

# Prevalence of Asthma Control and the Associated Disease Burden in US Patients With Asthma Treated With a Fixed-dose Combination of Inhaled Corticosteroid and Long-acting $\beta_2$ -agonist

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## Background and Aims

For patients with uncontrolled asthma requiring Step 3 or Step 4 treatment according to the Global Initiative for Asthma report, a combination of inhaled corticosteroid (ICS) and long-acting  $\beta_2$ -agonist (LABA) is recommended as a preferred maintenance treatment option.<sup>1</sup>

Despite optimal adherence to ICS/LABA, it has been estimated that approximately 30%–50% of patients with asthma remain uncontrolled.<sup>2–4</sup>

To address a paucity of real-world data describing asthma control, this study aimed to quantify asthma control in US patients treated with a fixed-dose combination (FDC) of ICS/LABA.

## Methods

### STUDY DESIGN AND STUDY POPULATION

Real world Linked administrative claims data with cross-sectional survey US cohort

### Primary objective:

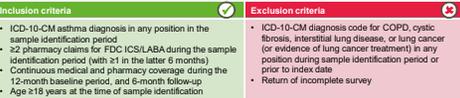
- Assess the prevalence of asthma control among patients treated with FDC ICS/LABA, as assessed by the ACT<sup>5</sup> (poorly controlled, somewhat controlled, controlled).

### Selected secondary objectives (reported here):

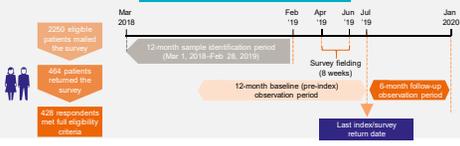
- Assess the prevalence of asthma control among patients treated with FDC ICS/LABA, as assessed by the ACOQ-6<sup>6</sup> (uncontrolled, partially controlled, controlled).
- Describe the concordance between ACT and ACOQ-6 in assessing asthma control.
- Assess asthma-related quality of life (mini-AQLQ<sup>7</sup>) and health status (EQ-5D-3L<sup>8</sup>) by asthma control.
- Describe baseline sociodemographic and clinical characteristics by asthma control (measured with the ACT).

**Data sources:** Optum Research Database claims data, linked to responses from a mailed cross-sectional survey to commercially insured patients in the US about health status, asthma control, asthma-related quality of life, and patient sociodemographic and clinical characteristics.

**Data analysis:** All study variables were analyzed descriptively, with additional bivariate analysis.



**Final analytical sample criteria:**  
 • Return of survey to survey vendor  
 • Self-reported healthcare provider diagnosis of asthma



The ACT is a 5-item tool for measuring asthma control, with scores ranging from 5 (poor control) to 25 (complete control); the recall period is 4 weeks. The ACOQ-6 is a 6-item tool relating to asthma symptoms and rescue medication and is used to assess asthma control over a 1-week recall period, with scores ranging from 0 (no impairment) to 6 (maximum impairment). The mini-AQLQ is a 15-item questionnaire on symptoms, activities, emotions, and environment, on a scale from 1 to 7, with lower scores indicating greater impairment; the recall period is 2 weeks. The EQ-5D-3L contains two components: the first is a 5-item questionnaire covering mobility, self-care, usual activities, pain/discomfort, and anxiety/depression; all on the day the respondent is answering, across three levels (no problems [level 1], some/moderate problems [level 2], and extreme problems [level 3]); the second consists of a visual analog scale (EQ-VAS) that records a respondent's self-rated health on a vertical VAS where endpoints are 'best imaginable health' and 'worst imaginable health'. ACT, Asthma Control Test; ACOQ, Asthma Control Questionnaire; AQLQ, Asthma Quality of Life Questionnaire; COPD, chronic obstructive pulmonary disease; ICD, International Classification of Disease; VAS, visual analog scale.

**Disclosures**  
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 • On behalf of all authors, an audio recording of this poster was prepared by William Zhang, who did not receive any payment for this recording.

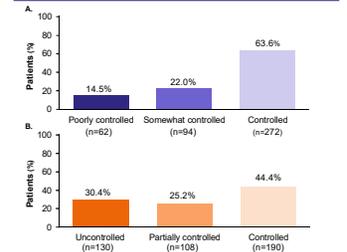
## Results

- Of 2260 patients mailed the survey, 464 responded, and 428 met the full eligibility criteria (overall survey sample).

