Xolair® (*omalizumab*)

Clinical summary

Disease characteristics and drug therapy

- **Moderate-to-severe persistent allergic asthma** – a chronic inflammatory airway disease characterized by variable airflow obstruction, bronchial hyperresponsiveness, and airway remodeling. The allergic phenotype reflects IgE-mediated sensitization to a perennial aeroallergen together with underlying type 2 (eosinophilic) airway inflammation; severe asthma — disease that remains uncontrolled despite high-dose inhaled corticosteroid (ICS) therapy plus a second controller, or that requires near-continuous oral corticosteroids — represents a minority of the overall asthma population.[1]
    - **Adults and adolescents (12 years of age and older):**
        - Standard care follows a stepwise, severity-based approach beginning with ICS-based controller therapy, with or without a long-acting beta-agonist (LABA); current GINA guidance suggests escalation to biologic add-on therapy for patients with severe allergic asthma that remains uncontrolled at treatment step 5 despite optimized ICS/LABA.[2]
        - Xolair is FDA-approved as add-on maintenance therapy for adults and adolescents 12 years of age and older with moderate-to-severe persistent asthma, a positive skin test or in vitro reactivity to a perennial aeroallergen, and symptoms inadequately controlled with inhaled corticosteroids; dosing is individualized by pretreatment serum total IgE level and body weight.[3]
        - Selection among the biologic classes now available for this population (anti-IgE, anti-IL-5/5R, anti-IL-4Rα, and anti-TSLP agents) is guided by clinical phenotype — including allergic sensitization, blood eosinophil count, and exhaled nitric oxide — rather than by a single preferred agent.[4]
    - **Pediatric patients (6 to less than 12 years of age):**

[1] Sharma S, Carr TF. Treatment of severe asthma in adolescents and adults. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)
[2] Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2026. https://ginasthma.org
[3] U.S. Food & Drug Administration. Xolair (omalizumab) Prescribing Information. Genentech, Inc., Revised 2/2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf
[4] Sharma S, Carr TF. Treatment of severe asthma in adolescents and adults. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)

    - Pediatric asthma management follows a similarly stepwise approach to controller therapy under National Asthma Education and Prevention Program (NAEPP) and GINA guidance, with specialist referral suggested when step 3 or higher therapy is required.[5,6]
    - Xolair carries the same core FDA indication, extended to children 6 to less than 12 years of age with a positive perennial-aeroallergen sensitization and inadequate control on inhaled corticosteroids, using a separate pediatric dosing table based on serum IgE level and body weight.[7]
- **Chronic rhinosinusitis with nasal polyps (CRSwNP) – adults (18 years of age and older)** – a chronic inflammatory disorder of the nasal and paranasal sinus mucosa lasting 12 weeks or longer, with development of bilateral nasal polyps. Chronic rhinosinusitis overall is estimated to affect up to 5% of the population, of which the nasal-polyp phenotype represents roughly one-third of cases; CRSwNP is frequently associated with eosinophilic, type 2 (elevated IgE) inflammation.[8]
    - Initial management consists of intranasal corticosteroids together with saline irrigation; functional endoscopic sinus surgery (FESS) is generally offered next for patients with an insufficient response.[9]
    - Four biologic agents are FDA-approved as add-on maintenance therapy for adults with CRSwNP and inadequate response to nasal corticosteroids: dupilumab, omalizumab, mepolizumab, and tezepelumab. Current UpToDate synthesis notes that, for most patients, dupilumab or tezepelumab is suggested first; biologic therapy generally is considered for patients with recurrent polyps following FESS, or for those with another indication for a biologic (e.g., comorbid severe asthma or chronic spontaneous urticaria) or a contraindication to surgery.[10,11]

[5] National Heart, Lung, and Blood Institute. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. December 2020 (NIH publication no. 20-HL-8140). https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines

[6] Sawicki G, Haver K. Asthma in children younger than 12 years: Overview of initiating therapy and monitoring control. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)

[7] U.S. Food & Drug Administration. Xolair (omalizumab) Prescribing Information. Genentech, Inc., Revised 2/2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf

[8] Buchheit KM, Holbrook EH. Chronic rhinosinusitis with nasal polyposis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)

[9] Buchheit KM, Holbrook EH. Chronic rhinosinusitis with nasal polyposis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)

[10] Buchheit KM, Holbrook EH. Chronic rhinosinusitis with nasal polyposis: Management and prognosis. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)

[11] The most recent published multinational consensus guideline specific to rhinosinusitis (the European Position Paper on Rhinosinusitis and Nasal Polyps, EPOS 2020) is now more than five years old; the treatment-positioning information above is therefore drawn from the more current UpToDate synthesis rather than from EPOS alone.

