Treatment Supplementation Following Dupilumab Initiation in Real-World Patients With Atopic Dermatitis in the US

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Synopsis

- AD is a chronic, remitting-relapsing inflammatory dermatitis characterized by dryness, erythema and lichenification[1,2]
- Alongside established systemic and topical treatments, dupilumab, a monoclonal antibody, is an FDA-approved treatment for patients with moderate-to-severe AD[3]
  - Until December 2021, dupilumab was the only approved targeted biologic systemic treatment
- Although real-world rates of treatment persistence have been reported, primarily among adults, information regarding the proportion of patients with AD who supplement dupilumab with other prescription medications is limited

Objectives

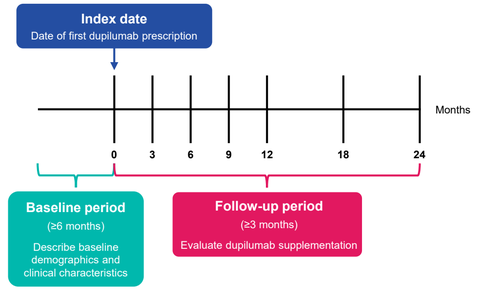
- To describe baseline demographics and clinical characteristics of a cohort of patients with AD, stratified by age group, who have initiated dupilumab treatment
- To evaluate real-world topical and systemic treatment supplementation for a cohort of patients with AD, stratified by age group, who have initiated dupilumab treatment

Methods

Study design

- This retrospective cohort study included US patients with AD in the OM1 PremiOM™ AD dataset who initiated dupilumab treatment between March 2017 and September 2021, with follow-up through to December 2021
- The dataset comprised patients from the AAD DataDerm™ Registry with linked EHR and claims data from the OM1 Real-World Data Cloud
- Patients were required to have ≥6 months of baseline period data prior to, and ≥3 months of follow-up data after index (defined as the first date of dupilumab prescription; **Figure 1**)
- Supplementation, with systemic and/or topical therapies, were identified at six defined time periods (3, 6, 9, 12, 18, and 24 months, respectively) following initiation
  - Systemic therapies included any of: methotrexate, mycophenolate and derivatives, omalizumab, benralizumab, mepolizumab, reslizumab, tralokinumab, upadacitinib, abrocitinib, azathioprine, cyclosporine, and oral or injectable steroids
  - Topical therapies included any of: calcineurin inhibitors, phosphodiesterase 4 inhibitors, Janus kinase inhibitors, and topical steroids

Figure 1. **Study design schema**



Patient eligibility

- To be eligible for the OM1 PremiOM™ AD dataset, patients met the following conditions:
  - 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 patients to have:
  - Been present in the DataDerm Registry™ contained within 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 were stratified by age group: children (<13 years), adolescents (13–17 years), and adults (≥18 years)

Conclusions

- Systemic and topical treatment supplementation increased during a two-year period for patients with AD after dupilumab initiation
  - This trend was consistent across all ages with approximately one-third of adults and one-quarter of adolescents receiving a systemic therapy and over half of patients for all age groups receiving a topical therapy at 24 months
- These results demonstrate that supplemental treatments were received by a considerable proportion of patients with AD across all ages during a two-year period after dupilumab initiation, indicating the potential need for novel AD treatments that limit the need for concomitant medication
- Strengths of the study include use of a large cohort of real-world patients with AD with up to 24-months of follow-up time
- Study limitations include no data describing reasons for supplementation and no measures for dupilumab treatment effectiveness
- Future studies, to determine the most common reasons for patients who initiated dupilumab to use supplement therapies, would be of interest

Results

Baseline characteristics

- Baseline demographics and clinical characteristics across all patients are shown in **Table 1**

Table 1. **Baseline demographics and clinical characteristics (N=5200)**

Age (years), mean (SD)
44.3 (20.8)

Age group, n (%)	
Children	208 (4.0)
Adolescent	430 (8.3)
Adult	4562 (87.7)

Females, n (% of each age group)	
Children	110 (52.9)
Adolescent	243 (56.5)
Adult	2561 (56.1)

