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Biologic Therapies in Chronic Rhinosinusitis with Nasal Polyposis: Current Evidence and Future Perspectives

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ABSTRACT

Chronic rhinosinusitis with nasal polyposis (CRSwNP) is a common type 2 inflammatory disease affecting approximately 1–4% of the population and is characterized by persistent nasal obstruction, olfactory dysfunction, facial pain, and substantial impairment in quality of life. Although standard therapies such as intranasal corticosteroids and endoscopic sinus surgery remain the mainstay of treatment, a significant proportion of patients experience recurrent or inadequately controlled disease. Improved understanding of the immunopathogenesis of CRSwNP has highlighted the central role of type 2 inflammation, driven by cytokines including interleukin-4, interleukin-5, interleukin-13, and immunoglobulin E, thereby enabling the development of targeted biologic therapies. Biologic agents such as dupilumab, mepolizumab, benralizumab, and omalizumab have demonstrated consistent efficacy in phase III randomized controlled trials and real-world studies, leading to significant reductions in nasal polyp burden, improvements in Sino-Nasal Outcome Test (SNOT-22) scores, restoration of olfactory function, and decreased need for systemic corticosteroids and revision surgery. Patient selection is increasingly guided by clinical phenotype and biomarkers, including blood eosinophil counts, total serum IgE levels, and the presence of comorbid asthma or aspirin-exacerbated respiratory disease. Emerging evidence supports the integration of biologic therapy with surgical management in refractory cases, while ongoing trials targeting upstream mediators such as interleukin-33 and thymic stromal lymphopoietin may further expand therapeutic options. Overall, biologic therapies represent a paradigm shift in the management of severe CRSwNP, paving the way toward precision-based, individualized treatment strategies.

Keywords

Biologics, Chronic Rhinosinusitis, Nasal Polyposis, Dupilumab, Precision Medicine

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INTRODUCTION

Sepsis is a life-threatening clinical syndrome arising from a dysregulated host immune response to infection that leads to acute organ dysfunction [1]. It represents a continuum of disease severity, ranging from sepsis to septic shock, the latter of which is characterized by profound circulatory, cellular, and metabolic abnormalities associated with a substantially increased risk of death [2]. Despite advances in critical care, sepsis remains a significant global health burden. Reported mortality rates vary according to patient characteristics, comorbidities, and healthcare resources; however, contemporary estimates suggest an in-hospital mortality rate of approximately 10–20% for sepsis overall, increasing to 40% or more among patients with septic shock [3,4].

This review focuses on the evaluation and management of sepsis and septic shock in adults, largely reflecting recommendations from established international guidelines and consensus statements [3–6]. The discussion primarily adopts the definitions proposed by the Society of Critical Care Medicine (SCCM) and the

European Society of Intensive Care Medicine (ESICM), collectively known as the Sepsis-3 criteria [1]. These definitions emphasize organ dysfunction, operationalized by an increase in the Sequential Organ Failure Assessment (SOFA) score, as a defining feature of sepsis. Nevertheless, the Sepsis-3 framework has not achieved universal acceptance in all clinical and regulatory settings.

Notably, the Centers for Medicare and Medicaid Services (CMS) in the United States continue to endorse earlier sepsis definitions that incorporate systemic inflammatory response syndrome (SIRS) criteria to classify sepsis, severe sepsis, and septic shock for quality reporting and reimbursement purposes [6]. In addition, the Infectious Diseases Society of America (IDSA) has cautioned that while strict application of the Sepsis-3 definitions is critical and potentially lifesaving in patients with septic shock, their broader application in less severe infections may inadvertently promote excessive use of broad-spectrum antimicrobial therapy [7]. Detailed discussions of sepsis definitions, epidemiology, diagnosis, pathophysiology, and emerging or investigational pharmacologic therapies are beyond the scope of this review and have been addressed comprehensively elsewhere [8–10]. Similarly, the clinical features, diagnostic evaluation, and management of fever in patients with impaired or absent splenic function have been discussed in a separate dedicated review [11].

