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BIOLOGICAL TREATMENT OF SEVERE ASTHMA: A COMPARATIVE ANALYSIS OF TEZEPELUMAB, MEPOLIZUMAB, BENRALIZUMAB, AND DUPILUMAB

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ABSTRACT

Introduction: Bronchial asthma remains a significant clinical problem despite advances in pharmacological treatment. Approximately 5–10% of asthma patients suffer from a severe, uncontrolled form of the disease associated with frequent exacerbations, impaired lung function, reduced quality of life, and increased hospitalization rates. The introduction of biologic therapies targeting Th2-dependent inflammatory pathways has significantly improved treatment outcomes in this group of patients.
Aim of the Study: The aim of this study was to analyze and compare the efficacy and safety of biologic therapies used in the treatment of severe asthma, with particular emphasis on tezepelumab, mepolizumab, benralizumab, and dupilumab, based on clinical trials and real-world studies.
Materials and Methods: A literature review was conducted using the PubMed database. Original clinical trials, prospective studies, and real-world observational studies published between 2020 and 2026 were included in the analysis. The effects of biologic therapies on asthma exacerbation reduction, improvement in lung function, reduction in oral corticosteroid use, achievement of clinical remission, and long-term treatment safety were evaluated.
Results: All analyzed biologic therapies demonstrated significant clinical efficacy in the treatment of severe asthma. Tezepelumab led to a substantial reduction in the number of exacerbations, improvement in pulmonary function parameters, and reduction in oral corticosteroid use regardless of eosinophil levels. Mepolizumab and benralizumab showed comparable efficacy, particularly in patients with eosinophilic asthma. Dupilumab demonstrated high efficacy in patients with type 2 inflammation, especially regarding improvement in lung function. Real-world studies confirmed the effectiveness and favorable safety profile of biologic therapies observed in randomized clinical trials.
Conclusions: Biologic therapies constitute an effective and safe treatment option for severe asthma and significantly improve disease control and patients' quality of life. The strongest clinical evidence concerns tezepelumab, mepolizumab, benralizumab, and dupilumab; however, treatment efficacy may depend on the disease phenotype and inflammatory biomarkers. Further studies are needed to optimize the personalization of biologic therapies and to standardize remission criteria in severe asthma.

KEYWORDS

Severe Asthma, Biologic Therapy, Tezepelumab, Mepolizumab, Benralizumab, Dupilumab, Eosinophilic Asthma, Biologic Treatment, Clinical Remission, Monoclonal Antibodies

CITATION

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Introduction

Bronchial asthma remains a significant clinical and social problem despite considerable advances in the diagnosis and treatment of obstructive airway diseases. It is estimated that approximately 5–10% of asthma patients suffer from severe asthma, which is characterized by persistent symptoms such as chronic cough, dyspnea, wheezing, frequent exacerbations, and the need for high doses of inhaled and oral corticosteroids despite treatment according to current guidelines (Okuducu and Kinane, 2025; Lin et al., 2023). This condition leads to a substantial deterioration in quality of life, an increased number of hospitalizations, and rising healthcare costs. In recent years, biologic therapies have gained particular importance, enabling a more personalized approach to the treatment of patients with severe asthma, especially those with eosinophilic and Th2-dependent phenotypes (Okuducu and Kinane, 2025; Lin et al., 2023; Xiao et al., 2025). Th2-dependent asthma is a phenotype characterized by chronic airway inflammation driven by Th2 lymphocytes and cytokines such as IL-4, IL-5, and IL-13. It is typically associated with eosinophilia and allergic sensitization.

