UNIVERSAL INTERNATIONAL SCIENTIFIC JOURNAL
Homepage of the Journal https://universaljurnal.uz

UNIVERSAL INTERNATIONAL SCIENTIFIC JOURNAL
e-ISSN: 3060-4540 (online)
Year: 2026 Issue: 3 Volume: 6
Published: 4.06.2026
https://universaljurnal.uz

International indexes
GOOGLE SCHOLAR
CROSSREF
ZENODO
RESEARCHGATE
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RESEARCHBIB

OMALIZUMAB IN ASTHMA MANAGEMENT: FROM GUIDELINES TO PRACTICE

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Article Info
2 May 2026
Accepted:
14 May 2026
Available Online:
4 June 2026

Language: Uzbek

Annotatsiya:
Og'ir astma kattalarda yuqori yuklamali holat bo'lib qolmoqda, bu esa ingalyatsiya qilingan davolashni optimallashtirish, rioya qilish, komorbidlikni nazorat qilish va qo'zg'atuvchi omillarni yumshatishdan so'ng fenotipga yo'naltirilgan qo'shimcha terapiyani talab qiladigan heterojen endotiplar tufayli yuzaga keladi. Immunoglobulin E (IgE) ni nishonga oluvchi insonlashtirilgan monoklonal antikor bo'lgan Omalizumab og'ir allergik (IgE vositachiligidagi) astma bilan og'rigan kattalar uchun biologik variant bo'lib, asosiy xalqaro strategiyalar va jamiyat ko'rsatmalariga ko'ra standart yuqori dozali ingalyatsiya qilingan kortikosteroid/uzoq muddatli β_2-agonistga asoslangan rejimlar nazoratga erisha olmagan hollarda qo'shimcha terapiya sifatida belgilanadi. Mexanik jihatdan, omalizumab aylanib yuruvchi erkin IgE bilan bog'lanadi va asosiy effektor hujayralardagi yuqori affinlikli IgE retseptorlarini pasaytirish orqali IgE–FcεRI signalizatsiyasini kamaytiradi, shu bilan allergen tomonidan boshqariladigan mast hujayralar, bazofil faollashuvi va 2-toifa yallig'lanishni susaytiradi. Tasodifiy sinovlar va real hayotdagi tadqiqotlardan olingan dalillar, noyob anafilaksi va marketingdan keyingi yurak-qon tomir xavfi kabi xavfsizlik signallariga doimiy e'tibor qaratgan holda, tanlangan bemorlarda alevlenmelerning klinik jihatdan sezilarli darajada kamayishi, simptomlarni nazorat qilish va hayot sifatining yaxshilanishi va steroidlarni tejashning afzalliklarini qo'llab-quvvatlaydi. Ushbu sharhda ko'rsatmalar bo'yicha tavsiyalar, bemorni tanlash, dozalash va monitoring

qilish tamoyillari hamda kattalar amaliyotiga moslashtirilgan amaliy amalga oshirish bosqichlari umumlashtirilib, muntazam parvarishda javobni baholash va davolashni optimallashtirishga urg'u beriladi.
Kalit so`zlar:
og'ir astma; allergik astma, anti-IgE, omalizumab, biologik terapiya, zo'rayishlar, ko'rsatmalarni amalga oshirish.
Аннотация:
Тяжелая форма астмы остается распространенным заболеванием у взрослых, обусловленным гетерогенными эндотипами, требующими дополнительной терапии, направленной на конкретный фенотип, после оптимизации ингаляционного лечения, повышения приверженности терапии, контроля сопутствующих заболеваний и снижения количества провоцирующих факторов. Омализумаб, гуманизированное моноклональное антитело, нацеленное на иммуноглобулин Е (IgE), является признанным биологическим препаратом для взрослых с тяжелой аллергической (IgE-опосредованной) астмой. В соответствии с основными международными стратегиями и рекомендациями медицинских сообществ, он позиционируется как дополнительная терапия в случаях, когда стандартные схемы лечения с высокими дозами ингаляционных кортикостероидов/длительно действующих β_2-агонистов не позволяют достичь контроля. Механистически омализумаб связывает циркулирующий свободный IgE и снижает передачу сигналов IgE–FcεRI путем подавления высокоаффинных рецепторов IgE на ключевых эффекторных клетках, тем самым ослабляя вызванную аллергенами активацию тучных клеток и базофилов, а также последующее воспаление 2-го типа. Данные рандомизированных исследований и исследований в реальной клинической практике подтверждают клинически значимое снижение частоты обострений, улучшение контроля симптомов и качества жизни, а также преимущества снижения потребности в стероидах у отдельных пациентов, при этом уделяется постоянное внимание сигналам безопасности, таким как редкая анафилаксия, и обсуждению рисков сердечно-сосудистых заболеваний после выхода препарата на рынок. В этом обзоре обобщены рекомендации руководств, принципы отбора пациентов, дозирования и мониторинга, а также практические шаги по внедрению, адаптированные для практики со взрослыми пациентами, с акцентом на оценку ответа на лечение и оптимизацию терапии в условиях обычной медицинской практики.
Ключевые слова:
тяжелая форма астмы; аллергическая астма, анти-IgE, омализумаб, биологическая терапия, обострения, внедрение рекомендаций.
Abstract:
Severe asthma remains a high-burden condition in adults, driven by heterogeneous endotypes that require phenotype-directed add-on therapy after optimization of inhaled treatment, adherence, comorbidity control, and trigger mitigation. Omalizumab, a humanized monoclonal antibody targeting immunoglobulin E (IgE), is an established biologic option for adults with severe allergic (IgE-mediated) asthma, positioned by major international strategies and society guidelines as an add-on therapy when standard high-dose inhaled corticosteroid/long-acting β_2-agonist based regimens fail to achieve control. Mechanistically, omalizumab binds circulating free IgE and reduces IgE–FcεRI signaling by downregulating high-affinity IgE receptors on key effector cells, thereby attenuating allergen-driven mast cell, basophil activation and downstream type 2 inflammation. Evidence from randomized trials and real-world studies

