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Consensus

Expert Consensus on Physician–Pharmacist Co-management Model and Standardized Application of Anti-IgE Monoclonal Antibody Therapy for Allergic Asthma

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Abstract

This Consensus aims to establish a physician–pharmacist co-management model to standardize the rational clinical application of anti-immunoglobulin E monoclonal antibodies in the treatment of allergic asthma. Focusing on the critical components of physician–pharmacist co-management, key issues related to anti-immunoglobulin E monoclonal antibody therapy were identified through a systematic literature review and clinical practice experience. Evidence quality was evaluated using an evidence grading system, and the Delphi method was applied to reach expert consensus. Centered on omalizumab, the Consensus presents 12 recommendations covering the work model of physician–pharmacist co-management, clinical management pathways, hierarchical diagnosis and treatment systems, as well as training and competency assessment. The Delphi process achieved a high degree of consensus (agreement >80%) on 12 key recommendations, emphasizing a 60-min observation period post-injection and quarterly follow-up evaluations. It establishes a standardized framework for the co-management of omalizumab therapy in allergic asthma. Results highlighted that co-management effectively monitors omalizumab dosage (75–600 mg) and maintains a consensus threshold of >80% for patient safety protocols. The Consensus provides a standardized framework for physician–pharmacist co-management, which is expected to facilitate rational drug use and improve patient care pathways in omalizumab therapy.

Introduction

Bronchial asthma (commonly referred to as "asthma") is a heterogeneous disease characterized by chronic airway inflammation and airway hyperresponsiveness. Clinically, it presents with respiratory symptoms such as wheezing, shortness of breath, chest tightness, and coughing, often accompanied by varying degrees of expiratory airflow limitation.[1,2] In China, the prevalence of asthma among individuals aged 20 years and above is approximately 4.2%, corresponding to an estimated 45.7 million patients.[3] Allergic asthma is the most common clinical subtype, typically induced and triggered by allergen exposure, and accounts for more than 50% of adult cases and 80% of pediatric cases.[4,5] Approximately 20% of children with asthma remain poorly controlled, and about 5% may progress to severe asthma due to recurrent exacerbations.[6–8]

Immunoglobulin E (IgE)-mediated type I hypersensitivity plays a pivotal role in the pathophysiology of allergic asthma, contributing to the persistence of symptoms and disease exacerbations.[9] Studies have shown that 86% of adult patients with preschool-onset asthma exhibit allergic sensitization, while 64% of those aged 25–45 years have atopic sensitization.[10,11] The severity of asthma correlates closely with serum IgE levels. Furthermore, a nationwide survey conducted by the China Alliance of Research on Respiratory Allergic Diseases reported that 75.4% of asthma patients tested positive for allergen-specific IgE.[12]

Keywords: Allergic asthma; Physician–pharmacist co-management; Anti-IgE monoclonal antibody; Omalizumab.

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Omalizumab is currently the only globally approved anti-IgE monoclonal antibody that specifically binds circulating IgE, thereby blocking IgE-mediated allergic reactions and reducing asthma exacerbations. It has been recommended by both domestic and international guidelines for the treatment of allergic asthma.[3,4,13–17] The *Chinese Expert Consensus on the Use of Omalizumab in Allergic Asthma (2021 Edition)* and the *Global Initiative for Asthma 2024 Report* recommend omalizumab for children, adolescents, and adults aged ≥6 years with IgE-mediated allergic asthma who continue to experience persistent symptoms or exacerbations despite treatment with medium-to-high doses of inhaled corticosteroids (ICS) and long-acting β_2-agonists (LABA).[1,12] Dosage and administration frequency are determined by baseline serum IgE levels and body weight.

However, challenges remain in clinical practice. These include inappropriate indications (e.g., absence of regular ICS/LABA therapy, normal serum IgE levels, or use in children under six years), unreasonable dosing due to limited access to IgE testing, suboptimal dosing or injection intervals inconsistent with manufacturer recommendations, and the complex reconstitution process of omalizumab lyophilized powder.[18–20] Additionally, economic constraints and insufficient disease awareness contribute to poor medication adherence, while the risk of drug allergy further limits the rational use of anti-IgE therapy.[12,21,22]

In traditional clinical practice for omalizumab therapy in allergic asthma, the diagnostic process, severity assessment, and therapeutic decision-making have been predominantly physician-led. Pharmacists have historically been restricted to foundational services such as prescription review and medication dispensing, with limited involvement in critical stages including collaborative treatment decision-making, therapeutic drug monitoring, and follow-up management. To enhance pharmacists' participation in omalizumab therapy—particularly in monitoring treatment implementation, assessing medication use, and managing potential adverse drug reactions—and to further standardize the rational use of anti-IgE therapy, the Subcommittee on Respiratory Diseases of the Division of Drug-Induced Diseases, Chinese Pharmacological Society, in collaboration with the Guangdong Pharmaceutical Association and the Allergy Branch of the Guangdong Medical Association, convened a multidisciplinary panel of experts from pharmacy, respiratory medicine, allergy, otorhinolaryngology, pediatrics, and related specialties.

Together, they developed the Expert Consensus on Physician–Pharmacist Co-management of Anti-IgE Monoclonal Antibody Therapy for Allergic Asthma (hereafter referred to as the *Consensus*). The *Consensus* aims to establish a practical model of physician–pharmacist co-management and to provide evidence-based recommendations and management pathways for omalizumab therapy in allergic asthma. It is intended for use by physicians and pharmacists across all levels of medical institutions involved in the management of patients receiving omalizumab. Compared with existing domestic expert consensuses, this document places greater emphasis on physician–pharmacist collaboration, individualized therapy, comprehensive disease management, and patient education—moving beyond the sole focus on drug use and clinical efficacy. This approach is expected to improve medication rationality and adherence, optimize healthcare resource allocation, and foster innovation in medical service delivery.[12,20]

The *Consensus* has been registered on the International Practice Guideline Registry and Transparency Platform (Registration No. PREPARE-2024CN1221).

Formulation of the Consensus

Evidence search for the Consensus

A systematic search was conducted across databases including PubMed, China National Knowledge Infrastructure, and WANFANG DATA, as well as guideline-dissemination websites, from their inception to May 31, 2024. Key search terms included "bronchial asthma," "allergic asthma," "anti-IgE monoclonal antibody," "omalizumab," "pharmacy intervention," "pharmaceutical care," and "Physician–Pharmacist Co-management." Priority was given to high-quality literature published within the last five years, specifically retrospective studies, prospective studies, randomized controlled trials, meta-analyses, and systematic reviews.

Inclusion criteria were: (1) studies related to the diagnosis, treatment, and management of allergic asthma, omalizumab, and physician–pharmacist co-management; (2) study designs including randomized controlled trials, cohort studies, case-control studies, systematic reviews, and meta-analyses; and (3) publications in English or Chinese. Exclusion criteria were: (1) duplicate, outdated, or translated versions of existing literature; and (2) case reports or studies with incomplete data.