Current FDA-Approved Biologics for Chronic Rhinosinusitis with Nasal Polyps

As of 2025, three biologic agents have received approval from the United States Food and Drug Administration (FDA) for the treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) dupilumab, omalizumab, and mepolizumab [11]. These monoclonal antibodies selectively target key components of the type 2 inflammatory pathway, which underlies the majority of CRSwNP cases. Evidence from pivotal randomized controlled trials and accumulating real-world studies consistently demonstrates that these therapies effectively reduce nasal polyp burden, improve sinonasal symptoms—including nasal obstruction, facial pressure, and olfactory dysfunction—and enhance overall disease control in patients with refractory or inadequately controlled disease [12,13].

Table 1. Pivotal Phase 3 Randomized Controlled Trials of FDA-Approved Biologics for Chronic Rhinosinusitis with Nasal Polyps

Biologic	Key Phase 3 Trials	Primary Endpoints	Selected Secondary Endpoints	Key Clinical Outcomes
Dupilumab	LIBERTY NP SINUS-24 LIBERTY NP SINUS-52	Endoscopic nasal polyp score (NPS) Daily nasal congestion score	Lund–Mackay CT score SNOT-22 total score UPSIT olfactory test Need for systemic corticosteroids or surgery	Significant and sustained reductions in NPS and nasal congestion at 24 and 52 weeks; marked improvement in olfaction and health-related quality of life; reduced need for rescue corticosteroids and revision surgery
Omalizumab	POLYP 1 POLYP 2	Endoscopic nasal polyp score (NPS) Daily nasal congestion score	SNOT-22 total score UPSIT olfactory test	Clinically meaningful reductions in NPS and congestion at 24 weeks; consistent improvement in sinonasal symptoms and quality-of-life indices
Mepolizumab	SYNAPSE	Endoscopic nasal polyp score (NPS) Nasal congestion VAS score	Lund–Mackay CT score SNOT-22 total score Need for systemic corticosteroids or surgery	Significant reductions in polyp burden and nasal obstruction at 52 weeks; prolonged time to surgery; greatest benefit observed in patients with elevated baseline eosinophil counts

Dupilumab is a fully human monoclonal antibody that inhibits signaling through the interleukin-4 receptor alpha (IL-4Rα) subunit, thereby blocking the biological effects of both IL-4 and IL-13 [14]. Initially approved in 2017 for moderate-to-severe atopic dermatitis, dupilumab became the first biologic agent approved for CRSwNP in 2019 following robust results from the phase III LIBERTY NP SINUS-24 and SINUS-52 trials [15,16].

Table 2. FDA-Approved Indications and Safety Profiles of Biologic Therapies Used in CRSwNP

Biologic	Relevant FDA-Approved Indications	Common Adverse Events	Serious or Notable Adverse Events
Dupilumab	Atopic dermatitis; asthma; CRSwNP; eosinophilic esophagitis; chronic spontaneous urticaria; COPD	Injection-site reactions; conjunctivitis; transient eosinophilia	Hypersensitivity reactions; rare cases of clinically significant eosinophilia
Mepolizumab	Severe eosinophilic asthma; CRSwNP; eosinophilic granulomatosis with polyangiitis; hypereosinophilic syndrome	Injection-site reactions; headache; fatigue	Herpes zoster reactivation; hypersensitivity reactions
Omalizumab	Moderate-to-severe persistent asthma; CRSwNP; chronic spontaneous urticaria; IgE-mediated food allergy	Injection-site reactions; headache; upper respiratory symptoms	Anaphylaxis (boxed warning); serum sickness-like reactions

These studies demonstrated statistically significant and clinically meaningful reductions in endoscopic nasal polyp score (NPS), improvements in nasal congestion severity, and substantial gains in sinonasal-related quality of life compared with placebo, alongside a reduced need for systemic corticosteroids and revision sinus surgery [15–17]. Omalizumab, an anti-IgE monoclonal antibody that binds circulating free IgE and prevents its interaction with the high-affinity FcεRI receptor on mast cells and basophils, was originally approved in 2003 for moderate-to-severe persistent allergic asthma [18]. In 2020, omalizumab received FDA approval for CRSwNP based on favorable outcomes from the phase III POLYP 1 and POLYP 2 trials [19,20]. In these studies, omalizumab significantly reduced nasal polyp size and nasal congestion scores while producing clinically meaningful improvements in patient-reported symptom burden and quality-of-life measures when added to standard intranasal corticosteroid therapy [19–21].