supports clinically meaningful reductions in exacerbations, improvements in symptom control and quality of life, and steroid-sparing benefits in selected patients, with ongoing attention to safety signals such as rare anaphylaxis and post-marketing cardiovascular risk discussions. This review summarizes guideline recommendations, patient selection, dosing and monitoring principles, and practical implementation steps tailored to adult practice, emphasizing response assessment and treatment optimization in routine care.

Keywords:
severe asthma; allergic asthma, anti-IgE, omalizumab, biologic therapy, exacerbations, guideline implementation.

Introduction

Asthma control in adults is typically achieved with inhaled anti-inflammatory therapy and bronchodilation. However, a subset of patients continues to experience frequent exacerbations, impaired quality of life or persistent symptoms despite optimized standard therapy. International frameworks define “severe asthma” as asthma that remains uncontrolled despite high-dose ICS/LABA (and management of modifiable factors), or that worsens when high-intensity therapy is reduced. In this context, biologic therapies targeting type 2 pathways have transformed outcomes by aligning treatment with endotype.

Omalizumab was the first biologic approved for asthma and remains central for adults with severe allergic asthma. It is a monoclonal antibody that neutralizes IgE, thereby reducing IgE-mediated effector responses and modulating allergic inflammation. Contemporary guidance documents (e.g., GINA updates and ERS/ATS guidelines) position omalizumab as an add-on option for severe allergic asthma after careful confirmation of diagnosis, optimization of inhaled therapy, and assessment of phenotype/eligibility.

This review focuses on adult asthma practice and aims to translate guideline recommendations into an implementable clinical workflow.

Materials and Methods

Literature search strategy

A narrative review was conducted using PubMed-indexed literature and international guideline documents. Searches (last updated December 2025) used combinations of keywords and MeSH terms including: asthma, severe asthma, omalizumab, anti-IgE, allergic asthma, exacerbation, oral corticosteroid, real-world, safety, anaphylaxis. Guideline sources were obtained from official publisher sites (e.g., GINA).

Selection criteria

Included sources emphasized:

1. Adults with moderate-to-severe or severe allergic asthma;
2. Randomized controlled trials, meta-analyses, and robust observational studies;

3. Major international guidelines and society recommendations;

4. Safety evaluations relevant to adult practice (anaphylaxis, malignancy, cardiovascular/cerebrovascular outcomes).

Results

1) Guideline positioning: where omalizumab fits. GINA (2025 update) places biologics as add-on therapy for patients with persistent symptoms/exacerbations despite optimized high-dose ICS/LABA and management of contributory factors, with biologic choice guided by phenotype (allergic sensitization, eosinophils, FeNO, comorbidities, etc.).

ERS/ATS severe asthma guidance similarly supports phenotype-directed biologics and provides a framework for defining severe asthma and selecting add-on targeted treatments in appropriate candidates.

Practical implication: omalizumab is most appropriate when the clinical picture is consistent with IgE-mediated allergic asthma (sensitization plus relevant allergen exposure) and the patient meets local dosing-table eligibility (total IgE and body weight within approved ranges), alongside a history of exacerbations or ongoing poor control despite optimized therapy.