- **IgE-mediated food allergy – adult and pediatric patients (1 year of age and older)** – an immune-mediated hypersensitivity in which allergen-specific IgE antibodies trigger mast-cell and basophil activation upon exposure to a food allergen, producing reactions that range from mild cutaneous symptoms to anaphylaxis.[12]
    - Standard management is strict avoidance of the causative food(s) together with ready access to self-injectable epinephrine for accidental exposures. Current UpToDate guidance suggests avoidance alone, rather than avoidance plus omalizumab, for most patients with food allergy, reserving add-on omalizumab for selected patients such as those with multiple food allergies to foods that are difficult to avoid or a history of severe reactions to trace exposures.[13]
    - Xolair was the first FDA-approved medication indicated to reduce the risk of allergic reactions (Type I), including anaphylaxis, following accidental exposure to one or more foods in adult and pediatric patients 1 year of age and older with IgE-mediated food allergy; it is used in conjunction with continued food allergen avoidance and is not approved for emergency treatment of an allergic reaction.[14] Omalizumab has not been shown to induce permanent tolerance, and treatment benefit requires continued, indefinite dosing.[15]
- **Chronic spontaneous urticaria (CSU) – adults and adolescents (12 years of age and older)** – recurrent wheals, pruritus, and/or angioedema present on most days for six weeks or longer without an identifiable external trigger; associated angioedema occurs in an estimated 40% of patients.[16]
    - First-line management is second-generation H1-antihistamines; short courses of systemic corticosteroids may be used for severe exacerbations.[17]
    - The international EAACI/GA²LEN/EuroGuiDerm/APAAACI urticaria guideline gives a strong-consensus recommendation for adding omalizumab in patients who remain symptomatic despite maximum H1-antihistamine therapy because of its demonstrated efficacy and favorable safety profile; ciclosporin has been used for

[12] Nowak-Węgrzyn A. Management of IgE-mediated food allergy: An overview. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)
[13] Nowak-Węgrzyn A. Food allergy management: Allergen-nonspecific therapies. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)
[14] U.S. Food & Drug Administration. Xolair (omalizumab) Prescribing Information. Genentech, Inc., Revised 2/2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf
[15] Nowak-Węgrzyn A. Food allergy management: Allergen-nonspecific therapies. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)
[16] Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)
[17] Khan DA. Chronic spontaneous urticaria: Treatment of refractory symptoms. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on July 31, 2026.)

the minority of patients who do not respond to the combination of maximal antihistamine therapy and omalizumab.[18]

Clinical comparison: monoclonal antibody therapies

Table 1 Clinical comparison of the review drug and its therapeutic alternatives

Drug	Formulation	Asthma (mod. to severe)	Severe asthma	CRSwNP	CSU	IgE-mediated food allergy	Expected Biosimilar Availability
Xolair (omalizumab)	SC pen/syringe	Yes	-	Yes	Yes	Yes	Omlyclo approved 2025, anticipated launch Sept. 2026
Cinqair (reslizumab)	IV Infusion	-	Yes*	-	-	-	~March 2028
Dupixent (dupilumab)	SC pen/syringe	Yes	-	Yes	Yes	-	~March 2031
Fasenra (benralizumab)	SC pen/syringe	-	Yes	-	-	-	-
Nucala (mepolizumab)	SC pen/syringe	-	Yes*	Yes*	-	-	~November 2027
Tezspire (tezepelumab-ekko)	SC pen/syringe	-	Yes	Yes	-	-	~September 2028
Products may have additional FDA-approved indications not included in the table *Add-on maintenance treatment with eosinophilic phenotype.							

Additional information on the drug and therapeutic equivalents is included in the appendix.

[18] Zuberbier, T., Abdul Latiff, A. H., Abuzakouk, M., et al. (2022). The international EAACI/GA²LEN/EuroGuiDerm/APAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy, 77(3), 734–766.