Biologic agents used in the treatment of severe asthma act through selective inhibition of key mediators of the immune response responsible for chronic airway inflammation. The most important groups include monoclonal antibodies directed against immunoglobulin E (IgE), interleukin-5 (IL-5), the IL-5 receptor (IL-

5Rα), the IL-4/IL-13 receptor, and thymic stromal lymphopoietin (TSLP) (Okuducu and Kinane, 2025; Lin et al., 2023). Omalizumab was the first biologic therapy introduced for severe allergic asthma, whereas mepolizumab and reslizumab neutralize IL-5, which is responsible for eosinophil proliferation and activation. Benralizumab binds to the IL-5Rα receptor, leading to near-complete eosinophil depletion through antibody-dependent cellular cytotoxicity (Ramakrishnan et al., 2025; Korn et al., 2021; Izumo et al., 2020). Dupilumab inhibits IL-4 and IL-13 signaling, thereby reducing type 2 inflammatory responses, while tezepelumab blocks TSLP, an epithelial cytokine initiating the inflammatory cascade, which allows efficacy regardless of eosinophil count or IgE concentration (Jackson et al., 2026; Maspero et al., 2023; Menzies-Gow et al., 2021; Akenroye et al., 2022).

The introduction of biologic treatment has significantly improved asthma control, reduced the number of exacerbations, and decreased the need for chronic oral corticosteroid therapy. Particularly promising results have been observed with tezepelumab, which in the PATHWAY, NAVIGATOR, and WAYFINDER studies demonstrated significant improvement in lung function, quality of life, and the possibility of reducing or completely discontinuing oral corticosteroids in patients with severe uncontrolled asthma (Jackson et al., 2026; Menzies-Gow et al., 2023; Menzies-Gow et al., 2021; Corren et al., 2021). Similar effects were observed with mepolizumab and benralizumab, which effectively reduced blood eosinophil counts and the frequency of asthma exacerbations (Bonato et al., 2025; Ramakrishnan et al., 2025; Crimi et al., 2024; Laorden et al., 2024; Izumo et al., 2020). Dupilumab showed particularly high efficacy in patients with severe type 2 inflammation and concomitant eosinophilia (Maspero et al., 2023; Kyriakopoulos et al., 2024).

An increasing number of studies also indicate the possibility of achieving clinical remission in severe asthma through biologic therapies. Clinical remission includes the absence of exacerbations, good symptom control, improved lung function, and elimination of the need for oral corticosteroids ("Clinical remission in severe asthma," 2025; Bonato et al., 2025; Lupia et al., 2026; Crimi et al., 2024; Gates et al., 2025). Real-world studies further confirm the effectiveness of biologic therapies outside randomized clinical trial settings, demonstrating their favorable safety profile and long-term efficacy ("Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; Kayser et al., 2024; Laorden et al., 2024; Jesenak et al., 2023; Izumo et al., 2020; Charles et al., 2022).

Despite the growing number of available biologic therapies, challenges remain regarding the optimal selection of treatment for specific patient phenotypes, assessment of long-term effectiveness, and identification of biomarkers predictive of therapeutic response. Therefore, comparative analyses evaluating the efficacy, safety, and impact of individual biologic agents on the course of severe asthma are still necessary (Kyriakopoulos et al., 2024; Kearney et al., 2024).

The aim of this study is to compare the efficacy and safety of selected biologic therapies used in the treatment of severe asthma based on available clinical trials, real-world studies, and meta-analyses. Particular attention was paid to the impact of these therapies on reducing exacerbation rates, improving lung function, decreasing the need for oral corticosteroids, and achieving clinical remission.

Methods

This study constitutes a comparative analysis of the efficacy and safety of biologic therapies used in the treatment of severe bronchial asthma. The analysis was conducted based on current clinical trials, real-world evidence studies, observational studies, and review publications concerning modern biologic therapies, particularly tezepelumab, mepolizumab, benralizumab, and dupilumab (Jackson et al., 2026; Maspero et al., 2023; "Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; "Clinical remission in severe asthma," 2025; Papi et al., 2022; Erroz Ferrer et al., 2025; Kayser et al., 2024; Bonato et al., 2025; Kim et al., 2026; Ramakrishnan et al., 2025; Bourdin et al., 2024; Okuducu and Kinane, 2025; Korn et al., 2021; Lupia et al., 2026; Crimi et al., 2024; Kobayashi et al., 2021).

