Type 2 Inflammatory Comorbidities in Patients Initiating Dupilumab for Asthma: Real-World Evidence from a National US Database

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Asthma

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Conclusions

- In this real-world study, patients with asthma presented with substantial T2 inflammatory conditions in the pre-index period across both cohorts
- The results indicate distinct comorbid T2 inflammatory conditions among biologic-naïve patients compared with non-biologic-naïve patients with ≥1 any ICS fill
- Given the approval of dupilumab across multiple T2 inflammatory conditions, including asthma, future research evaluating its clinical impact in patients with asthma and comorbid T2 inflammatory conditions is warranted

Objective

To describe the baseline demographics and clinical characteristics of patients with asthma initiating dupilumab in the current United States (US) clinical setting

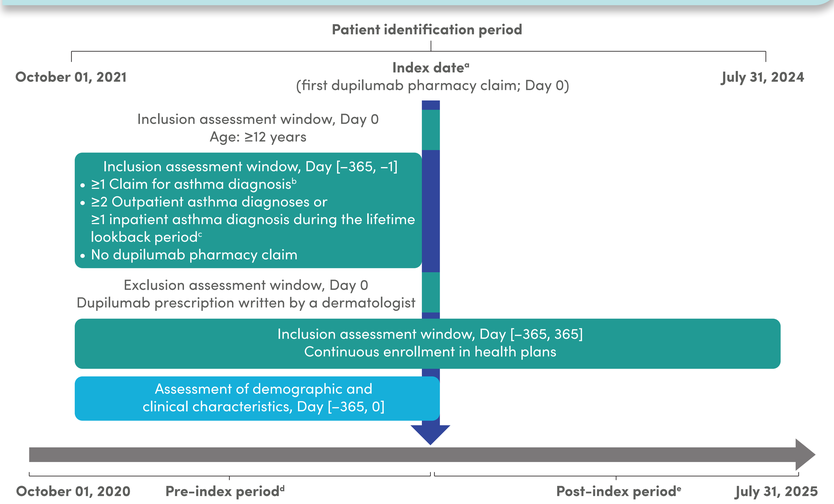
Background

- Dupilumab received its first US Food and Drug Administration approval in 2017 for atopic dermatitis, followed by approval in 2018 for moderate-to-severe asthma with type 2 (T2) inflammation. Subsequently, dupilumab has been approved for several other T2 conditions[1]
- The Global Initiative for Asthma (GINA) guidelines emphasize the importance of considering T2 inflammation-driven conditions when selecting an appropriate treatment strategy[2]

Methods

- This retrospective observational study used administrative claims data from the Healthcare Integrated Research Database (HIRD)® to identify patients with asthma aged ≥12 years who initiated dupilumab (index date) between October 2021 and July 2024
- The HIRD® contains claims integrated across data sources, including professional claims, facility claims, outpatient pharmacy claims, and enrollment information
- The study design is illustrated in **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 diagnoses were identified using International Classification of Diseases, Tenth revision (ICD-10) code J45. [c]All time before the index date, as early as January 2016, was used to support 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).

Study population

- The analysis cohorts included the following patients:
  - Patients with asthma aged ≥12 years with ≥1 medium-dose or high-dose inhaled corticosteroids (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

Study outcomes

- Patient characteristics were recorded during the 12-month pre-index period in both cohorts, including demographics, socioeconomic status (SES), and clinical profile with T2 inflammatory conditions
- Study variables were summarized using descriptive statistics. Continuous variables were reported as means±standard deviations (SDs), and categorical variables were reported as frequencies and percentages

Results

Baseline demographic characteristics

- **≥1 Medium-dose or high-dose ICS fill cohort**: among 3,018 patients (59.9% female), with a mean age of 47.7 (SD: 16.1) years, 86.6% were biologic-naïve (**Table 1**)
- **≥1 Any ICS fill cohort**: among 3,423 patients (59.1% female), with a mean age of 46.9 (SD: 16.6) years, 87.4% were biologic-naïve (**Table 1**)

Table 1. Key baseline demographic characteristics of patients with asthma in the pre-index period

