Real-World Effectiveness of Dupilumab in Reducing Oral and Inhaled Corticosteroid Use Among US Patients with Asthma: Analysis from the Healthcare Integrated Research Database

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Asthma

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Conclusions

- This real-world analysis was associated with a significant decrease in use of high-dose ICS post dupilumab initiation, providing novel insights
- Significant reduction in OCS use after dupilumab initiation is also consistent with the GINA guidelines that emphasize minimizing systemic corticosteroid exposure in asthma management
- Future research evaluating long-term real-world impact of dupilumab on clinical outcomes is warranted for informed clinical decision-making

Objective

This study aimed to assess the real-world impact of dupilumab on inhaled corticosteroid (ICS) and oral corticosteroid (OCS) use in patients with asthma in the United States

Background

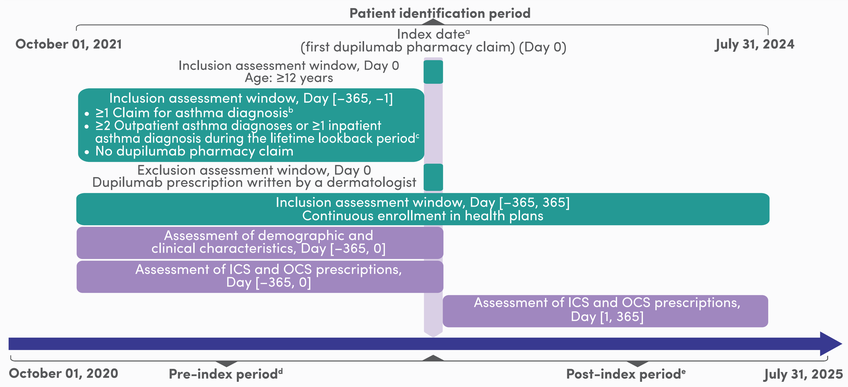
- Patients with moderate-to-severe asthma often rely on ICS and OCS to control asthma symptoms, but long-term use of these medications can lead to serious adverse effects[1,2]
- The Global Initiative for Asthma (GINA) 2025 guidelines recommend minimizing OCS use and using the lowest effective ICS dose with step-down once asthma is well controlled[3]
- Dupilumab, one of the approved biologics[4] for asthma, has been shown to reduce OCS use in real-world studies;[5,6] however, data on changes in ICS prescription patterns remain limited

Methods

Study design

- A retrospective observational study was conducted among patients with asthma (aged ≥12 years) identified from the US-based Healthcare Integrated Research Database® (HIRD), who initiated dupilumab (index date) between October 1, 2021, and July 31, 2024
- A pre–post index study design was employed (**Figure 1**)

Figure 1. Study design



Note: all prescriptions were identified and captured using the National Drug Codes.
[a]Index date: date of the first-observed dupilumab prescription in the pharmacy claims data during the patient identification period. [b]Asthma diagnosis was identified using ICD-10 code J45. [c]All time before the index date, as early as January 2016, was used to support the accurate use of the ICD-10-CM coding system. [d]Pre-index period (baseline period): 365 days prior to and including the index date (i.e., index date – 365 days to index date). [e]Post-index period (follow-up period): 365 days following the index date, excluding the index date (i.e., index date+1 to index date+365 days).

ICD-10, International Classification of Diseases, Tenth Revision; ICS, inhaled corticosteroids; OCS, oral corticosteroids.

Study population

- The analysis cohorts included the following patients:
  - Patients with asthma aged ≥12 years with ≥1 medium-dose or high-dose ICS fill
  - Patients with asthma aged ≥12 years with ≥1 ICS fill (of any strength), stratified by prior biologic use during the pre-index period

Outcomes

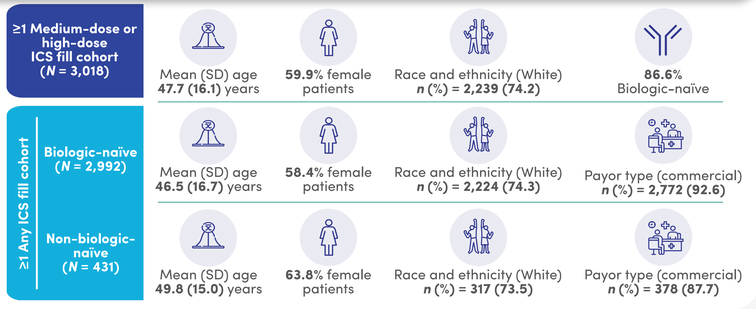
- ICS and OCS fills were evaluated in the 12-month pre-index and post-index periods
- The proportion of patients with ≥1 high-dose ICS fills and annualized OCS exposure were analyzed using the paired McNemar's test or Wilcoxon signed-rank test. All other outcomes were summarized descriptively