Appendix 1: Clinical information

Drug indications

- FDA Approved:
    - Xolair is an anti-IgE antibody indicated for:
        - Moderate to severe **persistent asthma** in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.
        - **Chronic rhinosinusitis with nasal polyps (CRSwNP)** in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.
        - **IgE-mediated food allergy** in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.
        - **Chronic spontaneous urticaria (CSU)** in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
- Limitations of use:
    - Not indicated for acute bronchospasm or status asthmaticus.
    - Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
    - Not indicated for other forms of urticaria.
- Off label uses:
    - Allergic bronchopulmonary aspergillosis, treatment-dependent; adjunct
    - Allergic rhinitis; prophylaxis
    - Allergy to latex
    - Subcutaneous immunotherapy; adjunct[19]

Clinical efficacy

Efficacy in asthma (adults and adolescents)

Xolair efficacy in moderate to severe persistent asthma was demonstrated in three randomized, double-blind, placebo-controlled multicenter trials in adult and adolescent patients 12 years of age and older with positive perennial allergen sensitivity and inadequate control on inhaled corticosteroids (ICS). Patients received stable inhaled corticosteroids during a 16-week stable-steroid phase followed by a 12-week steroid-reduction phase. In all three trials, an exacerbation was defined as a worsening of asthma that required treatment with systemic corticosteroids or a doubling of the baseline ICS dose. Among those patients who experienced

[19]Omalizumab. Merative Micromedex. Merative. Ann Arbor, MI. Accessed July 17, 2026. https://www.micromedexsolutions.com/

an exacerbation, the distribution of exacerbation severity was similar between treatment groups. Xolair significantly reduced exacerbations compared with placebo in both phases (Table 2). Measures of airflow (FEV1) and asthma symptoms were also evaluated in these trials. The clinical relevance of the treatment-associated differences is unknown.

Table 2 Frequency of asthma exacerbations per patient by phase in asthma trials 1 and 2

Stable steroid phase (16 weeks)				
	Asthma trial 1		Asthma trial 2	
Exacerbations per patient	**Xolair (N=268)**	**Placebo (N=257)**	**Xolair (N=274)**	**Placebo (N=272)**
0	85.8%	76.7%	87.6%	69.9%
1	11.9%	16.7%	11.3%	25.0%
≥2	2.2%	6.6%	1.1%	5.1%
p-Value	0.005		<0.001	
Mean number exacerbations/patient	0.2	0.3	0.1	0.4

Steroid reduction phase (12 weeks)				
	Asthma trial 1		Asthma trial 2	
Exacerbations per patient	**Xolair (N=268)**	**Placebo (N=257)**	**Xolair (N=274)**	**Placebo (N=272)**
0	78.7%	67.7%	83.9%	70.2%
1	19.0%	28.4%	14.2%	26.1%
≥2	2.2%	3.9%	1.8%	3.7%
p-Value	0.004		<0.001	
Mean number exacerbations/patient	0.2	0.4	0.2	0.3

Asthma trial 3 evaluated patients receiving high-dose fluticasone (≥1000 µg/day), with a subset also receiving corticosteroids. Unlike trials 1 and 2, long-acting β2-agonists were allowed. Over a 16-week stable-steroid phase and 16-week reduction phase, the number of exacerbations in patients treated with Xolair was similar to that in placebo-treated patients, possibly due to differences in population severity, study sample size, or concomitant therapy (Table 3). In all three of the trials, a reduction of asthma exacerbations was not observed in the Xolair-treated patients who had FEV1>80% at the time of randomization. Reductions in exacerbations were not seen in patients who required oral steroids as maintenance therapy.

