Real-World Dupilumab Continuation in US Adults With Atopic Dermatitis Over a 24-Month Period

Digital poster

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Introduction

AD is a common chronic, remitting-relapsing inflammatory skin disease characterized by intense itching, often leading to erythematous lesions and lichenification[1]

AD typically begins in childhood, but can start at any age[1]

Recently, alongside established systemic and topical treatments, biologics have come into focus as alternative, targeted treatments for patients with moderate-to-severe AD[1,2]

- Until December 2021, the monoclonal antibody dupilumab was the only US-approved biologic systemic treatment[3]

Although dupilumab has demonstrated improvements in clinical and patient-reported outcomes, some patients experience adverse events that may prevent continued treatment, while others have inadequate response[4–6]

Objectives

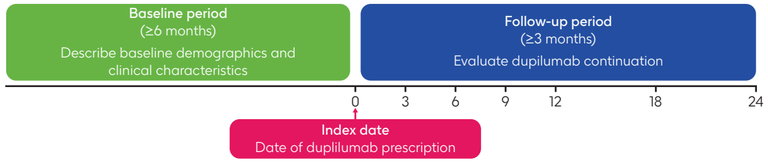
- To describe baseline demographics and clinical characteristics of a cohort of adult patients with AD who have initiated dupilumab treatment
- To evaluate real-world utilization of dupilumab among a cohort of adult patients with AD by assessing treatment continuation over time
- To characterize the time to discontinuation of dupilumab using KM curves for a cohort of adult patients with AD

Methods

Study design

- This retrospective cohort study used the OM1 PremiOM™ AD dataset to assess US adults (≥18 years) with AD who first initiated dupilumab (index date) between March 2017 and September 2021, with follow-up through to December 2021
- The dataset comprised patients from the American Academy of Dermatology DataDerm™ Registry linked with EHR and claims data from the OM1 Real-World Data Cloud
- Patients had ≥6 months baseline period data and ≥3 months of follow-up data (**Figure 1**)
- Dupilumab continuation was defined by ≥1 prior prescription with an end-date within ≤90 days of subsequent prescription
- Discontinuation-free time was estimated for each patient for a maximum of 24 months from initiation or until the time of the event of discontinuation or censoring
- KM methods estimated continuation over a period of 24 months
- Analyses were stratified by age (18–39, 40–59, and ≥60 years)

Figure 1 **Study design schema**



Patient eligibility

- Eligibility for the OM1 PremiOM™ AD dataset included:
  - One of the following:
    - ≥2 diagnosis codes for AD, ≥30 days apart, from a dermatologist/dermatology specialty source
    - ≥1 inpatient visit with an AD diagnosis code
    - ≥2 outpatient records for AD diagnosis, ≥30 days apart within a year, regardless of physician specialty
  - AND
    - ≥2 clinical notes from a dermatologist/dermatology specialty source, ≥30 days apart
  - AND one of the following:
    - ≥1 observation of an AD-specific outcome
    - ≥1 record for a non-steroidal systemic medication
- Study specific eligibility included:
  - Present in the DataDerm Registry™ of the PremiOM™ AD Dataset
  - Received dupilumab as prescribed by a dermatologist in routine clinical care
  - ≥1 diagnosis code for AD during the 6 months prior to the index date
  - Available EHR or claims data for ≥6 months prior to and ≥3 months after the index date

Analyses

- Analyses encompassed all adult patients, with additional stratifications by age group (18–39, 40–59, and ≥60 years)

Conclusions

- Over 70% of adult patients with AD who initiated dupilumab had continued treatment at 12 months post-index. By Month 24, the estimated proportion of patients with continued treatment decreased to approximately half of those who initiated treatment
- Results at 12 months post-index are consistent with a prior real-world study of US healthcare claims;[7] however, results at 24 months post-index are below dupilumab continuation rates reported in two European registry studies[8,9]
- Patients initiating dupilumab aged ≥60 years had the lowest rate of continuation at all time periods when compared with patients 18–39 and 40–59 years of age
- Strengths of the current study include that it is one of the largest studies of adult patients since the US approval of dupilumab, with over 4500 patients who initiated dupilumab treatment, and that patients were followed for up to 24 months after treatment initiation
- Limitations of the study include the lack of information on reasons for discontinuation and a large proportion of patients who were censored

Results

Baseline characteristics

- Of 4562 eligible adult patients, 56% were female and patients had a mean (SD) age of 48.6 (18.4) years (**Table 1**)
- Overall, 19% had received systemic therapy and 97% had received any corticosteroid therapy prior to dupilumab treatment

Table 1 **Baseline demographics and clinical characteristics of adult patients with AD (N=4562)**

	(N=4562)
Age, years, mean (SD)	**48.6 (18.4)**
Age groups, n (%)	
18–39 years	1523 (33)
40–59 years	1640 (36)
≥60 years	1399 (31)
Females, n (% of each age group)	
18–39 years	897 (59)
40–59 years	974 (59)
≥60 years	690 (49)
Race and ethnicity, n (%)	
White	2846 (62)
Black	585 (13)
Other	235 (5)
Unknown/missing	896 (20)

	(N=4562)
BMI (kg/m²), mean (SD)*	**29.0 (6.7)**
Time since AD diagnosis (months), mean (SD)	**24.2 (24.1)**
Treatment history, n (%)	
Any corticosteroid therapy	4418 (97)
Any topical therapy (other than corticosteroids)	3628 (80)
Any systemic therapy (excluding dupilumab)	881 (19)
Select comorbidities, n (%)	
Hypertension	1112 (24)
Malignancies	1024 (20)
Dyslipidemia	935 (21)
Allergic rhinitis	642 (14)
Asthma	573 (13)
Psoriasis	478 (11)