Race, n (%)	
White	3162 (60.8)
Black	747 (14.4)
Other	285 (5.5)
Missing	1006 (19.3)

BMI, mean (SD)
28.3 (7.1)

Time since AD diagnosis (months), mean (SD)
25.8 (24.8)

Treatment history, n (%)	
Any corticosteroid therapy	4992 (96.0)
Any other topical therapy	4174 (80.3)
Any systemic therapy (excluding dupilumab)	1013 (19.5)

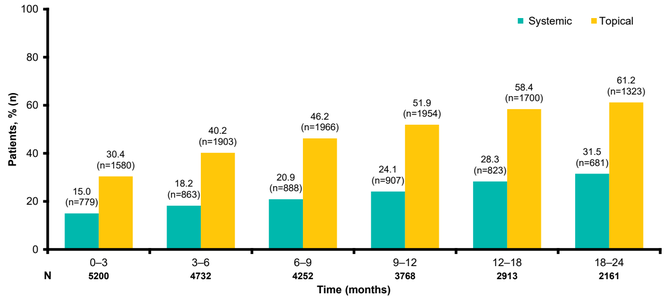
Select comorbidities, n (%)	
Hypertension	1113 (21.4)
Malignancies	1034 (19.9)
Dyslipidemia	940 (18.1)
Allergic rhinitis	821 (15.8)
Asthma	692 (13.3)
Psoriasis	492 (9.5)

- Of 5200 eligible patients who initiated dupilumab, 208 (4.0%) were children, 430 (8.3%) were adolescents, and 4562 (87.7%) were adults.
- Across all patients, prior to dupilumab initiation, 4174 (80.3%) patients had previously received any topical therapy and 1013 (19.5%) had previously received any systemic therapy excluding dupilumab

Supplementation

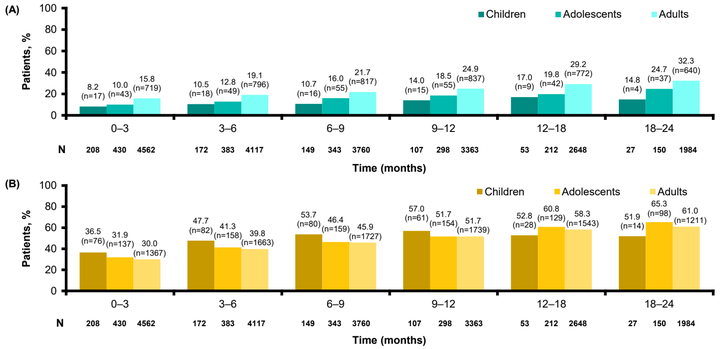
- Supplementation of systemic and topical therapies increased consistently over 24 months of follow-up (**Figure 2**)

Figure 2. **Supplementation of dupilumab with systemic and topical therapies over 24 months across all patients**



- At least one supplemental systemic therapy was received by 15.0% of patients at 3 months, 24.1% at 12 months and 31.5% by 24 months post-index, while supplemental prescription topical medications were received by 30.4% of patients at 3 months, 51.9% at 12 months, and 61.2% at 24 months
- Proportions of patients who received supplemental treatments increased over time for all age groups (**Figure 3**)

Figure 3. **Supplementation of dupilumab with systemic (A) and topical (B) therapies over 24 months by age group**



- Systemic treatment supplementation was reported for 14.8% of child patients, 24.7% of adolescent patients, and 32.3% of adult patients by 24 months
- Topical treatment supplementation was reported by 51.9% of child patients, 65.3% of adolescent patients, and 61.0% of adult patients by 24 months

Abbreviations

AAD, American Academy of Dermatology; AD, atopic dermatitis; BMI, body mass index; EHR, electronic health record; FDA, Food and Drug Administration; SD, standard deviation; US, United States

References

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Disclosures

JMS, **UK**, **SN**, and **DSP** are employees and shareholders of GSK. **JB**, **SGS**, and **SW** are employees of OM1

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