Table 3 Percentage of patients with asthma exacerbations by subgroup and phase in asthma trial 3

Stable steroid phase (16 weeks)				
	Inhaled only		Oral + inhaled	
	Xolair (N=126)	Placebo (N=120)	Xolair (N=50)	Placebo (N=45)
% of Patients with ≥ 1 exacerbations	15.9%	15.0%	32.0%	22.2%
Difference (95% CI)	0.9 (-9.7, 13.7)		9.8 (-10.5, 31.4)	

Steroid Reduction phase (16 weeks)				
	Inhaled only		Oral + inhaled	
	Xolair (N=126)	Placebo (N=120)	Xolair (N=50)	Placebo (N=45)
% of Patients with ≥ 1 exacerbations	22.2%	26.7%	42.0%	42.2%
Difference (95% CI)	-4.4 (-17.6, 7.4)		-0.2 (-22.4, 20.1)	

Efficacy in asthma (pediatrics)

The safety and efficacy of Xolair in pediatric patients 6 to <12 years of age with moderate to severe asthma is based on one randomized, double-blind, placebo controlled, multi-center trial (Asthma trial 4[20]) and an additional supportive study (Asthma trial 5). Asthma trial 4 was a 52-week randomized, double-blind study in 628 children with moderate to severe asthma inadequately controlled on inhaled corticosteroids. During the 24-week fixed-steroid phase, Xolair significantly reduced exacerbations. Over the full 52-week period, exacerbation rates remained lower (Table 4). Other measures such as nocturnal symptoms, rescue medication use, and FEV1 showed no significant differences.

Asthma trial 5 was a 28-week randomized, placebo-controlled safety study in 334 children, primarily evaluating tolerability but also measuring exacerbations. Xolair again reduced exacerbation rates during both the 16-week fixed steroid phase and the full 28-week period (Table 5).

[20] Efficacy and Safety of Omalizumab in Children (6 - 12 Years) With Moderate-severe, Inadequately Controlled Allergic Asthma. (n.d.-b). https://clinicaltrials.gov/study/NCT00079937?tab=study

Table 4 Rate ratio of asthma exacerbations rate in asthma trial 4

	Asthma Trial 4			
	Fixed Steroid Treatment Phase (24 weeks)		Full Treatment Period (52 weeks)	
	Xolair	Placebo	Xolair	Placebo
Rate of asthma exacerbations	0.45	0.64	0.78	1.36
Estimated Rate Ratio (95% CI)	0.69 (0.53, 0.90)		0.57 (0.45, 0.72)	

Table 5 Rate ratio of asthma exacerbations rate in asthma trial 5

	Asthma Trial 5			
	Steroid Treatment Period (16 weeks)		Steroid Dose Reduction Period (12 weeks)	
	Xolair	Placebo	Xolair	Placebo
Rate of asthma exacerbations	0.18	0.32	0.38	0.76
Estimated Rate Ratio (95% CI)	0.58 (0.35, 0.96)		0.50 (0.36, 0.71)	

Efficacy in chronic rhinosinusitis with nasal polyps (CRSwNP)

Xolair efficacy in CRSwNP was demonstrated in two randomized, double-blind, placebo-controlled trials in adult patients 18 years of age and older with severe bilateral nasal polyps (baseline NPS ≥5) and persistent congestion despite nasal corticosteroids. Xolair produced statistically significant improvements in both co-primary endpoints: nasal polyp score (NPS) and nasal congestion score (NCS) by Week 24, with benefits evident as early as Week 4 (Table 6). Secondary endpoints, including sense of smell, post-nasal drip, and runny nose, also favored Xolair.

Table 6 Change from baseline at week 24 in NPS and 7-day average of daily NCS in trials 1 and 2

	Trial 1		Trial 2	
	Xolair LS mean change (N=72)	Placebo LS mean change (N=65)	Xolair LS mean change (N=62)	Placebo LS mean change (N=65)
NPS	-1.1	0.1	-0.9	-0.3
Difference (95% CI) p-value	-1.1 (-1.6, -0.7) <0.0001		-0.6 (-1.1, -0.1) 0.0140	
NCS	-0.9	-0.4	-0.7	-0.2
Difference (95% CI) p-value	-0.6 (-0.8, -0.3) 0.0004		-0.5 (-0.8, -0.2) 0.0017	

LS = least-square

Efficacy in IgE-mediated food allergy

Xolair efficacy in IgE-mediated food allergy was demonstrated in a randomized, double-blind, placebo-controlled multicenter trial in adult and pediatric patients 1 year of age and older with peanut allergy and at least two additional food allergies. After 16–20 weeks of treatment, Xolair significantly increased the proportion of patients able to tolerate clinically meaningful doses of peanut, cashew, milk, and egg compared with placebo without dose-limiting symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms). For example, 68% of Xolair-treated patients tolerated ≥600 mg of peanut protein versus 5% with placebo (Table 7). Similar improvements were observed across multiple foods, with many patients achieving tolerance to more than one allergen.