Formulation and revision of the Consensus

Based on a comprehensive literature review and recent clinical experience in chronic respiratory disease management, the working group identified key issues related to omalizumab treatment and developed the initial framework of the "Consensus." A multidisciplinary expert panel was established, comprising 48 specialists from Class A tertiary hospitals with senior professional titles and extensive theoretical and clinical expertise. The panel included 12 respiratory specialists, 5 allergists, 1 otolaryngologist, 4 pediatricians, and 26 pharmacists. The 26 participating pharmacists were senior clinical pharmacists specializing in respiratory medicine or medication therapy management with clinical practice experience. Following the initial round of deliberation and revision by this panel, the preliminary draft was formulated. The expert panel conducted three rounds of face-to-face discussions addressing core content, including key controversial points, specific recommendations, and supporting evidence. Subsequently, two rounds of online Delphi surveys were administered to evaluate the proposed recommendations. Experts anonymously rated and reviewed the rationality, strength of recommendation, and quality of evidence. Consensus was defined as an agreement rate of over 80%. Based on the feedback from these discussions and surveys, the working group underwent multiple iterations of revisions to finalize the Consensus.

Consensus was defined as agreement by more than 80% of experts. All contributors declared no conflicts of interest related to the content.

Evidence grading of the Consensus

The expert panel adopted the Grading of Recommendations Assessment, Development, and Evaluation approach to classify evidence and recommendations systematically. Evidence quality was categorized into four levels: High (I), Moderate (II), Low (III), and Very Low (IV). Recommendation strength was divided into three levels: Strong Recommendation (A), Weak Recommendation (B), and Good Practice Statement (C) (Table 1).[23]

Following the Delphi method principles,[24] voting on each consensus item was conducted under two criteria:

- For controversial topics, support or opposition to an intervention required approval from at least 50% of participants, while

Table 1. Grading of evidence quality and recommendation strength

Category	Level	Definition
Evidence quality	High (I)	Very confident that the true effect is close to the estimated effect
	Moderate (II)	Moderate confidence in the estimated effect; the true effect is likely close to the estimate, but a substantial difference remains possible
	Low (III)	Limited confidence in the estimated effect; the true effect may differ considerably from the estimate
	Very Low (IV)	Little confidence in the estimated effect; the true effect is likely to be substantially different from the estimate
Recommendation strength	Strong Recommendation (A)	Indicates that the benefits of the intervention clearly outweigh the risks, or vice versa
	Weak Recommendation (B)	Evidence of uncertainty or variable quality suggests that benefits and risks are approximately balanced
	Good Practice Statement (C)	Recommendations based primarily on indirect evidence, expert opinion, or clinical experience
Evidence quality	High (I)	Very confident that the true effect is close to the estimated effect
	Moderate (II)	Moderate confidence in the estimated effect; the true effect is likely close to the estimate, but a substantial difference remains possible

disagreement had to remain below 20%; otherwise, no recommendation was issued.

- A recommendation was classified as "strong" only if approved by ≥70% of participants.

Ultimately, 12 consensus recommendations were established.

Physician–pharmacist co-management promotes anti-IgE monoclonal antibody treatment for allergic asthma

Anti-IgE therapy has emerged as an effective targeted approach for the management of allergic asthma. Clinical studies have shown that in patients with moderate-to-severe allergic asthma, treatment with omalizumab significantly reduced the rate of acute exacerbations by 61.8% compared with the pre-treatment period [95% confidence interval: −68.5 to −54.0, $P < 0.0001$], markedly improved forced expiratory volume in one second (hereinafter referred to as FEV_1), decreased the proportion of patients requiring oral corticosteroids, and significantly lowered hospitalization rates.[25–27]

Studies conducted by Xu *et al.* and Su Nan further demonstrated that omalizumab improved FEV_1 by 3.0% (1.0–5.0%),[28,29] reduced fractional exhaled nitric oxide (FeNO) levels from 39.28 ± 21.64 ppb to 12.44 ± 4.90 ppb, and significantly decreased peripheral blood eosinophil (EOS) counts, thereby enhancing lung function and alleviating airway inflammation. However, the widespread implementation of anti-IgE therapy remains limited by disparities in patients' economic capacity and awareness of disease management.[22]

Both domestic and international studies underscore the pivotal role of pharmacists in asthma management. Internationally, physician–pharmacist co-management is realized through joint training programs, bidirectional patient referrals, regular updates to medication protocols, and the exchange of treatment recommendations between physicians and pharmacists.[30] An Australian study reported that integrating pharmacists into general practitioner-led asthma care was feasible, well accepted, and yielded potential clinical benefits.[31]

In China, however, physician–pharmacist co-management systems are still developing. Current regulations restrict pharmacists' prescribing authority; therefore, their roles primarily focus on enhancing medication adherence, monitoring adverse drug reactions, assisting physicians in therapy adjustments, and optimizing medical insurance costs during treatment.[32] In recent years, the physician–pharmacist co-management model has demonstrated significant efficacy in the management of various chronic diseases, including diabetes,[33] hypertension,[34] and chronic obstructive pulmonary disease.[35] Therefore, it can be inferred that the physician–pharmacist co-management model holds significant potential to enhance the clinical management of omalizumab therapy for allergic asthma.

> ***Consensus Recommendation 1:*** The physician–pharmacist co-management model can effectively standardize the appropriate use of anti-IgE monoclonal antibodies, improve patient medication adherence, asthma control, and quality of life, and facilitate the achievement of optimal management goals for allergic asthma. *(II, B)*

Process and workflow for physician–pharmacist co-management of anti-IgE monoclonal antibody treatment in allergic asthma

The implementation of the physician–pharmacist co-management model has been supported by several consensus documents, including the *Chinese Expert Consensus on the Use of Omalizumab in Allergic Asthma* and the *Expert Consensus on Physician–Pharmacist Collaborative Drug Therapy Management*.[12,36] This model harnesses the complementary expertise of physicians and pharmacists to deliver more comprehensive, patient-centered care, resulting in significant clinical benefits.

Workflow for physician–pharmacist co-management of anti-IgE monoclonal antibody treatment in allergic asthma

