Tripple, and William J. Calhoun. “Biologic therapy in the management of asthma.” *Current opinion in allergy and clinical immunology* 16, no. 4 (2016): 375.

³⁰ For example, patients have told us that biologics allowed them to “walk, dance, [and] sing,” or be able to “visit friends with cats.”



biologic treatment.³¹ Despite the promise of biologics, if they are cost-prohibitive for the majority of the population, their overall impact will be minimal.

Conclusion

Thank you for providing us with the opportunity to share our experiences as well as the experiences of those for whom we represent. We look forward to further sharing the insights of our patient community and of our scientific advisors when the Draft Evidence Report is released. Should you have any questions, please contact me at 202-974-1231 or kmendez@aafa.org.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

³¹ For example, one patient wrote to AAFA “It was difficult to get my insurance to cover the Xolair. I’m concerned if I stop the Xolair but then need to restart it that my insurance will give me problems again. I have not been well enough to get my allergy shots.” Another wrote, “The Xolair did not lower my eosinophils but the Nucala helped until my funding program ran out so I had to stop it.”