### Asthma control and concordance between ACT and ACOQ-6

- Using the ACT, over a third of patients were classified as uncontrolled (poorly/somewhat controlled) (Figure 1).
- Approximately two-fifths of these patients reported shortness of breath once or twice a week in the past 4 weeks (n=175, 40.9%).
- Three-quarters of those classified as 'controlled' on the ACT reported no nighttime awakening in the past week due to asthma symptoms, while 18% reported hardly ever awakening (Table 2).
- There was a high degree of concordance between ACT and ACOQ-6 scores in identifying asthma control (Pearson correlation coefficient -0.85, P<0.001 where high ACT score or low ACOQ-6 score both indicate greater control), though the proportion of controlled patients was greatest with the ACT; 90% of those 'poorly controlled' on the ACT were also 'uncontrolled' on the ACOQ-6; 51% of those 'somewhat controlled' or 'controlled' on the ACT were also 'controlled' on the ACOQ (Table 2).

Figure 1. Level of asthma control by ACT<sup>5</sup> (A) or ACOQ-6<sup>6</sup> (B)



\*ACT recall: 4 weeks; score thresholds: <16, poorly controlled; 16–19, somewhat controlled; >19, controlled. \*ACOQ-6 recall: 1 week; score thresholds: >1.5, uncontrolled; >0.75–1.5, partially controlled; <0.75, controlled.

### Sociodemographic and clinical characteristics, HCRU and costs (Table 1)

- The majority of patients overall were white, female and overweight/obese, with an average age at asthma diagnosis of 24 years.
- Comorbidities and obesity were generally more common among those categorized as 'poorly controlled' on the ACT; the frequency of asthma exacerbations during the baseline period was also twice as high among 'poorly controlled' patients, compared with those who were 'controlled'.
- The proportion of patients with optimal adherence (medication possession ratio [MPR]  $\geq 0.8$ ) was highest among those classified as 'controlled' by ACT, versus those classed as uncontrolled (46.7% vs 35.6%, respectively).
- All-cause and asthma-related healthcare resource utilization (HCRU) and costs during baseline tended to be higher among those classified as 'poorly controlled' on the ACT as compared with patients with better levels of ACT-based asthma control.

### Health status and asthma-related quality of life (Table 3)

- Mini-AQLQ and EQ-5D-3L scores were higher among patients classified as 'controlled' by the ACT or ACOQ-6.

Table 1: Baseline<sup>†</sup> sociodemographic and clinical characteristics, HCRU, and costs

	Overall <sup>‡</sup> N=428	ACT-assessed level of asthma control		
		Poorly controlled; n=62	Somewhat controlled; n=94	Controlled; n=272
Age (years) <sup>§</sup> , mean (standard deviation [SD])	49.8 (12.0)	48.6 (11.4)	49.8 (12.4)	50.1 (12.1)
Female, n (%)	296 (69.8)	47 (75.8)	66 (70.2)	173 (63.0)
Race, white n (%)	378 (88.3)	47 (75.8)	86 (91.5)	245 (90.1)