	≥1 Medium-dose or high-dose ICS fill cohort (*N*=3,018)	≥1 Any ICS fill cohort (*N*=3,423)	
	Overall	Biologic-naïve patients (*N*=2,992)	Non-biologic-naïve patients (*N*=431)
Age, years, mean (SD)	47.7 (16.1)	46.5 (16.7)	49.8 (15.0)
Age group, *n* (%)			
12–17 years	190 (6.3)	248 (8.3)	17 (3.9)
18–39 years	920 (30.5)	933 (31.2)	122 (28.3)
40–64 years	1,567 (51.9)	1,490 (49.8)	244 (56.6)
≥65 years	341 (11.3)	321 (10.7)	48 (11.1)
Gender, female, *n* (%)	1,807 (59.9)	1,748 (58.4)	275 (63.8)
Region, *n* (%)			
South	1,198 (39.7)	1,177 (39.3)	162 (37.6)
Midwest	679 (22.5)	659 (22.0)	97 (22.5)
West	572 (19.0)	591 (19.8)	98 (22.7)
Northeast	<575	<575	74 (17.2)
Unknown or missing	<5	<5	0
Race and ethnicity[a], *n* (%)			
White, non-Hispanic	2,239 (74.2)	2,224 (74.3)	317 (73.5)
Black or African American, non-Hispanic	331 (11.0)	304 (10.2)	54 (12.5)
Hispanic of any race	230 (7.6)	224 (7.5)	41 (9.5)
Asian, non-Hispanic	95 (3.1)	106 (3.5)	8 (1.9)
Other race, non-Hispanic	61 (2.0)	<77	<5
Unknown or undisclosed	48 (1.6)	47 (1.6)	5 (1.2)
Member-level urbanicity, *n* (%)			
Urban	1,639 (54.3)	1,624 (54.3)	233 (54.1)
Suburban	856 (28.4)	861 (28.8)	116 (26.9)
Rural	445 (14.7)	429 (14.3)	75 (17.4)
Unknown or missing	78 (2.6)	78 (2.6)	7 (1.6)
Neighborhood-level SES[b], *n* (%)			
Quartile 1	379 (13.8)	364 (13.4)	59 (14.8)
Quartile 2	637 (23.2)	606 (22.3)	94 (23.6)
Quartile 3	739 (26.9)	726 (26.7)	107 (26.9)
Quartile 4	991 (36.1)	1,026 (37.7)	138 (34.7)

[a]Data for American Indian or Alaska Native (non-Hispanic) and Native Hawaiian or Other Pacific Islander (non-Hispanic) populations are not presented, as these groups represent <1% of study population. [b]Distribution of the area-level indicator of neighborhood SES index for 2016–2020, which is a composite score. A score of 4 indicates the top 25% of SES, and a score of 1 indicates bottom 25% of SES, based on national census sample. Sample size (*n*) for the overall cohort=2,746, biologic-naïve cohort=2,722, and non-biologic-naïve cohort=398.

ICS, inhaled corticosteroids; *N*, size of population; *n*, sample size; SD, standard deviation; SES, socioeconomic status.

Clinical characteristics

- Among patients with ≥1 medium-dose or high-dose ICS fill, dupilumab prescriptions were mostly initiated by allergists (36.6%) and pulmonologists (24.0%), with a similar prescribing pattern observed in patients with ≥1 any ICS fill, stratified by biologic use in the pre-index period (**Table 2**)

Table 2. Dupilumab prescriptions were most commonly initiated by specialists (allergist/pulmonologist) in non-biologic-naïve patients with ≥1 any ICS fill