Results

Baseline characteristics of patients

- **≥1 Medium-dose or high-dose ICS fill cohort:** 3,018 patients with asthma (mean age: 47.7 years) were included; 59.9% were female and 86.6% were biologic-naïve (**Figure 2**)
- **≥1 Any ICS fill cohort:** 2,992 patients were biologic-naïve, and 431 were non-biologic-naïve, with the majority being female in both cohorts (biologic-naïve: 58.4%, and non-biologic-naïve: 63.8%) (**Figure 2**)

Figure 2. Key baseline demographic and clinical characteristics of both cohorts



ICS, inhaled corticosteroid; SD, standard deviation.

ICS fills

- The proportion of patients receiving high-dose ICS fills decreased after dupilumab initiation (**Table 1**)

Table 1. Proportion of patients receiving medium-dose or high-dose ICS in the 12 months prior and post dupilumab initiation

ICS fill	≥1 Medium-dose or high-dose ICS fill cohort		≥1 Any ICS fill cohort			
	Overall		Biologic-naive		Non-biologic-naïve	
	Pre-index	Post-index	Pre-index	Post-index	Pre-index	Post-index
Patients with ≥1 high-dose ICS fill, *n* (%)	1,558 (51.6)*	1,216 (40.3)*	1,312 (43.9)	1,042 (34.8)	246 (57.1)	199 (46.2)
Patients with ≥1 medium-dose ICS fill, *n* (%)	1,460 (48.4)	1,149 (38.1)	1,303 (43.5)	1,039 (34.7)	157 (36.4)	156 (36.2)

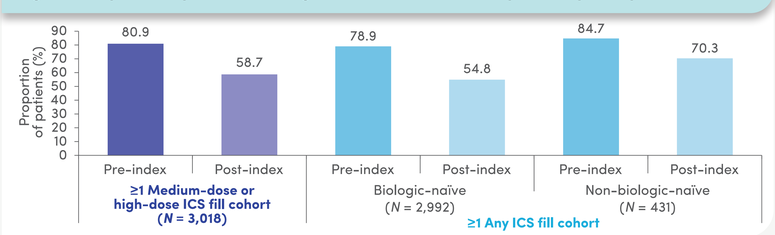
*$P<0.0001$. These results were analyzed as the difference in the proportion of patients with ≥1 high-dose ICS fill in the post-index period versus the pre-index period: −11.3 % (95% CI: −13.8, −8.8).

CI, confidence interval; ICS, inhaled corticosteroid.

OCS fills

- The proportion of patients receiving ≥1 OCS fill decreased in both cohorts after dupilumab initiation (**Figure 3**)

Figure 3. Proportion of patients receiving ≥1 OCS fill in the 12 months prior and post dupilumab initiation

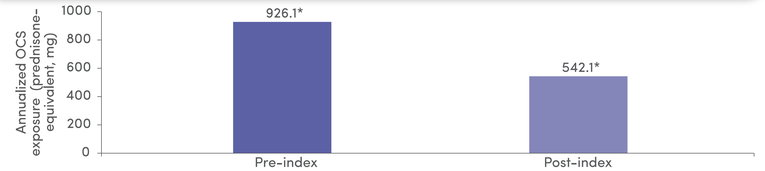


ICS, inhaled corticosteroid; OCS, oral corticosteroid.

OCS dose (expressed as mean [standard deviation, SD] prednisolone-equivalent dose in mg)

- A significant reduction in annualized OCS exposure was observed after dupilumab initiation in the ≥1 medium-dose or high-dose ICS fill cohort (**Figure 4**)
- Among patients with ≥1 OCS fill, a reduction in OCS dose was observed after dupilumab initiation across both cohorts (**Table 2**)

Figure 4. Annualized OCS exposure in the 12 months prior and post dupilumab initiation (≥1 medium-dose or high-dose ICS fill cohort)–Overall cohort



Note: the mean annualized OCS exposure in the pre-index versus post-index periods was tested using the Wilcoxon signed-rank test. *$P<0.0001$, these results were analyzed as the mean difference in the annualized OCS exposure in the post-index period versus pre-index period: −384.0 mg (95% CI: −426.2, −341.8).