Publications included in the analysis met the following criteria: availability of the full-text article, publication in the English language, studies involving patients with severe or uncontrolled bronchial asthma, and the presence of clinical data related to the efficacy or safety of biologic treatment. Both phase III randomized clinical trials and observational studies conducted in routine clinical practice were included (Jackson et al., 2026; Maspero et al., 2023; "Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; "Clinical remission in severe asthma," 2025; Papi et al., 2022; Erroz Ferrer et al., 2025; Kayser et al., 2024; Bonato et al., 2025; Kim et al., 2026; Ramakrishnan et al., 2025; Bourdin et al., 2024; Okuducu and Kinane, 2025; Korn et al., 2021; Lupia et al., 2026; Crimi et al., 2024;

Kobayashi et al., 2021). Exclusion criteria comprised review articles, single case reports, and studies not related to severe asthma.

The analyzed studies included adult and adolescent populations with severe eosinophilic asthma and severe asthma that remained difficult to control despite high doses of inhaled corticosteroids and additional controller therapy. Some studies also evaluated patients dependent on long-term oral corticosteroid therapy (Jackson et al., 2026; Menzies-Gow et al., 2021; Pelaia et al., 2025).

The study compared the efficacy of individual biologic therapies based on the following clinical parameters: frequency of asthma exacerbations, improvement in pulmonary function parameters—particularly forced expiratory volume in one second (FEV1), reduction in oral corticosteroid use, achievement of clinical remission, and improvement in patients' quality of life (Jackson et al., 2026; Maspero et al., 2023; Papi et al., 2022; Bonato et al., 2025; Ramakrishnan et al., 2025; Laorden et al., 2024; Menzies-Gow et al., 2021; Corren et al., 2021; Lin et al., 2023; Akenroye et al., 2022). Additionally, the effects of therapy on inflammatory biomarkers, including eosinophil counts and concentrations of proteins associated with eosinophil activation, were analyzed (Ramakrishnan et al., 2025; Jesenak et al., 2023).

As part of the comparative analysis, the results of studies concerning monoclonal antibodies targeting interleukin-5 or its receptor (mepolizumab, benralizumab), the IL-4/IL-13 receptor (dupilumab), and thymic stromal lymphopoietin (TSLP) (tezepelumab) were compared (Jackson et al., 2026; Maspero et al., 2023; Kayser et al., 2024; Okuducu and Kinane, 2025; Lupia et al., 2026; Menzies-Gow et al., 2021; Pelaia et al., 2025). Particular attention was paid to the possibility of achieving long-term clinical remission, durability of therapeutic effects, and the effectiveness of therapies under real-world clinical practice conditions (Papi et al., 2022; Bonato et al., 2025; Laorden et al., 2024; Menzies-Gow et al., 2023; Izumo et al., 2020; Gates et al., 2025; Corren et al., 2021; Lin et al., 2023).

Treatment safety was assessed based on the frequency of mild adverse events, serious adverse events, and treatment discontinuation due to side effects. The analysis also included data regarding the long-term safety of biologic therapies, including observations of up to five years of treatment (Korn et al., 2021; Crimi et al., 2024).

Data obtained from individual publications were subjected to qualitative analysis. The methodology of the studies, sample size, duration of follow-up, patient characteristics, and clinical outcomes were compared. This allowed for a comprehensive assessment of the current role of biologic therapies in the treatment of severe asthma and the identification of potential differences among individual biologic agents.

Results

The analysis of the included clinical and observational studies on biologic treatment of severe asthma demonstrated the high efficacy of modern biologic therapies in reducing the number of exacerbations, improving disease control, enhancing pulmonary function parameters, and decreasing the use of systemic glucocorticoids (Jackson et al., 2026; Maspero et al., 2023; "Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; Kayser et al., 2024; Okuducu and Kinane, 2025).