The Consensus outlines a standardized workflow for physician–

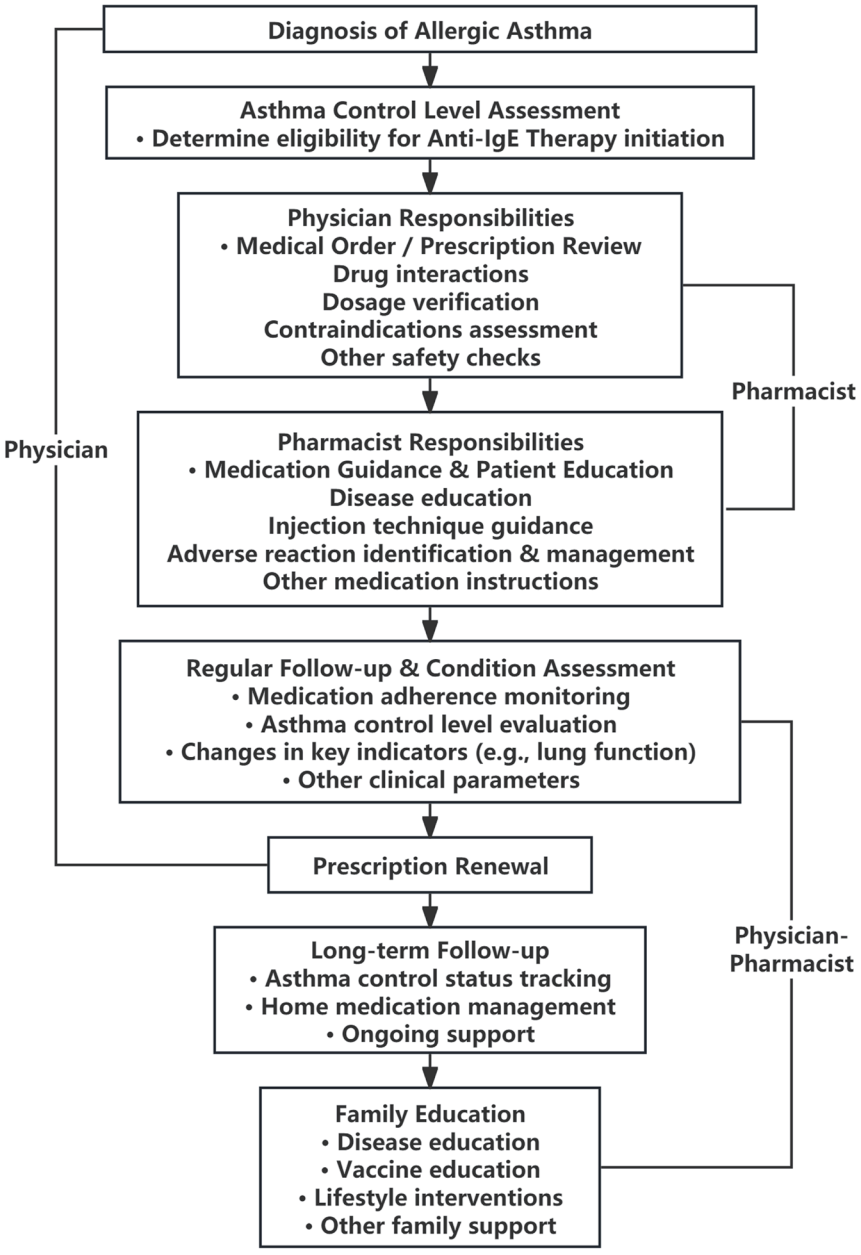

Fig. 1. Physician–pharmacist co-management pathway for omalizumab therapy.

pharmacist co-management of anti-IgE monoclonal antibody therapy in allergic asthma, grounded in the respective professional responsibilities of physicians and pharmacists.

Physicians are primarily responsible for disease diagnosis, evaluation of omalizumab indications, management of acute allergic reactions, and adjustment of treatment regimens. Pharmacists are responsible for prescription review, medication counseling, and monitoring of adverse drug reactions.

Through close collaboration, both parties jointly develop individualized treatment plans, conduct follow-up evaluations, deliver patient education, and coordinate hierarchical referrals, thereby ensuring the safety, efficacy, and continuity of anti-IgE therapy (Fig. 1).

Referring to the physician–pharmacist co-management framework described above, the Consensus introduces two clinical models to guide the implementation of collaborative care in the management of allergic asthma.

Physician–pharmacist joint clinic

In this model, physicians and pharmacists conduct outpatient consultations simultaneously. During the consultation, the physician evaluates the patient's condition and prescribes appropriate medications. The pharmacist reviews the prescription and provides comprehensive support, including:

- *Medication guidance,* covering proper administration, precautions, and potential adverse effects;

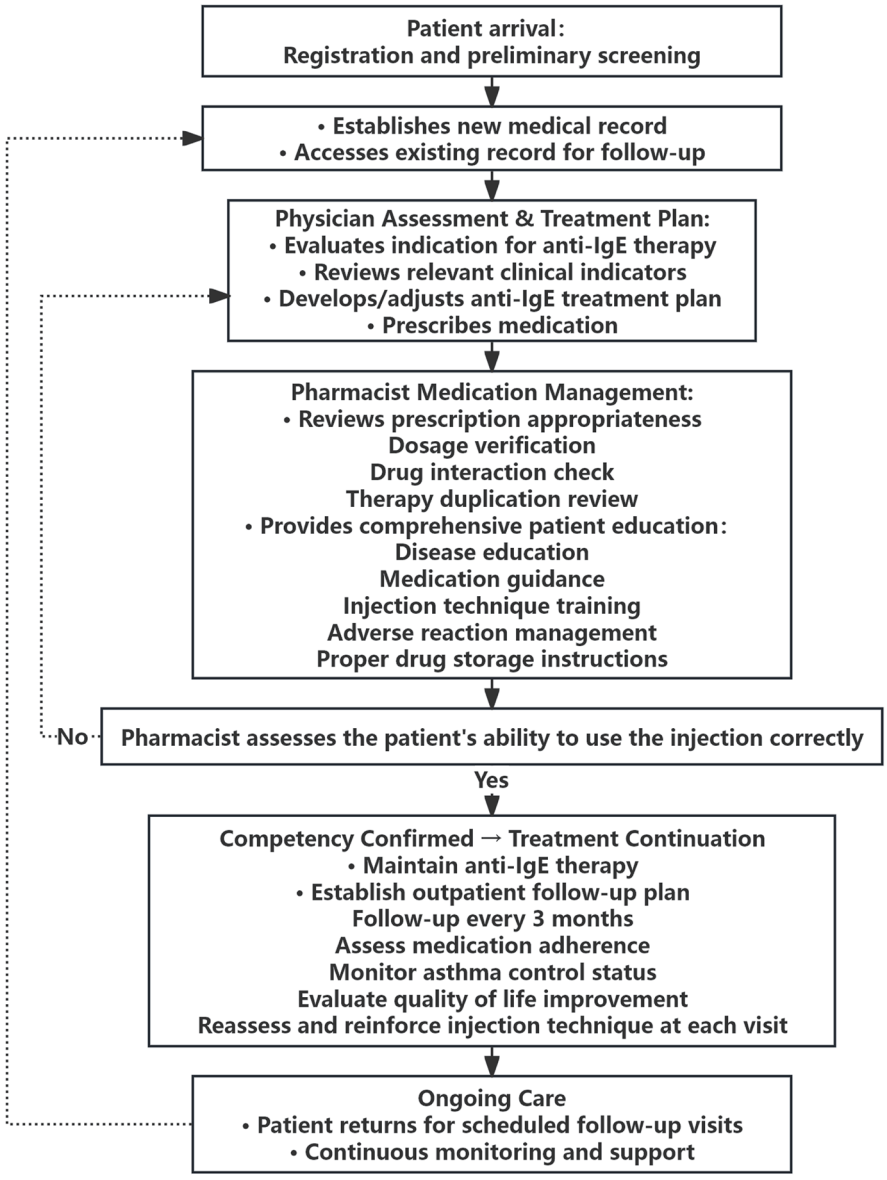

Fig. 2. Workflow of the physician–pharmacist joint clinic.

- *Patient education,* including disease knowledge, self-management strategies, and lifestyle counseling.

This model is straightforward to implement and facilitates real-time collaboration between physicians and pharmacists (Fig. 2).

Pharmacist independent clinic

In this model, physicians refer stable allergic asthma patients who have received omalizumab for at least four months to the pharmacist-led clinic. Pharmacists provide ongoing medication guidance and disease education. Patient status is monitored every three months using the Asthma Control Test (ACT) and pulmonary function tests.[1]

If acute exacerbations or other clinical changes occur, patients are promptly referred back to the physician. For patients who remain stable, pharmacists continue management for up to nine months before transferring them back to the physician for reassessment. Within this model, pharmacists can implement protocol-based prescriptions, allowing them to repeat the physician's prescription within a predefined timeframe according to the established protocol.[37]

The pharmacist independent clinic model empowers pharmacists with greater clinical responsibilities, reduces physician workload, and lowers patient visit costs. However, it requires higher pharmacist competency and effective integration within the collaborative healthcare framework (Fig. 3).

