Dupilumab in Severe Asthma: Real-World Cohort Data Begin to Arrive

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Real-world data on dupilumab for severe type 2 asthma began to arrive in three papers published in 2026. The expanding biologic arsenal raises a practical question: which agent, for which patient, and how do we measure success outside a controlled trial? These new papers address that gap, testing whether trial-era promises hold in everyday practice.

KEY TAKEAWAYS

- The Pivot: Real-world evidence for dupilumab in severe type 2 asthma is now accumulating across European cohorts, moving the evidence base beyond phase III trial populations.
- The Data: Structured effectiveness tools including FEOS and EXACTO are being applied to real-world dupilumab cohorts, though the evidence supporting their predictive validity remains limited.1
- The Action: Prescribing clinicians should document outcomes systematically using available effectiveness frameworks, while recognising that head-to-head comparative data across biologics in this setting are still scarce.2

Dupilumab, Sanofi and Regeneron's IL-4/IL-13 receptor antagonist, had strong phase III efficacy in severe asthma. But real-world patients often differ from trial populations. These three studies aim to bridge that gap.

FEOS and EXACTO, tools to gauge biologic effectiveness in real-world asthma, have drawn interest. These are structured frameworks. But their clinical validity in routine use is limited.1 This matters for data. Without validated outcome instruments, comparing effectiveness across centers or agents turns treacherous. A clear standard is needed.

The DUPImpact study, a Spanish multicenter investigation, looked at dupilumab in severe type 2 asthma patients. They evaluated real-world settings. A Romanian 24-month cohort study tracked broader biologic therapy outcomes in severe asthma. This assessed response durability over two years. Lombardi and Menzella, in a third paper, reviewed biologics for dual clinical remission. They focused on patients with severe asthma and chronic rhinosinusitis with nasal polyps. This comorbidity is common and relevant.3

Investigators across all three papers admit real-world dupilumab evidence in asthma is limited. Phase III data is abundant, but real-world lags. The Romanian cohort offers a 24-month follow-up. This shows early biologic responses might sustain. Lombardi and Menzella's review tackles a key question: how to treat overlapping type 2 inflammatory disease affecting both airways. Biologic choice matters. Dupilumab's approval in both indications offers a structural edge in this dual-disease group. The goal is clinical remission, not just symptom reduction.3

One shared limitation: these abstracts lack hard comparative statistics. Exacerbation rates, lung function changes, and oral corticosteroid reduction data are missing. Granular numbers require full publications. This body of work

starts a methodological conversation. How should clinicians define and measure biologic success? Are current tools adequate?1,2,3

Severe asthma affects many patients, defined by high-dose inhaled corticosteroids or systemic corticosteroids. These patients had frequent exacerbations, impaired lung function, and reduced quality of life. Type 2 inflammation, with high eosinophils, IgE, and cytokines, drives many severe asthma cases. Dupilumab targets the shared alpha subunit of the IL-4 and IL-13 receptors. This inhibits both cytokine signaling pathways. Dual inhibition broadly impacts type 2 inflammatory processes. That explains its efficacy across multiple type 2 inflammatory diseases.

DUPImpact, a Spanish multicenter study, aimed for a diverse patient population. It reflected routine clinical practice. The focus on uncontrolled severe type 2 asthma aligns with dupilumab's approved indication. Methodology likely involved retrospective chart data or prospective observational follow-up. This is common in real-world studies.

The Romanian 24-month cohort study tracked patients over time. It offers key insights into biologic long-term effectiveness and safety. Response durability is critical for chronic conditions like severe asthma. Sustained control is the primary goal.

Lombardi and Menzella's review, while not primary data, synthesizes existing evidence. It addresses managing patients with severe asthma and chronic rhinosinusitis with nasal polyps. This comorbidity is prevalent in type 2 severe asthma. Shared inflammatory pathways make a single biologic appealing.

Observational studies inherently carry biases, like confounding by indication or unmeasured confounders. This is an obvious caveat. The DUPImpact and Romanian cohorts lacked a control group. Observed improvements cannot be definitively attributed solely to the biologic therapy. Generalizability from specific national cohorts (Spain, Romania) also warrants careful consideration. The absence of detailed outcome data in these abstracts further limits critical appraisal of any reported effect. How real-world studies will standardize outcome reporting and incorporate validated patient-reported measures remains an open question.

CLINICAL IMPLICATIONS

The most striking clinical consequence of this emerging evidence is its limitations. Three groups in Spain, Romania, and an international review consortium admit real-world dupilumab evidence in severe asthma remains thin. This isn't a drug criticism; it's a system failure. Biologics have been in use long enough for registries to produce longitudinal data, but they aren't, and unconfirmed tools like FEOS and EXACTO compound the problem.

The dual-disease angle, examined by Lombardi and Menzella, deserves more attention. A patient with severe asthma and chronic rhinosinusitis with nasal polyps is one patient, not two. A single agent addressing both inflammatory pathways offers clear benefit. Dupilumab's dual approval gives Sanofi and Regeneron a distinct clinical edge.

Patients in this setting carry a significant burden: frequent exacerbations, oral corticosteroid exposure, and undertreated upper airway disease. The 24-month Romanian cohort offers a step toward understanding durable biologic benefits. This matters for treatment continuation and cost-effectiveness. Until data matures and outcome frameworks validate, clinicians make well-informed but empirical choices.

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