2) Mechanistic basis (molecular overview, targeted). Omalizumab is a humanized IgG monoclonal antibody that binds free IgE, lowering circulating IgE available to bind FcεRI (high-affinity IgE receptor). This reduces FcεRI expression and signaling on mast cells and basophils, dampening allergen-driven degranulation and mediator release.

Downstream effects relevant to adult severe allergic asthma (partial list): reduced immediate hypersensitivity effector activation (mast cell/basophil mediator cascade); attenuation of type 2 inflammatory amplification (clinical correlates: fewer exacerbations, improved control in responders); potential reduction in steroid requirement in selected populations (steroid-sparing effect reflects reduced inflammatory instability rather than bronchodilation).

3) Clinical effectiveness in adults: outcomes that matter. Exacerbation reduction and control improvement. A foundational randomized trial in allergic asthma demonstrated that omalizumab improved asthma control and reduced exacerbations and steroid requirements versus comparator therapy. (Another early trial in ICS-dependent allergic asthma supported improved outcomes with add-on omalizumab.

In adults with severe allergic asthma inadequately controlled on standard therapy, randomized data show clinically meaningful improvements consistent with omalizumab’s role as add-on therapy in difficult-to-control disease.

Real-world effectiveness. A large real-world meta-analysis found improvements across clinically relevant domains (exacerbations, steroid exposure, lung function, and patient-reported outcomes) after omalizumab initiation in severe allergic asthma populations. Real-life studies also highlight response heterogeneity and emphasize the need for structured response assessment.

4) Biomarkers and patient selection. Although omalizumab is anchored in an allergic phenotype, response is not determined by total IgE alone. Biomarker analyses (e.g., FeNO, blood eosinophils, periostin as markers of type 2 inflammation) have been investigated as predictors of differential benefit, supporting a broader view that omalizumab may work best when allergic sensitization co-exists with active type 2 inflammatory signaling.

Use a structured pre-biologic assessment: confirm asthma diagnosis and assess severity (spirometry, variability, exacerbation history); Verify adherence, inhaler technique, and comorbidity management (rhinitis/sinus disease, GERD, obesity, OSA, smoking); Document allergic sensitization (skin prick or specific IgE) and clinical relevance; Check total IgE and weight vs local dosing table; review exacerbation frequency and steroid exposure.

5) Steroid-sparing role in adults. Reducing maintenance oral corticosteroids (OCS) is a major objective in severe asthma due to cumulative toxicity. An open-label study demonstrated OCS-sparing benefits with omalizumab in severe allergic asthma, supporting its role in appropriately selected patients where steroid dependence reflects uncontrolled allergic/type 2 inflammation.

Discussion

Omalizumab occupies a well-defined niche in adult asthma care, severe allergic asthma that remains uncontrolled despite optimized inhaled therapy and systematic management of modifiable factors. The strongest “guideline-to-practice” message is that biologics should not compensate for poor fundamentals—misdiagnosis, incorrect inhaler technique, nonadherence, untreated comorbidities, or ongoing exposures can mimic therapeutic failure.

Mechanistically, omalizumab’s IgE neutralization and FcεRI downregulation provide a coherent biologic rationale for reducing allergen-driven instability and exacerbation susceptibility, aligning with improvements observed in both trials and real-world settings. However, adult clinical response varies. Biomarker work suggests that patients with stronger type 2 inflammatory signatures may derive greater reduction in exacerbations, supporting a phenotype-plus-endotype approach rather than reliance on total IgE alone.

From an implementation standpoint, the most consequential practice elements are:

1. Correct identification of severe asthma;
2. Evidence-based patient selection;
3. Structured response assessment with predefined continuation/switch rules;
4. Proactive safety management (especially anaphylaxis preparedness and awareness of post-marketing safety discussions).

Limitations of the evidence base include heterogeneity of "severe asthma" definitions across older trials, mixed-age enrollment in some pivotal studies, and confounding in observational safety analyses. Still, the convergence of guideline positioning, mechanistic plausibility, randomized efficacy, and consistent real-world effectiveness supports omalizumab as a cornerstone biologic option for adults with severe allergic asthma when used within an optimized, systematic care model.

Conclusion

In adult severe asthma, omalizumab provides a guideline-supported, mechanism-based add-on option for IgE-mediated allergic disease not controlled by optimized high-dose ICS/LABA-centered therapy. The transition from guidelines to practice requires rigorous confirmation of severe asthma status, careful eligibility and phenotype assessment, protocolized monitoring of response, and structured decisions to continue, adjust, or switch biologic therapy. Safety considerations particularly rare anaphylaxis and post-marketing cardiovascular discussions should be integrated into shared decision-making and monitoring workflows.

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