Work pathway for physician–pharmacist co-management

Establish patient record

For first-visit patients, a personal information file should be created to document detailed medical history, disease characteristics, and medication use.

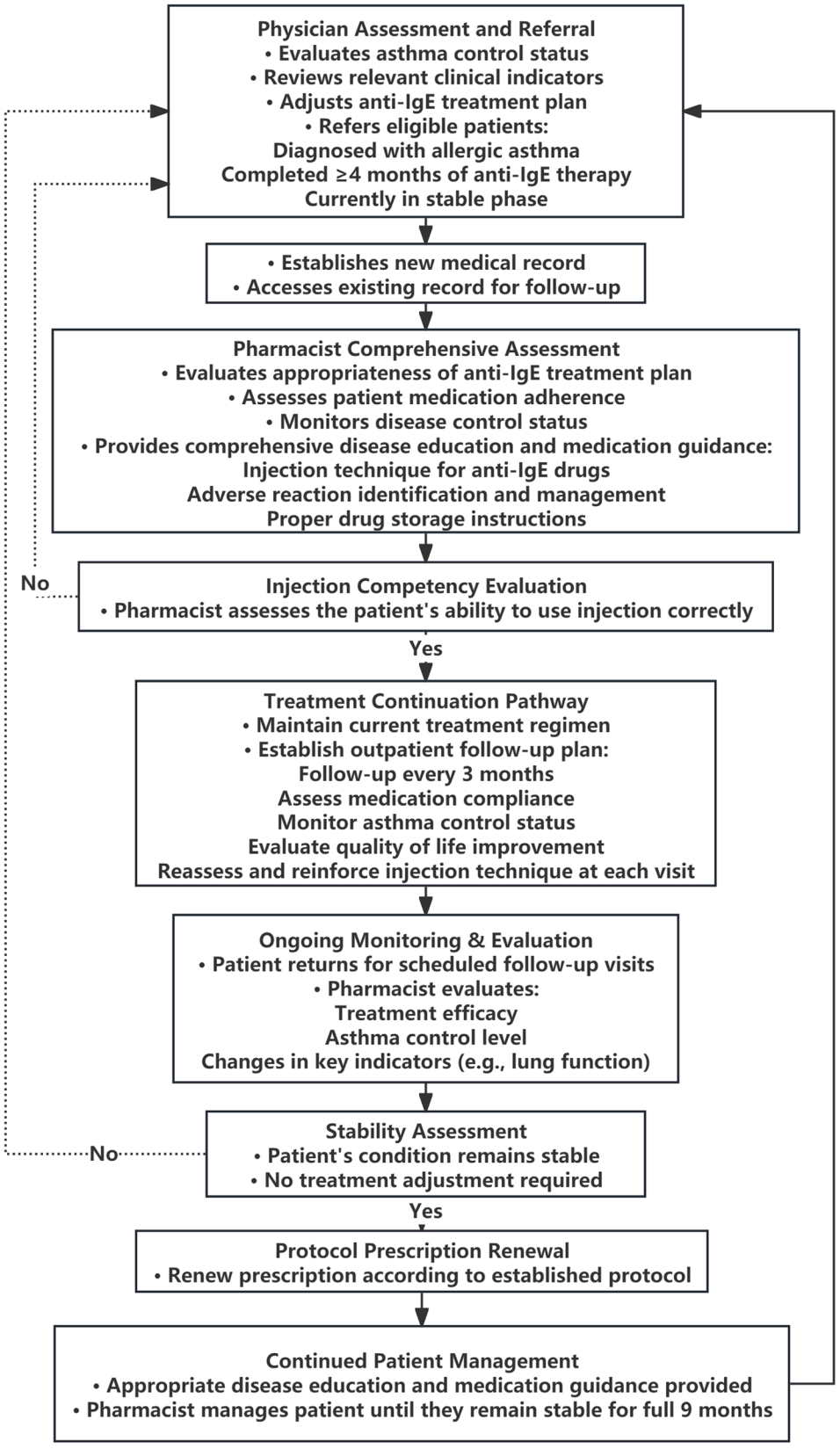

Fig. 3. Workflow of the pharmacist-led independent clinic.

Physician evaluation

Medication indication assessment

Confirm that the patient is aged ≥6 years, evaluate whether serum IgE levels fall within the therapeutic range, review previous standardized asthma therapies (e.g., ICS and LABA), and determine suitability for omalizumab therapy. Li *et al.*[18] reported that 4.79% of outpatient prescriptions for omalizumab were inappropriate due to incorrect indications.

Dosage evaluation

Determine the omalizumab injection dose based on body weight (20–150 kg) and serum IgE (30–1,500 $U \cdot mL^{-1}$). The recommended dose ranges from 75–600 mg per administration, administered every two or four weeks. Patients with body weight >150 kg or IgE >1,500 $U \cdot mL^{-1}$ should receive a maximum of 600 mg every two weeks, while those <20 kg or IgE <30 $U \cdot mL^{-1}$ may receive 0.016 $mg \cdot kg^{-1} \cdot U^{-1}$ every four weeks.[12,20] In cases where serum total IgE levels cannot be detected, allergic status can be confirmed via specific sIgE testing or skin prick tests. Under such circumstances, empirical dosing may be administered at 75–600 mg every two or four weeks,[1,38,39] based on clinical symptoms, to facilitate the assessment of rational pharmacological therapy.

Asthma control evaluation

Use the ACT to assess symptom frequency, severity, and acute exacerbations.

Clinical indicator evaluation

Assess EOS levels, FeNO, peak expiratory flow, and pulmonary function. Real-world data (PROSPERO study) indicate that 87% of patients with moderate-to-severe allergic asthma experienced a significant reduction in acute attacks after omalizumab treatment, with efficacy independent of baseline EOS and FeNO.[40] Other studies suggest higher efficacy when FeNO ≥ 19.5 ppb and EOS ≥ 260 μL^{-1}, highlighting the need for further research on the role of clinical indicators in guiding therapy.[41]

Consensus Recommendation 2: Omalizumab should be used with caution in patients with total IgE <30 $U \cdot mL^{-1}$ or >1,500 $U \cdot mL^{-1}$, or body weight <20 kg or >150 kg. *(II, A)*. Omalizumab should be used cautiously in patients who cannot undergo serum IgE testing but have positive sIgE or skin prick test results and relevant clinical symptoms. *(II, A)*. Before initiating omalizumab therapy, physicians should evaluate medication indications, dosage requirements, asthma control status, and relevant clinical indicators. *(II, B)*

Pharmaceutical guidance

Injection guidance

Recommended injection sites include the deltoid muscle, anterior thigh, or lower abdomen at least 5 cm from the umbilicus, avoiding areas of skin damage or induration. Lyophilized omalizumab powder should be reconstituted within 15–20 min after thawing and administered by healthcare professionals in facilities equipped for emergency care. Pre-filled syringes do not require reconstitution and can be injected subcutaneously at room temperature after removal from refrigeration. With adequate training, patients or caregivers may self-administer at home, though pediatric patients should be supervised by professionals.