The largest body of evidence concerned tezepelumab, whose efficacy was evaluated both in randomized clinical trials and real-world clinical practice analyses. The WAYFINDER study demonstrated a significant reduction in the need for oral corticosteroids in patients with severe steroid-dependent asthma, and some patients were able to completely discontinue systemic treatment (Jackson et al., 2026). The NAVIGATOR trial confirmed improvement in lung function and a reduction in severe asthma exacerbations following tezepelumab therapy (Menzies-Gow et al., 2023). Similar findings were observed in a study involving adults and adolescents with severe uncontrolled asthma, where significant improvement in disease control was noted regardless of baseline eosinophil count (Menzies-Gow et al., 2021).

Real-world studies concerning tezepelumab demonstrated the possibility of achieving clinical and biological remission in some patients with severe asthma (Gates et al., 2025). Short-term observations also indicated rapid improvement in symptoms and patients' quality of life after initiation of therapy (Pelaia et al., 2025). Furthermore, the PATHWAY study showed improvements in patient-reported quality of life, including daily functioning and asthma symptom control (Corren et al., 2021). Imaging analysis using chest computed tomography demonstrated a beneficial effect of tezepelumab on airway remodeling and the possibility of achieving clinical remission (Lupia et al., 2026).

Dupilumab showed high efficacy in patients with moderate-to-severe uncontrolled asthma. In the LIBERTY ASTHMA QUEST trial, a significant reduction in exacerbation rates and improvement in FEV1 values were observed, particularly in patients with type 2 inflammation and elevated eosinophil levels

(Maspero et al., 2023). These findings confirmed the effectiveness of blocking the IL-4/IL-13 pathway in the treatment of severe asthma.

An important group of analyzed studies focused on mepolizumab. The therapy was shown to effectively reduce eosinophil levels and the frequency of asthma exacerbations while simultaneously improving disease control (Bonato et al., 2025; Crimi et al., 2024; Laorden et al., 2024; Jesenak et al., 2023). The REMI-M study demonstrated the possibility of achieving long-term clinical remission during chronic mepolizumab treatment (Crimi et al., 2024). Real-world studies also confirmed the therapy's effectiveness in daily clinical practice, indicating reductions in hospitalization rates and systemic steroid use (Laorden et al., 2024; Jesenak et al., 2023).

A study evaluating the effect of mepolizumab on inflammatory biomarkers demonstrated reductions in galectin-10 and eosinophilic cationic protein concentrations, confirming the biological effect of therapy and decreased eosinophilic activity (Kobayashi et al., 2021). Additionally, mepolizumab was effective in patients with eosinophilic granulomatosis with polyangiitis, leading to reduced steroid requirements and higher remission rates (Kim et al., 2026).

Benralizumab, an antibody targeting the IL-5 receptor, resulted in rapid and nearly complete depletion of eosinophils, which was associated with improved control of severe asthma (Ramakrishnan et al., 2025; Izumo et al., 2020). The ABRA study demonstrated the efficacy of benralizumab in the treatment of eosinophilic exacerbations of asthma and COPD (Ramakrishnan et al., 2025). The prospective J-BEST study confirmed the effectiveness and safety of therapy in real-world clinical practice (Izumo et al., 2020). Long-term safety analyses demonstrated a favorable tolerance profile for both benralizumab and mepolizumab during treatment lasting up to five years (Bourdin et al., 2024; Korn et al., 2021).

Comparative studies indicated that the efficacy of various monoclonal antibodies used in severe asthma is generally comparable; however, treatment response depends on the disease phenotype and the inflammatory profile of the individual patient ("Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; Kayser et al., 2024; Okuducu and Kinane, 2025). The EU-ADVANTAGE analysis demonstrated comparable effectiveness of biologic therapies in reducing exacerbations and improving asthma control in clinical practice ("Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024). Long-term multicenter observations also suggested similar efficacy among individual biologic agents used in severe asthma (Kayser et al., 2024).

The analyzed publications also emphasized the importance of personalized biologic treatment and the possibility of switching therapies in patients with insufficient clinical response. This was particularly relevant in pediatric patients, in whom tezepelumab may represent a new effective therapeutic option (Erroz Ferrer et al., 2025).