Former smoker, n (%)	119 (28.1)	19 (31.2)	27 (28.0)	73 (27.1)
Current smoker, n (%)	13 (3.1)	4 (6.5)	3 (3.2)	6 (2.2)
BMI (kg/m <sup>2</sup> ), mean (SD)	29.5 (6.9)	31.2 (7.1)	30.8 (6.3)	29.3 (6.2)
Body mass index category (kg/m <sup>2</sup> ), n (%)				
Underweight (<18.5)	n=425	n=1	n=54	n=270
Normal (18.5–24.9)	105 (24.7)	14 (23.0)	21 (22.3)	70 (25.9)
Overweight (25–29.9)	133 (31.3)	16 (26.2)	28 (29.8)	89 (33.0)
Obese ( $\geq 30$ )	183 (43.1)	31 (50.8)	44 (46.8)	108 (40.0)
Age (years) at asthma diagnosis, mean (SD)	23.9 (18.2)	24.1 (19.4)	24.7 (18.0)	23.6 (18.1)
Selected comorbidities <sup>¶</sup> , n (%)				
Asthma-related allergies	221 (51.6)	26 (41.9)	51 (54.3)	144 (52.9)
Upper respiratory tract infection (URTI)	81 (21.3)	21 (33.8)	23 (24.5)	47 (17.3)
Allergies with URTI	89 (20.8)	18 (29.0)	18 (19.2)	53 (19.5)
Anxiety	77 (18.0)	13 (21.0)	18 (19.2)	46 (16.9)
Depression	70 (16.4)	13 (21.0)	14 (14.9)	43 (15.9)
Pneumonia	14 (3.3)	6 (9.7)	2 (2.1)	6 (2.2)
ICSLABA use category <sup>§</sup> , n (%)				
Low	182 (42.5)	15 (24.2)	41 (43.6)	126 (46.3)
Medium	108 (25.3)	33 (53.2)	37 (39.4)	98 (36.0)
High	78 (18.2)	14 (22.6)	16 (17.0)	40 (14.7)
SABA use <sup>¶¶</sup> , n (%)	211 (63.3)	49 (79.0)	73 (77.7)	149 (54.8)
Adherence to FDC ICS/LABA therapy <sup>¶¶</sup> , n (%)				
MPR $\geq 0.8$	181 (42.9)	21 (35.4)	34 (36.3)	126 (46.7)
MPR $\geq 0.5$	314 (74.4)	38 (64.4)	64 (68.8)	212 (78.5)
Any asthma exacerbation <sup>¶¶¶</sup> , n (%)	75 (17.5)	19 (30.7)	17 (18.1)	39 (14.3)
All-cause HCRU, n (%)				
Respiratory visit	427 (99.8)	62 (100)	64 (100)	271 (99.6)
Outpatient visit	259 (60.5)	43 (69.4)	58 (61.7)	158 (58.1)
Emergency room visit	139 (32.5)	25 (40.3)	24 (25.5)	90 (33.1)
All-cause HCRU costs <sup>¶¶¶</sup> (\$), mean (SD)				
Total costs (medical + pharmacy)	14,504 (25,163)	17,837 (31,320)	12,431 (19,067)	15,122 (25,456)
Pharmacy costs	5966 (14,821)	5689 (10,570)	4,897 (6288)	6445 (17,514)
Medical costs	8529 (18,611)	12,148 (28,659)	7534 (10,444)	8677 (18,244)
Ambulatory costs	6027 (12,539)	8962 (23,690)	4762 (6815)	5708 (10,594)
Outpatient visit costs	3441 (11,063)	6668 (23,126)	2903 (6444)	3059 (7769)
Emergency room costs	139 (261)	291 (692)	57 (135)	132 (288)
Asthma-related HCRU, n (%)				
Respiratory visit	282 (61.2)	43 (69.4)	57 (60.6)	162 (59.6)
Outpatient visit	14 (3.2)	14 (22.6)	8 (8.5)	10 (3.7)
Emergency room visit	11 (2.6)	6 (9.7)	1 (1.1)	4 (1.5)
Asthma-related HCRU costs <sup>¶¶¶</sup> (\$), mean (SD)				
Total costs (medical + pharmacy)	3693 (3814)	3232 (2566)	3586 (3129)	3635 (4244)
Pharmacy costs	3411 (2053)	2537 (1658)	3271 (2937)	3091 (1749)
Medical costs	652 (2933)	695 (2107)	305 (1188)	744 (3499)
Ambulatory costs	611 (2871)	649 (2073)	341 (1142)	696 (3397)
Outpatient visit costs	112 (915)	436 (1989)	197 (1022)	13 (78)
Emergency room costs	9 (91)	43 (178)	4 (24)	3 (50)