Risk guidance

As a high-molecular-weight protein, omalizumab carries a risk of anaphylaxis (~0.2%). EAACI guidelines recommend monitoring for 60 min after the first three injections, as most reactions occur within 2 h, peaking within 15–30 min.[42] Severe reactions (e.g., anaphylactic shock, laryngeal edema, bronchospasm) require urgent hospital transfer (Fig. 4), whereas mild reactions (e.g., headache, injection-site redness, itching) may be managed symptomatically. Common pediatric symptoms such as fever, headache, or epigastric pain usually resolve spontaneously.[12,43–45]

Storage guidelines

Omalizumab should be refrigerated at 2–8 °C. Lyophilized powder must be used within 8 h after removal from refrigeration, while pre-filled syringes must be used within 4 h and cannot be re-refrigerated.

Consensus Recommendation 3: Patients should be observed in a medical facility for 60 min after the first three omalizumab injections. *(II, A)*. Before initiating omalizumab, pharmacists should provide guidance on drug administration, post-injection risks, and storage requirements. *(II, B)*

Long-term follow-up

Comprehensive treatment evaluation

Assess the efficacy of omalizumab using multiple indicators, including asthma control (C-ACT/ACT scores), medication adherence (MMAS-8 scores), quality of life (AQLQ scores), and pulmonary function measurements.

Drug interaction and adverse reaction screening

Evaluate potential drug interactions in patients with comorbidities. Studies indicate possible safety concerns when omalizumab is used concurrently with ICS, antihistamines, cyclosporine, methotrexate, or other medications. Physicians and pharmacists should collaboratively develop dose reduction or discontinuation protocols tailored to individual patient conditions (Table 2).[1,12,38] Pharmacists should also guide home-based treatment, instructing patients on the proper use of pre-filled injection devices, including injection techniques, dosage schedules, and treatment duration, while monitoring for and managing adverse reactions to ensure medication safety.

Treatment duration and dosage adjustments

Omalizumab therapy consists of two phases: an efficacy evaluation phase and a maintenance phase. During the evaluation phase, treatment continuation is assessed after 16 weeks of therapy based on overall asthma control:

- *Significant responders:* continue treatment;
- *Moderate or unclear responders:* reassess after 6–12 months;
- *Non-responders:* discontinue therapy.

Continuous treatment should last at least 12 months. For patients achieving good asthma control with medium-dose ICS + LABA, gradual dose reduction may be considered, either by decreasing the dose or extending dosing intervals. Initial reductions should not exceed 50%, and control should be maintained for at least six months before further adjustments. If asthma control dete-

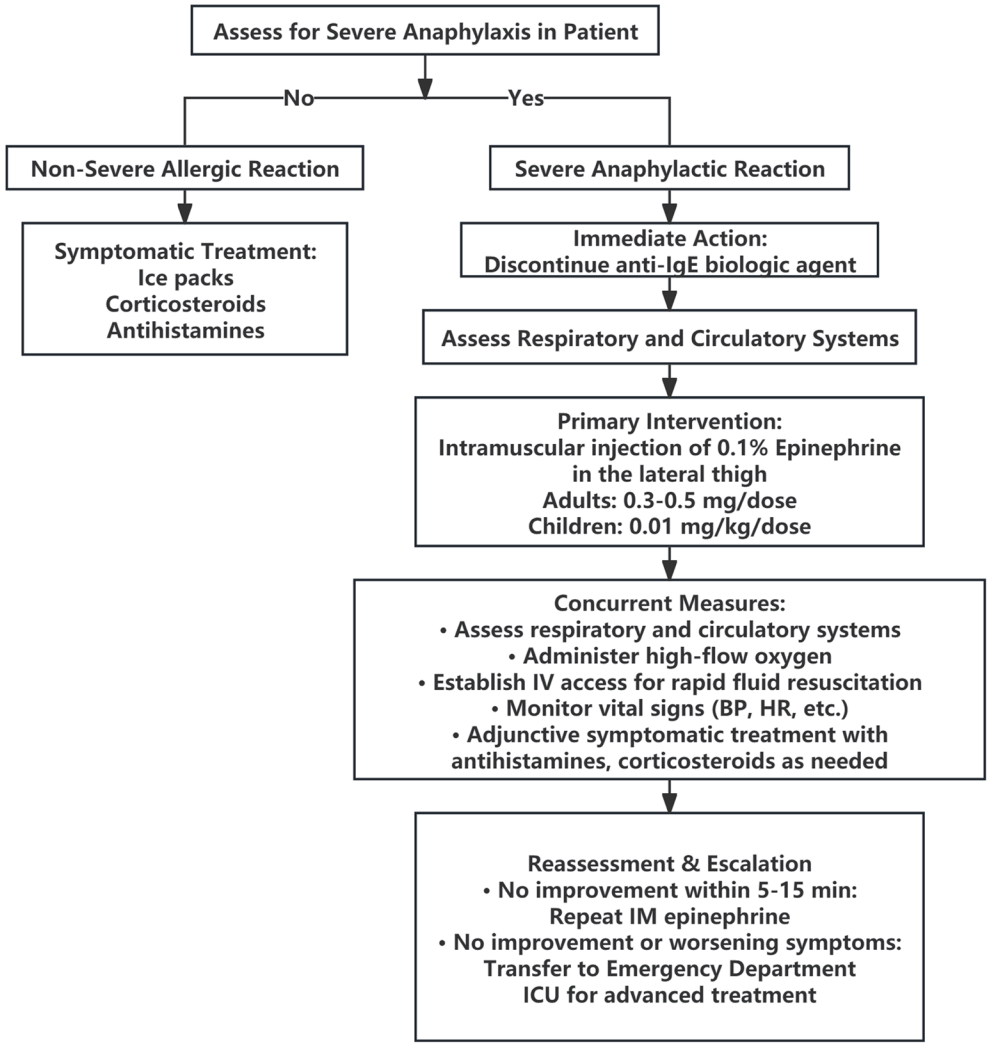

Fig. 4. Emergency management algorithm for severe allergic reactions to omalizumab.[44,45] BP, blood pressure; HR, heart rate; ICU, intensive care unit; IM, intramuscular; IgE, immunoglobulin E; IV, intravenous.

riorates, revert to the original dose or frequency (Fig. 5).[46]

Follow-up frequency adjustment

Based on clinical evaluations and symptom scores, follow-up schedules should be individualized. Long-term asthma patients are generally recommended to have quarterly follow-ups.[1] Patients with poor adherence, high exacerbation risk, multiple comorbidities, or polypharmacy may require more frequent follow-

Table 2. Adjustment recommendations for concomitant drug use during omalizumab therapy

Concomitant drug	Recommendation
ICS	Maintain according to disease status. For patients with a significant response to omalizumab and stable asthma control and lung function for ≥3 months, gradually reduce the dose by 25–50% to reach the lowest maintenance dose
Antihistamines	Use as needed based on disease condition. Gradually reduce or discontinue in patients with a significant response to omalizumab.
Immunosuppressants	Gradually reduce or discontinue dosage during omalizumab therapy, as clinically appropriate
Vaccines	Maintain at least a 2-week interval between omalizumab injection and vaccination. Urgent vaccinations (e.g., tetanus) may be administered immediately if necessary

ICS, inhaled corticosteroid.