*BMI was available for 998 (21.9%) adult patients

Dupilumab continuation

- Dupilumab continuation decreased steadily over the follow-up period
  - Dupilumab continuation was 73.2% and 55.7% at 12 and 24 months, respectively (**Table 2**)
  - Of the 4562 patients receiving dupilumab at index, 1232 patients were continuing with treatment at Month 24, with 1633 patients having discontinued dupilumab and 1697 patients censored over this period
  - The median (95% CI) discontinuation-free follow-up time was 23.5 (22.8, >24.0) months

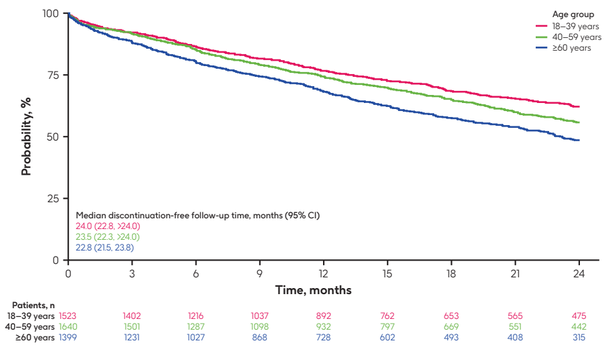
Table 2 **Probability of continuing dupilumab over time among adult patients with AD (N=4562)**

Time interval (post-index), months	Patients receiving dupilumab at start of time interval, n	Discontinued, n (%)	Censored*, n (%)	Estimated KM probability for cumulative continuance, % (95% CI)
0–3	4562	428 (9)	0†	90.6 (89.7, 91.4)
3–6	4134	291 (7)	313 (8)	84.0 (82.9, 85.0)
6–9	3530	219 (6)	308 (9)	78.5 (77.3, 79.7)
9–12	3003	195 (6)	256 (9)	73.2 (71.8, 74.5)
12–18	2552	293 (11)	444 (17)	63.9 (62.3, 65.4)
18–24	1815	207 (11)	376 (21)	55.7 (54.0, 57.4)

*Patients were censored (ended follow-up without discontinuing) on December 31, 2021 or after 90 days of follow-up without an encounter (lost to follow-up). Patients whose treatment extended beyond their last encounter, or whose dupilumab prescription ended within 90 days of their last encounter, were censored as of their last encounter date
†All patients completed follow-up during the first 3 months per the inclusion criterion

- Median (95% CI) discontinuation-free follow-up time varied slightly between age groups: 24.0 (22.8, >24.0) for patients aged 18–39 years, 23.5 (22.3, >24.0) for 40–59 years, and 22.8 (21.5, 23.8) months for ≥60 years (**Figure 2**)

Figure 2 **KM curves of the probability of dupilumab continuation among adult patients with AD, stratified by age group**



- The probability of continuing dupilumab treatment was lower for those aged ≥60 years compared with patients 18–39 and 40–59 years, at each time point assessed (**Table 3**)

Table 3 **Probability of continuing dupilumab over time among adult patients with AD (stratified by age)**

Time interval (post-index), months	Estimated KM probability for cumulative continuance, % (95% CI)		
	18–39 years N=1523	40–59 years N=1640	≥60 years N=1399
0–3	92.1 (90.6, 93.3)	91.5 (90.1, 92.8)	88.0 (86.2, 89.6)
3–6	86.3 (84.5, 87.9)	85.0 (83.2, 86.7)	80.1 (77.9, 82.2)
6–9	81.6 (79.5, 83.5)	79.1 (77.0, 81.1)	74.4 (72.0, 76.7)
9–12	76.5 (74.2, 78.7)	74.3 (72.0, 76.4)	68.2 (65.5, 70.7)
12–18	68.5 (65.9, 71.0)	65.0 (62.4, 67.5)	57.6 (54.6, 60.4)
18–24	62.1 (59.2, 64.9)	55.8 (52.9, 58.6)	48.6 (45.4, 51.7)

Abbreviations

AD, atopic dermatitis; BMI, body mass index; CI, confidence intervals; EHR, electronic health record; KM, Kaplan–Meier; SD, standard deviation; US, United States.

References

1. Galli E, et al. *Acta Biomed.* 2020;91(11-S):e2020011
2. Wollenberg A, et al. *J Eur Acad Dermatol Venereol.* 2022;36:1409–31
3. Regeneron. Dupilumab prescribing information. October 2023 https://www.regeneron.com/downloads/dupixent_fpi.pdf (Accessed: January 16, 2024)
4. Strober B, et al. *JAMA Dermatol.* 2022;158(2):142–50
5. Deleuran M, et al. *J Am Acad Dermatol.* 2021;82(2):377–88
6. Narla S, et al. *J Am Acad Dermatol.* 2022;86(3):628–36
7. Silverberg JI et al. *Ann Allergy Asthma Immunol.* 2021;126(1):40–45
8. Spekhorst L et al. *JAMA dermatol.* 2022;158(9):1048–56
9. Vittrup I et al. *J Eur Acad Dermatol Venereol.* 2023;37(5):1046–55

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Disclosures

JMS, **UK**, **SN**, and **DSP** are employees and shareholders of GSK. **JB** is an independent contractor for OM1, and **SGS**, and **SW** are employees of OM1

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