<sup>†</sup>Defined as 12 months up to and including survey (index) date. <sup>‡</sup>Respondents with claims data who met all eligibility criteria (overall survey sample). <sup>§</sup>Claims-based age calculated as of 2019. <sup>¶</sup>The 5 most common comorbidities are listed, in addition to pneumonia. <sup>¶¶</sup>Based on the latest claim for an ICS/LABA medication prior to completing survey. Patients invited to participate in the study were selected with a ratio of 1:1 (low/medium/high) dose ICS. <sup>¶¶¶</sup>SABA rescue medication fills from pharmacy claims in 12-month baseline period (including index date). MPR was calculated by summing the number of days supported for an ICS/LABA for all but the last fill in the observation period, divided by number of days between first and last refill. <sup>¶¶¶¶</sup>Hospitalization, emergency room, or steroid-defined exacerbation, based on medical and pharmacy claims and asthma diagnosis code. <sup>¶¶¶¶¶</sup>Physician office or outpatient setting visit. <sup>¶¶¶¶¶¶</sup>Total mean costs were adjusted using the annual medical care component of the Consumer Price Index to reflect inflation in year 2018.

Table 2: Concordance between ACT- and ACOQ- assessed asthma control, stratified by ACT level of control.

	Overall N=428	ACT <sup>5</sup> -assessed level of asthma control			P-value
		Poorly controlled; n=62	Somewhat controlled; n=94	Controlled; n=272	
ACT-6 score <sup>†</sup> , mean (SD)	1.06 (0.85)	2.33 (0.76)	1.49 (0.56)	0.61 (0.52)	<0.001
ACOQ-6 levels of asthma control, n (%)					
Uncontrolled	130 (30.4)	56 (90.3)	50 (53.2)	24 (8.8)	<0.001
Partially controlled	108 (25.2)	4 (6.5)	35 (37.2)	69 (25.4)	<0.001
Controlled	190 (44.4)	2 (3.2)	9 (9.6)	179 (65.8)	<0.001
On average, during the past week, how many times were you woken during the night by your asthma? n (%)					
Never	244 (57.0)	4 (6.5)	32 (34.0)	208 (75.5)	<0.001
Hardly ever	99 (23.1)	14 (22.6)	37 (39.4)	48 (17.7)	<0.001
A few times	63 (14.7)	28 (45.2)	21 (22.3)	14 (5.2)	<0.001
Several times	10 (2.3)	6 (9.7)	3 (3.2)	1 (0.4)	<0.001
Many times	7 (1.6)	6 (9.7)	0 (0.0)	1 (0.4)	<0.001
A great many times	5 (1.2)	4 (6.5)	1 (1.1)	0 (0.0)	<0.001
On average, during your past week, how bad were your asthma symptoms when you woke up in the morning? n (%)					
No symptoms	151 (35.3)	2 (3.2)	11 (11.7)	138 (50.7)	<0.001
Very mild symptoms	138 (32.2)	11 (17.7)	36 (38.3)	91 (33.5)	0.018
Mild symptoms	92 (21.5)	21 (33.8)	31 (33.0)	40 (14.7)	<0.001
Moderate symptoms	45 (10.5)	26 (41.9)	16 (17.0)	3 (1.1)	<0.001
Quite severe symptoms	2 (0.5)	2 (3.2)	0 (0.0)	0 (0.0)	<0.001

\*ACT recall: 4 weeks; score thresholds: <16, poorly controlled; 16–19, somewhat controlled; >19, controlled. \*ACOQ-6 recall: 1 week; score thresholds:  $\geq 1.5$ , uncontrolled; >0.75–1.5, partially controlled; <0.75, controlled. F-test/ANOVA used for continuous measures; Fisher exact test used for binary measures. ANOVA, analysis of variance.

Table 3: Health status (EQ-5D-3L) and asthma-related quality of life (mini-AQLQ) during the baseline period, by ACT and ACOQ-6 level of asthma control.

	Overall N=428	ACT <sup>5</sup> -assessed level of asthma control			ACOQ-6-assessed level of asthma control		
		Poorly controlled; n=62	Somewhat controlled; n=94	Controlled; n=272	Uncontrolled; n=130	Partially controlled; n=108	Controlled; n=190
Mini-AQLQ <sup>†</sup>							
Overall score, mean (SD)	5.34 (1.17)	3.81 (0.96)	4.73 (0.89)	5.89 (0.84)	4.19 (0.99)	5.28 (0.79)	
EQ-5D-3L <sup>‡</sup>							
Visual Analog Scale (VAS) <sup>§</sup> , mean (SD)	77.31 (13.97)	n=55	72.79 (14.70)	n=264	70.50 (15.18)	74.97 (12.73)	
Index (utility score), mean (SD)	0.87 (0.14)	0.80 (0.16)	0.84 (0.13)	0.90 (0.13)	0.81 (0.15)	0.88 (0.13)	

<sup>†</sup>Each mini-AQLQ question is answered on a scale from 1 to 7 and covers a 2-week recall period, with lower scores indicating greater impairment. VAS ranges from 0 to 100, where 100 is best health imaginable and 0 is worst health imaginable. EQ-5D-3L health states were converted into a single summary index score by applying weights to each of the levels in each dimension using the time trade-off valuation technique and is specific to the US population. An index score of 1 represents full health, with lower scores indicating worse health status on the day the respondent is answering. F-test/ANOVA was used for continuous measures. Fisher exact test was used for binary measures. All P-values are <0.0001.

### Limitations

- Whilst the Optum database is generally representative of the overall population, patients who chose to participate in the survey may not be fully representative of the asthma population prescribed ICS/LABA.
- Patients collecting pharmacy fills may not necessarily be taking their medication but may still be classified as adherent using MPR.
- Presence/absence of a diagnosis code does not always definitively prove the presence/absence of disease, though this was mitigated by asking patients to confirm a healthcare professional diagnosis of asthma.
- The survey was fielded in Spring, therefore seasonal variations in asthma symptoms were not accounted for.

### Conclusions

- Approximately a third to half of patients prescribed FDC ICS/LABA reported that they had inadequately controlled asthma based on responses on the ACT or ACOQ-6; these real-world findings align with the findings of other studies of asthma control conducted in the US among patients treated with ICS/LABA.<sup>2–4</sup>
- The proportion of patients with optimal adherence (MPR  $\geq 0.8$ ) was greater among patients classed as 'controlled' by the ACT, though a third of patients with optimal adherence were still classed as 'poorly controlled'.
- Although the ACT classified more patients in the 'controlled' category than the ACOQ, there was still a high degree of concordance between the ACT and ACOQ-6.
- In the 12 months prior to completing the survey, patients with asthma who were poorly controlled had increased HCRU and asthma-related costs, poorer overall health status and lower asthma-related quality of life in the 12 months prior to completing the survey.
- Overall, these observations indicate that a substantial unmet need remains among patients receiving FDC ICS/LABA maintenance therapy, which may be addressed by additional treatment options.

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