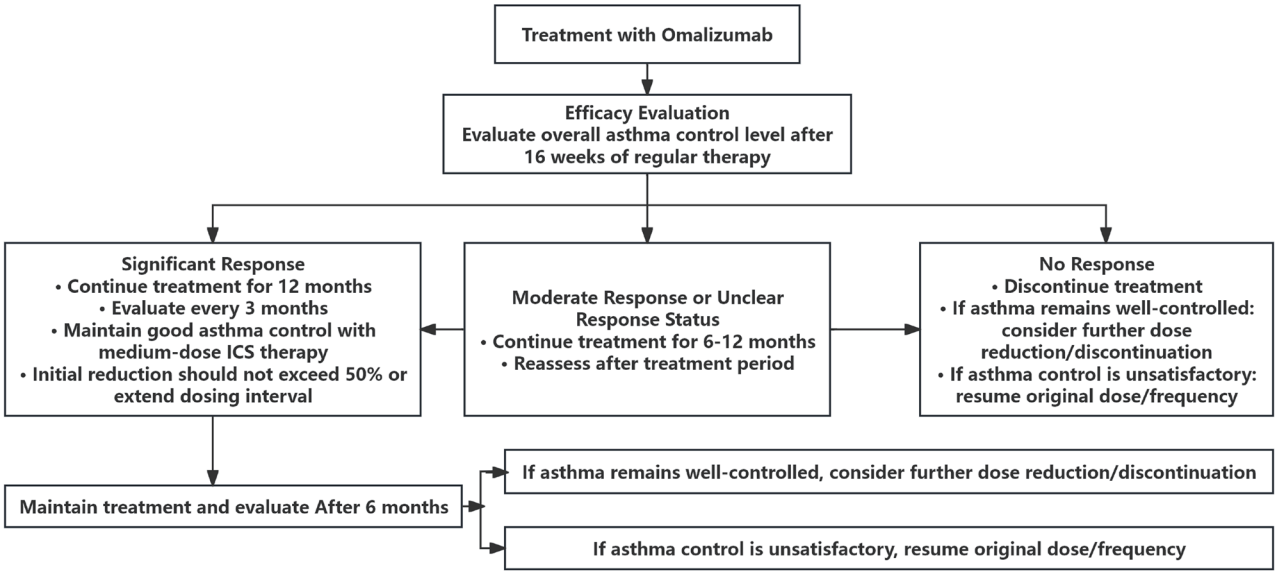

Fig. 5. Omalizumab treatment course and dose adjustment algorithm. ICS, inhaled corticosteroid.

up, whereas stable patients without treatment changes may have extended follow-up intervals. Acute exacerbations, rapid disease progression, or treatment intolerance should prompt referral to specialists for reassessment and modification of the treatment plan. Detailed follow-up procedures are outlined in Tables 3 and 4.[1,47]

Consensus Recommendation 4: During routine omalizumab therapy, asthma control and pulmonary function should be evaluated every three months. Patients demonstrating a response should continue treatment for at least 12 months. *(II, A)*. If adequate asthma control is achieved with medium-dose ICS + LABA, omalizumab dose reduction may be considered, with at least a six-month interval before the next dose adjustment assessment. *(II, B)*. During omalizumab therapy, pharmacists should monitor potential drug interactions between omalizumab and other concomitant medications. *(III, C)*

Family education

Patient education

Pharmacists and physicians should collaboratively employ the Information-Motivation-Behavior model to educate patients on allergic asthma, including disease knowledge, medication indications, proper usage and dosage, potential adverse reactions, and precautions, aiming to enhance disease awareness.[48] Treatment goals and individualized action plans should be established. Patients should be provided with an asthma diary to record daily medication use, symptom changes, and peak flow measurements to improve self-management.

Vaccination education

For patients undergoing routine vaccinations, a minimum two-week interval should be maintained between omalizumab injections and vaccinations, except in urgent cases such as tetanus immunization.[46]

Lifestyle education

Advise patients to avoid known allergenic foods and asthma-triggering irritants. Strenuous exercise should be avoided, whereas moderate exercise is encouraged to enhance immunity. Patients should minimize exposure to allergen-rich environments to reduce the risk of asthma exacerbations.

Additional considerations

As omalizumab may lower total IgE levels and potentially weaken immune defenses against parasitic or pathogenic infections, patients should inform physicians about potential infection risks prior to dental procedures or surgeries.

Consensus Recommendation 5: During omalizumab therapy, pharmacists should provide family education, including disease knowledge, vaccination guidance, and lifestyle counseling, to enhance patient self-management and reduce the risk of asthma exacerbations. *(II, B)*

Special populations

Pediatric patients

Omalizumab is primarily indicated for children aged ≥6 years. Adverse reactions are generally similar to those observed in adults, with no serious adverse events or medication discontinuations reported during long-term use. Limited data exist for children <6 years, and further studies are required to evaluate safety and efficacy.[1,49] For pediatric patients receiving long-term therapy, close monitoring of pulmonary function and adverse reactions is recommended. Comprehensive education should be provided to both patients and their caregivers to ensure adherence and safety.

Elderly patients

Elderly individuals often present with comorbidities such as cardiovascular disease, hepatic or renal insufficiency, and decreased immune function, necessitating careful monitoring of potential systemic immunomodulatory effects of anti-IgE therapy. When used concurrently with anticoagulants or immunosuppressants, the risks of bleeding and infection should be assessed. Although no

Table 3. Follow-up record form for patients with allergic asthma treated with omalizumab

Patient information	Details
Patient name	
Gender	
Age	
Clinical diagnosis	
Follow-up pharmacist	
Diagnosis date	
Start date of anti-IgE therapy	
Omalizumab dosage & administration	
Follow-up date	

Follow-up project	Follow-up content
Comprehensive treatment evaluation	
C-ACT/ACT score	☐ Full Control ☐ Partial Control ☐ No Control
MMAS-8 score	☐ Good Adherence ☐ Moderate Adherence ☐ Poor Adherence
AQLQ score	☐ Poor QoL ☐ Better QoL ☐ Good QoL
Relevant clinical indicators	Total IgE: _____ U/mL EOS: _____ μL^{-1} FeNO: _____ ppb Pulmonary Function: _____
Adverse drug reactions	Suspected Drug: _____ Clinical Symptoms: _____ Occurrence Time: _____ Management: _____
Omalizumab dose adjustment	☐ Maintain Current Dose ☐ Maintain Current Frequency ☐ Reduce Dose by 50% ☐ Reduce Frequency ☐ Increase Dose by 50% ☐ Increase Frequency ☐ Adjust Based on Changes in Body Weight/IgE Level
Follow-up adjustment	Asthma-related Risk Factors[1,47]: ☐ Family History ☐ Female Gender ☐ Recent Allergen Exposure ☐ Comorbidities (allergic rhinitis, urticaria, etc.) ☐ Inappropriate Use of Standard Asthma Medications (ICS, SABA) ☐ Decreased Pulmonary Function ☐ Elevated EOS ☐ Elevated FeNO ☐ Adverse Drug Reactions ☐ Respiratory Infections Risk Level: ☐ 1–2 Factors ☐ 3–5 Factors ☐ >5 Factors
Follow-up cycle	☐ Every 6 months ☐ Every 3 months ☐ Every month
Follow-up summary	Asthma Control Level: _____ Drug Adjustment Status: _____ Next Follow-up Date: _____

AQLQ, Asthma Quality of Life Questionnaire; C-ACT/ACT, Childhood Asthma Control Test/Asthma Control Test; EOS, eosinophils; FeNO, fractional exhaled nitric oxide; ICS, inhaled corticosteroid; IgE, immunoglobulin E; MMAS-8, 8-item Morisky Medication Adherence Scale; ppb, parts per billion; QoL, quality of life; SABA, short-acting β_2-agonist.

studies have specifically indicated the need for dose adjustment in the elderly, adjustments may be required if there are significant changes in body weight.[50,51]

Pregnant and lactating patients

Current evidence does not suggest a significant increase in pregnancy-related risks associated with omalizumab use. The necessity and potential risks of therapy should be carefully evaluated before initiation, and treatment is generally recommended during mid-pregnancy (14–28 weeks) to minimize fetal exposure.[52] For lactating patients, while studies indicate no direct or indirect adverse effects on breastfed infants, the potential for drug secretion into breast milk should be considered, and the infant's health should be closely monitored during maternal therapy.[53]

Hierarchical diagnosis and treatment model for physician–pharmacist co-management of anti-IgE monoclonal antibody therapy in allergic asthma

The hierarchical diagnosis and treatment system is a cornerstone of healthcare reform in China, designed to ensure primary care as the first point of contact, enable two-way referrals, differentiate treatment strategies for acute and chronic conditions, and optimize the allocation of medical resources across different levels of healthcare.