Mepolizumab, a humanized monoclonal antibody targeting interleukin-5 (IL-5), represents the most recent FDA-approved biologic for CRSwNP, having gained approval in 2021 [22]. Data from the phase III SYNAPSE trial demonstrated that mepolizumab significantly reduced nasal polyp burden, alleviated nasal obstruction, and prolonged the time to requirement for revision sinus surgery [23]. The therapeutic benefit was particularly pronounced among patients with elevated baseline eosinophil counts, underscoring the relevance of eosinophilic inflammation as a driver of disease severity and treatment response [23,24].

Type 2 Inflammatory Cascade in CRSwNP

Damage to the sinonasal epithelial barrier initiates the release of epithelial-derived alarmins, including thymic stromal lymphopoietin (TSLP),

Table 3. Selected Completed and Ongoing Clinical Trials Targeting Upstream Inflammatory Pathways in CRSwNP

Target Pathway	Representative Biologic	Trial Phase	Study Population	Primary Endpoint
IL-4 receptor α	TQH2722	Phase II	CRSwNP ± CRSsNP	Change in NPS and/or Lund–Mackay score
TSLP	Tezepelumab	Phase III (Completed)	CRSwNP	Change in NPS and nasal congestion at 52 weeks
TSLP receptor	Verekitug	Phase II	CRSwNP	Change in NPS at 24 weeks
TSLP	CM-326	Phase Ib/IIa	CRSwNP	Safety and change in NPS
TSLP	SHR-1905	Phase II	CRSwNP	Change in NPS at 24 weeks
TSLP	TQC2731 (with INCS)	Phase II	CRSwNP	Change in NPS at 24 weeks

interleukin-25 (IL-25), and interleukin-33 (IL-33) [25]. These upstream cytokines activate group 2 innate lymphoid cells (ILC2s) and T helper 2 (Th2) lymphocytes, leading to the secretion of the canonical type 2 cytokines IL-4, IL-5, and IL-13 [26]. Collectively, these mediators drive B-cell class switching with subsequent IgE production, recruitment and activation of eosinophils, goblet cell hyperplasia, and excessive mucus secretion [27]. Sustained activation of these pathways promotes tissue remodeling, extracellular matrix deposition, and ultimately the formation and persistence of nasal polyps, particularly in patients with concomitant allergic sensitization (Figure 1) [28].

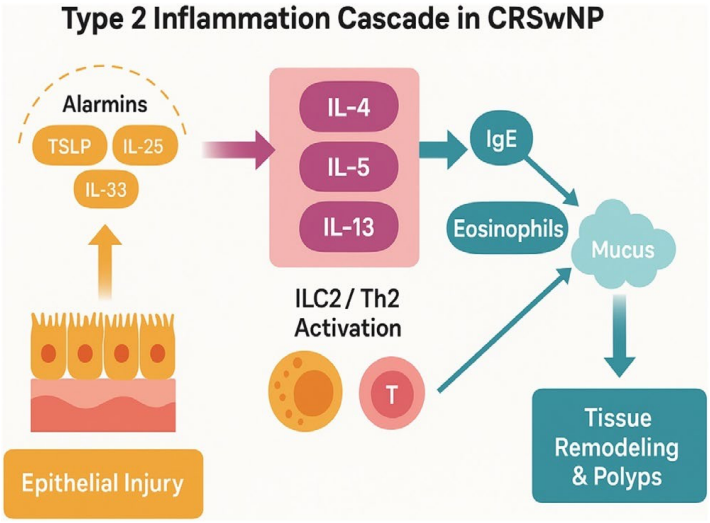

Figure 1 | Type 2 Inflammation Cascade in CRSwNP

Candidates for Biologic Therapy

Current clinical guidelines, including the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2020) and subsequent international expert consensus statements, recommend consideration of biologic therapy for patients with CRSwNP who exhibit objective evidence of type 2 inflammation and who remain symptomatic despite optimized conventional medical therapy and, when appropriate, prior endoscopic sinus surgery [29,30].