In terms of safety, all analyzed biologic therapies demonstrated favorable tolerability profiles. The most commonly reported adverse events included injection-site reactions, headache, and upper respiratory tract infections, whereas serious adverse events occurred rarely (Maspero et al., 2023; Bourdin et al., 2024; Korn et al., 2021; Izumo et al., 2020).

Discussion

In recent years, biologic treatment of severe asthma has become one of the most important directions in the development of modern pulmonology. The results of the analyzed studies indicate that monoclonal antibodies significantly improve disease control, reduce the number of exacerbations, and enable a reduction in the use of systemic corticosteroids, which are associated with numerous adverse effects (Jackson et al., 2026; "Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; Okuducu and Kinane, 2025; Lin et al., 2023). Particularly important are agents targeting the eosinophilic pathway and type 2 inflammatory mediators, such as mepolizumab, benralizumab, dupilumab, and tezepelumab.

One of the most frequently assessed parameters of biologic therapy effectiveness was the reduction in asthma exacerbations. Studies concerning mepolizumab demonstrated a significant decrease in the frequency of severe exacerbations and improvement in asthma symptom control both in clinical trials and real-world practice (Bonato et al., 2025; Crimi et al., 2024; Laorden et al., 2024; Jesenak et al., 2023). Similar results were obtained for benralizumab, whose effectiveness was confirmed in the J-BEST study and long-term analyses (Korn et al., 2021; Izumo et al., 2020). Dupilumab, in turn, showed high efficacy particularly in patients with severe Th2-dependent asthma and elevated eosinophil levels (Maspero et al., 2023; Kyriakopoulos et al., 2024; Kearney et al., 2024).

Particular attention should be paid to studies on tezepelumab, which acts by blocking thymic stromal lymphopoietin (TSLP), one of the main mediators initiating the inflammatory response. Unlike other biologic agents, its effectiveness is not limited only to patients with high eosinophil counts, which may constitute a significant clinical advantage (Jackson et al., 2026; Menzies-Gow et al., 2023; Menzies-Gow et al., 2021; Akenroye et al., 2022). The NAVIGATOR study demonstrated improvement in lung function parameters and reduction in exacerbation frequency regardless of baseline eosinophil count (Menzies-Gow et al., 2023; Menzies-Gow et al., 2021). Moreover, real-world studies suggest the possibility of achieving both clinical and biological remission in some patients treated with tezepelumab (Gates et al., 2025; Pelaia et al., 2025).

Analysis of the studies also indicates that achieving clinical remission is becoming one of the primary goals in the treatment of severe asthma. Remission includes not only the absence of exacerbations, but also improvement in quality of life, better lung function, and reduction of corticosteroid therapy ("Clinical remission in severe asthma," 2025; Bonato et al., 2025; Crimi et al., 2024; Gates et al., 2025). In the Swiss Severe Asthma Registry study, patients treated with biologics achieved remission significantly more often than those receiving only standard therapy ("Clinical remission in severe asthma," 2025). These findings confirm a shift in the therapeutic approach—from symptom control toward long-term disease modification.

An important issue remains the safety of long-term biologic therapy. Data from the MELTEMI and COLUMBA studies demonstrated a favorable safety profile for both benralizumab and mepolizumab even during five years of observation (Bourdin et al., 2024; Korn et al., 2021). Adverse effects were generally mild and mainly included injection-site reactions and upper respiratory tract infections. These findings are particularly important in the context of the chronic nature of severe asthma and the need for long-term treatment.

The analyzed publications also emphasized the role of therapy personalization. The selection of an appropriate monoclonal antibody should depend on the disease phenotype, eosinophil count, type 2 helper T-cell (Th2) inflammation, and the coexistence of atopic diseases (Okuducu and Kinane, 2025; Lin et al., 2023; Kyriakopoulos et al., 2024). In clinical practice, the possibility of switching biologic therapies in cases of insufficient treatment response is becoming increasingly important. Particularly in the pediatric population, potential benefits have been observed when switching to tezepelumab in patients inadequately controlled with other monoclonal antibodies (Erroz Ferrer et al., 2025).