Research by Xiang *et al*.[54] demonstrated that early identification of acute asthma attacks, dynamic monitoring of drug therapy and adverse reaction risks, and the rational application of add-on omalizumab therapy for IgE-mediated allergic asthma should be integrated into primary care initiation and two-way referral pathways. This ensures that patients receive continuous treatment and comprehensive follow-up management through coordinated resources across healthcare levels.[54] Liu *et al*.[55] further confirmed that the hierarchical system significantly improves medication adherence in asthma patients and achieves optimal disease control.

It is therefore recommended that patients initially suspected of allergic asthma at primary healthcare institutions should be referred to higher-level hospitals for definitive diagnosis. Physicians and pharmacists at these higher-level hospitals should evaluate the feasibility of anti-IgE therapy. Once the patient achieves stable disease control, they may be referred back to primary healthcare institutions for follow-up, with comprehensive reassessment

Table 4. Follow-up pathway for patients with allergic asthma treated with omalizumab

Timeline	Pharmacist's main tasks	Patient's main tasks	Medication adjustment
Baseline	Record vital signs (BP, SpO_2, respiration, heart rate); Complete C-ACT/ACT, MMAS-8, AQLQ assessments; Review current medication regimen; Educate on anti-IgE antibody use and adverse reaction management	Cooperate with vital signs monitoring; Complete pulmonary function, FeNO, IgE, and blood tests; Complete questionnaires; Participate in medication education	No Change/ Yes (Specify Reason)
Follow-up Day 1 (Pharmacy Clinic)	Assess proper use of anti-IgE antibodies; Provide ongoing medication guidance; Inquire about adverse reactions; Manage potential drug reactions or interactions	Report medication use experience; Provide updates on health status; Communicate any concerns	No Change/ Yes (Specify Reason)
Follow-up Day 2–29 (At Home)	Monitor vital signs; Repeat standardized assessments; Verify proper injection technique; Provide continued education; Refer to physician if needed	Participate in monitoring and testing; Complete follow-up evaluations; Engage in ongoing education	No Change/ Yes (Specify Reason)
Follow-up Week 4/8/12/16 (Pharmacy Clinic)	Continue comprehensive monitoring and assessment; Maintain education and support	Continue active participation in care	No Change/ Yes (Specify Reason)
Follow-up Month 6/9/12 (Pharmacy Clinic)	Conduct final assessments; Document treatment outcomes; Provide personalized recommendations; Update treatment plans as needed; Facilitate physician follow-up	Complete final evaluations; Provide treatment feedback; Update health records; Attend physician consultation	No Change/ Yes (Specify Reason)
Follow-up After 4 Months/1 Year (Physician Clinic)	Record vital signs (BP, SpO_2, respiration, heart rate); Complete C-ACT/ACT, MMAS-8, AQLQ assessments; Review current medication regimen; Educate on anti-IgE antibody use and adverse reaction management	Cooperate with vital signs monitoring; Complete pulmonary function, FeNO, IgE, and blood tests; Complete questionnaires; Participate in medication education	No Change/ Yes (Specify Reason)

AQLQ, Asthma Quality of Life Questionnaire; C-ACT/ACT, Childhood Asthma Control Test/Asthma Control Test; FeNO, fractional exhaled nitric oxide; IgE, immunoglobulin E; MMAS-8, 8-item Morisky Medication Adherence Scale.

and treatment plan adjustments at higher-level hospitals every three months. If asthma control deteriorates after referral, patients should return to higher-level hospitals for reassessment and modification of the treatment plan (Fig. 6).

Roles of pharmacists at different healthcare levels:

- *Primary hospitals:* Pharmacists assist higher-level hospital pharmacists in long-term medication management and follow-up. Patients with rapid disease progression, acute exacerbations, adverse reactions, or other complex conditions should be referred to specialist physicians within the institution or to higher-level hospitals.
- *Secondary hospitals:* Pharmacists support specialist physicians in evaluating patient indications for omalizumab therapy, developing individualized treatment and long-term medication management plans, and providing remote pharmaceutical guidance and training to primary hospitals. Patients showing insufficient

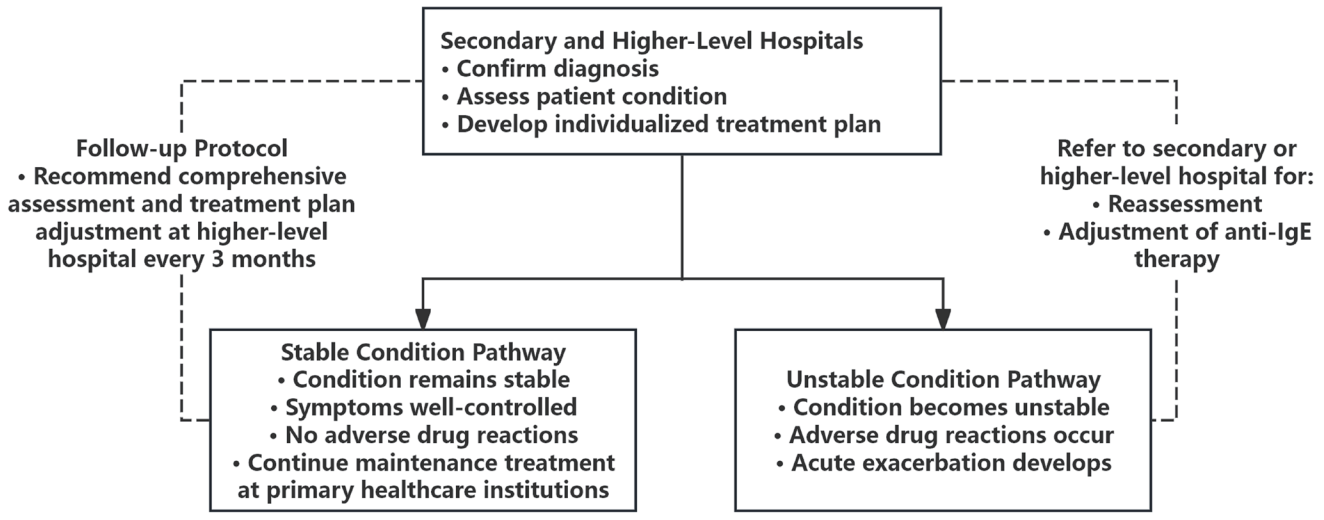

Fig. 6. Hierarchical diagnosis and treatment model.

improvement after comprehensive treatment or experiencing unmanageable conditions should be referred to tertiary hospitals. Patients with stable disease and no adverse reactions may be referred back to primary hospitals for follow-up under physician supervision.