CI, confidence interval; ICS, inhaled corticosteroid; OCS, oral corticosteroid.

Table 2. OCS exposure (prednisolone-equivalent dose in mg) in the 12 months prior and post dupilumab initiation–Patients with ≥1 OCS fills

OCS fill	≥1 Medium-dose or high-dose ICS fill cohort		≥1 Any ICS fill cohort			
	Overall		Biologic-naive		Non-biologic naïve	
	Pre-index (*N* = 2,442)	Post-index (*N* = 1,773)	Pre-index (*N* = 2,361)	Post-index (*N* = 1,639)	Pre-index (*N* = 365)	Post-index (*N* = 303)
Daily OCS dose on treated days[a], mean (SD)	30.0 (15.0)	28.8 (14.5)	30.1 (14.8)	28.7 (14.1)	29.2 (15.5)	28.8 (15.9)
Daily OCS dose, annually[b], mean (SD)	3.1 (3.6)	2.5 (4.2)	2.8 (3.3)	2.3 (4.1)	4.5 (4.9)	3.6 (4.2)
Cumulative, annual OCS use[c], mean (SD)	1,144.5 (1325.8)	922.7 (1515.22)	1,019.2 (1,192.7)	831.3 (1,490.6)	1,664.8 (1,790.9)	1,299.5 (1,538.1)

[a]Daily OCS dose on treated days calculated as the total prednisone-equivalent exposure divided by the number of treated days in the year. [b]Daily OCS dose, annually calculated as the total prednisone-equivalent exposure divided by 365 days. [c]Cumulative annual OCS use calculated as the total prednisone-equivalence exposure in the year.

ICS, inhaled corticosteroid; OCS, oral corticosteroid; SD, standard deviation.

Controller and reliever medications

- The proportion of patients receiving ≥1 controller and reliever medication fill decreased after dupilumab initiation for all medications except for the combination of ICS + short-acting beta agonists (**Table 3**)

Table 3. Controller and reliever medication fill in the 12 months prior and post dupilumab initiation (≥1 medium-dose or high-dose ICS fill cohort)–Overall cohort

		Pre-index	Post-index
Controller medications[a], *n* (%)		3,018 (100)	2,648 (87.7)
Triple therapy	ICS + LABA + LAMA	1,170 (38.8)	1,069 (35.4)
Dual therapy	ICS + LABA	2,253 (74.7)	1,566 (51.9)
	LABA + LAMA	35 (1.2)	23 (0.8)
Monotherapy	ICS	1,079 (35.8)	625 (20.7)
	LTRA	1,728 (57.3)	1,472 (48.8)
	LAMA	544 (18.0)	404 (13.4)
	LABA	27 (0.9)	24 (0.8)
Reliever medications, *n* (%)		2,431 (80.6)	1,966 (65.1)
Combination therapy	SABA + SAMA	451 (14.9)	303 (10.0)
	ICS + SABA	122 (4.0)	124 (4.1)
Monotherapy	SABA	2,382 (78.9)	1,893 (62.7)
	SAMA	85 (2.8)	49 (1.6)

[a]Dual or triple combination controller/maintenance inhaler therapy measured as a single inhaler with all classes of medication or separate inhalers filled within 30 days of one another with ≥30 days of overlap in days' supply.

ICS, inhaled corticosteroids; LABA, long-acting beta agonist; LAMA, long-acting muscarinic antagonist; LTRA, leukotriene receptor antagonist; SABA, short-acting beta agonist; SAMA, short-acting muscarinic antagonist.

Limitations

Given the pre–post study design, observed differences may reflect natural variability or regression to the mean rather than treatment effect; additionally, results may be influenced by confounding due to disease trajectory and prescribing behavior. Claims-based misclassification and lack of adherence confirmation may also have affected the findings

References:
1. Calzetta, L. *et al. Int J Mol Sci* 22, 7132 (2021). **2.** Canonica, G. W. *et al. Allergy* 80, 2113–2127 (2025). **3.** The GINA report–Reports - Global Initiative for Asthma–GINA. Accessed April 2026. **4.** Dupilumab–Product Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761055s070lbl.pdf. Accessed April 2026. **5.** Sher, L. D. *et al. Chest* 162, 46–55 (2022). **6.** Rupani, H. *et al. Thorax*, 79 (Suppl 2), A118 (2024).

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