It is also worth noting that comparative studies have not demonstrated a clear superiority of one biologic agent over another. Multicenter observations suggest similar effectiveness of mepolizumab, benralizumab, and dupilumab in improving asthma control and reducing exacerbations (Kayser et al., 2024; Kyriakopoulos et al., 2024; Kearney et al., 2024). This may indicate that the key element of therapy is appropriate patient qualification according to the disease phenotype rather than the selection of a specific biologic agent alone.

The limitations of the analyzed studies include the heterogeneity of patient populations, differences in follow-up duration, and varying criteria used to define clinical remission. Some analyses were based on observational studies and real-world data, which may affect the possibility of direct comparison between results ("Real-world comparative effectiveness of biologic therapies in severe asthma: EU-ADVANTAGE," 2024; "Clinical remission in severe asthma," 2025; Charles et al., 2022). Furthermore, most available studies involve patients with eosinophilic or Th2-dependent asthma; therefore, further analyses concerning non-eosinophilic phenotypes are still needed.

In summary, biologic therapy currently constitutes the foundation of treatment for severe asthma resistant to standard therapy. The greatest benefits are observed in the reduction of exacerbations, decreased use of systemic corticosteroids, and improvement in patients' quality of life. Study results suggest that the development of targeted therapies may in the future enable sustained disease remission in an increasing number of patients with severe asthma (Okuducu and Kinane, 2025; Menzies-Gow et al., 2021; Lin et al., 2023).

In Poland, patients receive biologic treatment under the B.44 drug program. Eligibility criteria for treatment with mepolizumab and benralizumab include:

1. Patients over 18 years of age with severe, treatment-resistant eosinophilic asthma identified by a blood eosinophil count of ≥350 cells/μL at the qualification visit or within 12 months prior to qualification, or ≥150 cells/μL if systemic corticosteroids at a dose of ≥5 mg daily were required for at least 6 months before qualification due to uncontrolled asthma, with a cumulative annual oral corticosteroid dose ≥1.0 g prednisone equivalent.
2. The need for high-dose inhaled corticosteroids (>1000 μg beclomethasone dipropionate daily or an equivalent dose of another inhaled corticosteroid according to current Global Initiative for Asthma (GINA)

guidelines) combined with another asthma controller medication such as a long-acting β2-agonist, leukotriene modifier, or long-acting muscarinic antagonist.

3. Two or more exacerbations within the previous year requiring systemic corticosteroid treatment or dose escalation for more than three days in patients receiving chronic systemic corticosteroid therapy.
4. Fulfillment of at least two of the following criteria:
5. a) uncontrolled asthma symptoms (Asthma Control Questionnaire [ACQ] score >1.5 points),
6. b) hospitalization within the previous 12 months due to asthma exacerbation,
7. c) history of life-threatening asthma attack,
8. d) persistent airflow obstruction (FEV1 <80% predicted or peak expiratory flow [PEF] variability >30%),
9. e) impaired quality of life due to asthma (mini-AQLQ score <5.0 points).
10. Exclusion of other hypereosinophilic syndromes.
11. Non-smoking status.
12. Exclusion of parasitic infection based on a negative stool examination.
13. Exclusion of other clinically significant pulmonary diseases.

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AI: AI was utilized for assistance in refining the academic English language of the manuscript, ensuring clarity, consistency, and adherence to scientific writing standards. It is important to emphasize that all AI tools were used strictly as assistive instruments under human supervision. The final interpretation of results, classification of errors, and conclusions were determined by human experts in clinical medicine and formal logic. In preparing this work, the author(s) used Grammarly for the purpose ofchecking and improving grammatical correctness. After using this tool, the author(s) have reviewed and edited the content as needed and accept full responsibility for the substantive content of the publication.

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