- *Tertiary hospitals:* Pharmacists provide pharmaceutical monitoring and individualized medication adjustments for high-risk patients, such as those with acute exacerbations or adverse reactions. Patients achieving stable disease control may be referred to secondary hospitals for inpatient observation or long-term follow-up. Tertiary hospitals are also responsible for training pharmacists at secondary and primary hospitals on individualized step-down medication strategies and monitoring key points.

Consensus Recommendation 6: Implementing the hierarchical diagnosis and treatment system is recommended. Patients initially suspected of allergic asthma at primary healthcare institutions should be referred to higher-level hospitals for diagnosis, and two-way referral and whole-process management should be carried out according to disease needs. *(III, C)*

Training and assessment

Pharmacists possess comprehensive pharmaceutical expertise, enabling them to understand the mechanism of action, indications, adverse reactions, and drug interactions of omalizumab, thereby assisting physicians in formulating individualized treatment plans. However, variations in educational background often result in limited knowledge of clinical diagnosis and treatment for allergic asthma, which can hinder the implementation of physician–pharmacist co-management. Apikoglu *et al*.[56] demonstrated that continuous professional training enables pharmacists to enhance their pharmaceutical service capabilities. Domestic studies also indicate that primary care pharmacists who received structured training provided pharmaceutical services 4.09 times more frequently than untrained counterparts, significantly improving patient medication adherence and disease outcomes.[57,58]

Based on these findings, this Consensus provides systematic training for pharmacists participating in the co-management of omalizumab therapy for allergic asthma, drawing on domestic and international best practices.[31,35] Pharmacists who successfully complete the training and pass assessments are required to sign physician–pharmacist co-management agreements with physicians, ensuring high-quality medication therapy management services for patients.

Training objectives

Trained pharmacists should complete systematic training, become familiar with the theoretical knowledge of allergic asthma diagnosis and treatment, master omalizumab treatment principles, identify and manage adverse drug reactions and interactions, and implement health education and medication therapy management for patients.[59]

Training content

Pharmacists should strengthen knowledge and skills in the following domains to effectively manage omalizumab therapy for allergic asthma:

Clinical diagnosis and treatment knowledge of allergic asthma

Recognize symptoms, signs, and diagnostic criteria of allergic asthma.

Interpret biomarkers, allergen screening, pulmonary function, and imaging results.

Understand clinical treatment pathways for allergic asthma.

Principles of omalizumab therapy

Administration methods and precautions for omalizumab.

Identification and management of omalizumab-related adverse reactions.

Implementation of medication therapy management for omalizumab.

Polypharmacy principles in allergic asthma

Rational use of medications for allergic asthma.

Rational use of drugs for comorbidities or complications.

Evaluate current medications for benefits and risks relative to disease treatment.[60]

Follow-up management skills

Assess treatment status using asthma control, medication adherence, and quality-of-life scales.

Identify acute exacerbation risk factors and implement referral protocols.

Detect and manage adverse drug reactions and drug interactions.

Apply follow-up precautions for ongoing drug therapy.

Patient education skills

Implement the Information-Motivation-Behavior health education model.

Provide medication guidance and consultation services.

Educate patients on emergency treatment for acute asthma attacks.

Monitor and document patient medication use.

Training assessment

Upon completion of systematic training, pharmacists should undergo assessment of theoretical knowledge and practical skills to ensure competency in physician–pharmacist co-management of allergic asthma with omalizumab therapy. Only those who pass the assessment can provide high-quality pharmaceutical services for patients.

Consensus Recommendation 7: Pharmacists must undergo systematic training and sign physician–pharmacist co-management agreements after passing assessments before engaging in co-management activities related to omalizumab therapy (III, C).

Multiple benefits and prospects of the physician–pharmacist co-management model and the standardized application of anti-IgE monoclonal antibody treatment for allergic asthma

Multiple benefits

Pharmacists fully leverage their professional expertise to participate in the entire treatment process, assessment, and follow-up of allergic asthma, without involvement in diagnostic evaluations. By assisting physicians in managing omalizumab therapy, pharmacists can help optimize treatment plans, reduce diagnostic time costs, support nurses in medication monitoring, and allow health-

care professionals to focus on their core duties. This collaborative approach improves the overall quality and efficiency of medical services, enhances patient satisfaction, and strengthens institutional competitiveness.[33,61,62]

For patients, physician–pharmacist co-management enhances self-management capabilities, improves medication adherence, efficacy, and safety, reduces the frequency and severity of acute attacks, lowers rehospitalization and emergency visit rates, and enhances long-term quality of life.[63] Real-world studies report that the incremental cost-effectiveness ratio for foreign asthma patients receiving omalizumab was £122,675.57 per quality-adjusted life year, and ¥107,723.05 per quality-adjusted life year for Chinese patients, both below the threshold of three times GDP per capita, indicating cost-effectiveness.[64,65] Further studies show that pharmaceutical services can achieve a median cost-effectiveness ratio of 5.05 (3.08–11.28), supporting the economic advantages of co-management.[66,67]

Thus, implementing physician–pharmacist co-management can standardize medical and medication behaviors, reduce treatment costs, alleviate the social medical burden, promote rational allocation of limited medical resources, and achieve benefits for multiple stakeholders.[68,69]

Prospects

Physician–pharmacist co-management is increasingly recognized as a major approach for chronic disease management domestically and internationally, with growing application in respiratory chronic disease care in China. The model is expected to evolve toward intelligent, precise, and cost-effective management. Pharmacists can integrate multidimensional patient data, develop risk prediction models using machine learning algorithms (e.g., random forests, neural networks), and utilize AI-based clinical decision support systems such as MedGPT to deliver cost-effective interventions and optimize clinical outcomes.[70]

By analyzing correlations between patient genetic data and drug responses, pharmacists can assist physicians in tailoring individualized treatment plans and prevention strategies, reducing unnecessary interventions and optimizing resource allocation.[71] Through cost-effectiveness analysis, pharmacists support physicians in selecting appropriate therapies, optimizing resource utilization, controlling medical costs, and promoting payment reform models such as Diagnosis-Related Groups and Diagnosis-Intervention Packet, thereby incentivizing healthcare institutions and professionals to actively implement co-management services.

Limitations of the consensus

While this Consensus provides a structured framework for physician–pharmacist co-management, it is limited by the inherent nature of the Delphi method, which relies on expert opinion. Furthermore, the clinical and economic benefits of this model require long-term validation through multicenter prospective studies in diverse clinical settings.

Conclusions

In conclusion, this Consensus clarifies the respective responsibilities and collaborative pathways of physicians and pharmacists in omalizumab therapy for allergic asthma. It establishes a comprehensive management system encompassing screening and assessment, therapeutic decision-making, efficacy monitoring, long-term follow-up, and tiered referral, providing a concrete and actionable framework for clinical physician–pharmacist co-management practice. While some recommendations are based on expert experience and low-to-moderate quality evidence, and the effectiveness and generalizability of this model require further validation across diverse clinical settings, this Consensus lays a foundational framework for integrating medical resources, optimizing service workflows, and enhancing treatment standardization and patient outcomes. These recommendations should be applied judiciously in clinical practice, adapted to local contexts, and continuously refined to promote sustainable improvements in the quality of allergic asthma management and healthcare delivery.

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Conflict of interest

All authors declare no conflict of interest.

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