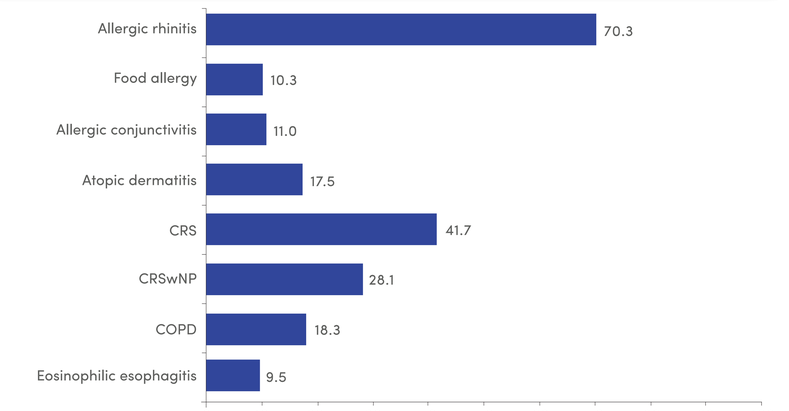
	≥1 Medium-dose or high-dose ICS fill cohort (*N*=3,018)	≥1 Any ICS fill cohort (*N*=3,423)	
	Overall	Biologic-naïve patients (*N*=2,992)	Non-biologic-naïve patients (*N*=431)
Allergist, *n* (%)	1,106 (36.6)	1,084 (36.2)	189 (43.9)
Pulmonologist, *n* (%)	725 (24.0)	619 (20.7)	134 (31.1)
Non-physician clinician, *n* (%)	628 (20.8)	667 (22.3)	64 (14.8)
Other or unknown, *n* (%)	473 (15.7)	534 (17.8)	36 (8.4)
Primary care provider, *n* (%)	86 (2.8)	88 (2.9)	8 (1.9)

ICS, inhaled corticosteroids; *N*, size of population; *n*, sample size.

Distribution of baseline comorbid T2 inflammatory conditions in the pre-index period

- Among patients with ≥1 medium-dose or high-dose ICS fill, the most common T2 inflammatory conditions were allergic rhinitis (70.3%), chronic rhinosinusitis (CRS, 41.7%), and chronic rhinosinusitis with nasal polyps (CRSwNP, 28.1%), as shown in **Figure 2**

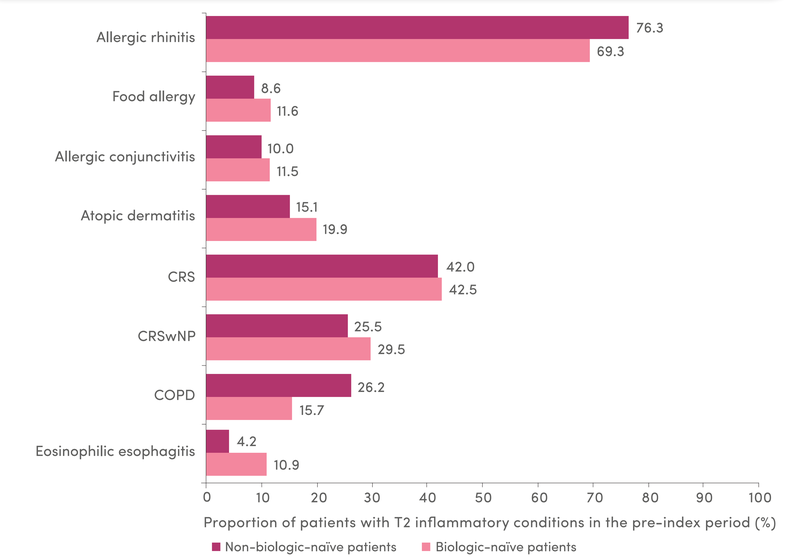
Figure 2. Allergic rhinitis was the most common baseline comorbid T2 inflammatory condition in the cohort of patients with ≥1 medium-dose or high-dose ICS fill



CRS, chronic rhinosinusitis; CRSwNP, chronic rhinosinusitis with nasal polyps; COPD, chronic obstructive pulmonary disease; ICS; inhaled corticosteroids; T2, type 2.

- Among patients with ≥1 any ICS fill, distinct distribution of T2 inflammatory conditions between biologic-naïve patients and non-biologic-naïve patients was observed for allergic rhinitis (69.3% vs 76.3%, respectively), chronic obstructive pulmonary disease (15.7% vs 26.2%, respectively), and eosinophilic esophagitis (10.9% vs 4.2%, respectively) (**Figure 3**)

Figure 3. Differences in distribution of comorbid T2 inflammatory conditions was observed in biologic-naïve patients and non-biologic-naïve patients, with ≥1 any ICS fill in the pre-index period



CRS, chronic rhinosinusitis; CRSwNP, chronic rhinosinusitis with nasal polyps; COPD, chronic obstructive pulmonary disease; ICS; inhaled corticosteroids; T2, type 2.

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1. Dupilumab – Product Information. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761055s070lbl.pdf. Accessed March 24, 2026.
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