Eligible patients typically present with refractory disease characterized by persistent nasal obstruction, substantial polyp burden, impaired olfaction, or recurrent polyp regrowth following surgery, supported by biomarkers of type 2 inflammation such as elevated blood or tissue eosinophils, increased total serum IgE, or dominant type 2 cytokine signatures [30,31]. Comprehensive evaluation by an otolaryngologist is essential prior to biologic initiation to confirm the endoscopic presence and severity of nasal polyps and to exclude alternative pathologies that may mimic polyposis, including benign or malignant sinonasal tumors or inverted papilloma [32]. Reports of misdiagnosis in the absence of specialist assessment further highlight the importance of expert confirmation to ensure appropriate patient selection [33].

Comparative Outcomes of Biologic Therapy and Endoscopic Sinus Surgery

Endoscopic sinus surgery (ESS) has long been the cornerstone treatment for patients with CRSwNP who fail maximal medical therapy [34]. Comparative studies evaluating ESS versus biologic therapy suggest that surgery produces more rapid and pronounced early reductions in nasal polyp burden. Dharmarajan et al. reported greater early improvements in polyp size following ESS compared with biologics [35], while a multicenter cohort study by Miglani and colleagues demonstrated that ESS yielded SNOT-22 improvements comparable to dupilumab and superior to omalizumab at 24 and 52 weeks, alongside significantly greater reductions in endoscopic polyp scores [36].

Systematic reviews and meta-analyses indicate that although ESS provides superior short-term polyp reduction, longer-term outcomes may converge. At one year, dupilumab has been associated with comparable

polyp control and superior improvement in olfactory function compared with surgery [37]. Health economic analyses further suggest that both approaches yield meaningful gains in quality-adjusted life years (QALYs), with mixed findings regarding relative cost-effectiveness across healthcare systems [38,39].

Combination and Sequential Strategies

Growing evidence suggests that biologic therapy and ESS should not be viewed as mutually exclusive but rather as complementary modalities [40]. Perioperative or postoperative biologic administration has been associated with reduced polyp recurrence, enhanced olfactory recovery, and more durable symptom control compared with surgery alone [41,42]. Early observational studies indicate potential synergistic effects when biologics are used as adjuvant therapy, although optimal timing, duration, and patient selection criteria remain to be clearly defined [43]. Large, prospective randomized trials are needed to establish evidence-based recommendations for integrated treatment strategies.

Emerging Therapies and Future Directions

Despite substantial progress, important unmet needs persist in CRSwNP management. Head-to-head randomized trials directly comparing currently approved biologics remain limited, and predictive biomarkers capable of guiding individualized biologic selection are insufficiently validated for routine clinical use [44]. Emerging agents targeting upstream mediators, including TSLP and IL-33, as well as long-acting IL-5 inhibitors such as depemokimab, represent promising future therapeutic avenues [45–47]. In parallel, expanding research into non–type 2 inflammatory endotypes is essential, as these patients remain poorly responsive to existing biologic options [48].

CONCLUSION

Effective management of suspected sepsis and septic shock depends on early recognition and rapid, coordinated interventions. Prompt diagnostic evaluation, including serum lactate assessment, timely microbiologic sampling prior to antibiotic administration, and early source identification, combined with immediate fluid resuscitation using 30 mL/kg crystalloid and early initiation of appropriate broad-spectrum antimicrobials, remains fundamental to improving outcomes. While early goal-directed therapy demonstrated benefits in initial studies, subsequent multicenter trials have shown that high-quality, individualized usual care achieves comparable outcomes in well-resourced settings. Procalcitonin-guided antibiotic stewardship is an effective strategy for safely reducing antimicrobial exposure without compromising survival. Ultimately, timely and individualized resuscitation is critical for reducing morbidity and mortality in patients with sepsis and septic shock.

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