Table 7 Food challenge response rates in pediatric patients for single dose of peanut, cashew, milk or egg protein in FA trial

Food, challenge Dose	Response rate (%) (n/N) Xolair	Placebo	Treatment difference (%) (Xolair-placebo) (95% CI)
Peanut, ≥600mg	68% (75/110)	5% (3/55)	63% (50%, 73%)
Peanut, ≥1000mg	65% (72/110)	0% (0/55)	65% (56%, 74%)
Cashew, ≥1000mg	42% (27/64)	3% (1/30)	39% (20%, 53%)
Milk, ≥1000mg	66%	11%	55%

Food, challenge Dose	Response rate (%) (n/N) Xolair	Placebo	Treatment difference (%) (Xolair-placebo) (95% CI)
	(25/38)	(2/19)	(29%, 73%)
Egg, ≥1000mg	67% (31/46)	0% (0/19)	67% (49%, 80%)

CI = Confidence interval; DBPCFC = Double-blind placebo-controlled food challenge; n = Number of responders; N = Total number of patients receiving food, challenge dose.
a Response defined as consumption of a single dose of the specified amount of food without dose-limiting symptoms.
b Consumption of a single dose of ≥1000 mg of peanut protein was an additional secondary endpoint. The key secondary efficacy endpoints were the percentage of patients who were able to consume a single dose of ≥ 1000mg of cashew, milk, or egg protein.
Notes: Subjects without an exit DBPCFC or evaluable exit DBPCFC were counted as non-responders; P-values from two-sided Fisher's exact tests were < 0.0001 for all the food challenge doses.

Efficacy in chronic spontaneous urticaria

Xolair efficacy in chronic spontaneous urticaria (CSU), previously referred to as chronic idiopathic urticaria (CIU), was demonstrated in two randomized, placebo-controlled, multiple-dose clinical trials in adult and adolescent patients 12 years of age and older, with treatment durations of 24 and 12 weeks. Patients received subcutaneous injections of Xolair 75mg, 150mg, or 300mg, or placebo every 4 weeks in addition to baseline H1 antihistamine therapy, followed by a 16-week washout observation period. By Week 12, Xolair produced significant reductions in weekly itch severity and hive count scores, with a substantial proportion of patients achieving complete response, defined as a weekly urticaria activity score (UAS7) of zero. Complete response was most pronounced at the 300 mg dose. The 75 mg dose was not consistently effective and is not approved for use. The appropriate duration of therapy for CSU with Xolair has not yet been established.

*Table 8 Change in baseline to week 12 in weekly itch severity score and weekly hive count score in CSU trial 1**

	Xolair 75mg (n=77)	Xolair 150mg (n=80)	Xolair 300mg (n=81)	Placebo (n=80)
Weekly Itch Severity Score				
Mean baseline score (SD)	14.5 (3.6)	14.1 (3.8)	14.2 (3.3)	14.4 (3.5)
Mean change week 12 (SD)	-6.46 (6.14)	-6.66 (6.28)	-9.40 (5.73)	-3.63 (5.22)
Difference in LS means vs. placebo	-2.96	-2.95	-5.80	-
95% CI for difference	-4.71, -1.21	-4.72, -1.18	-7.49, -4.10	
Weekly Hive Count Score†				
Mean baseline score (SD)	17.2 (4.2)	16.2 (4.6)	17.1 (3.8)	16.7 (4.4)
Mean change week 12 (SD)	-7.36 (7.52)	-7.78 (7.08)	-11.35 (7.25)	-4.37 (6.60)
Difference in LS means vs. placebo	-2.75	-3.44	-6.93	-

	Xolair 75mg (n=77)	Xolair 150mg (n=80)	Xolair 300mg (n=81)	Placebo (n=80)
95% CI for difference	-4.95, -0.54	-5.57, -1.32	-9.10, -4.76	

*Modified intent-to-treat (mITT) population: all patients who were randomized and received at least one dose of study medication.

† Score measured on a range of 0–21

Clinical safety

- FDA safety warnings and precautions:
  - Anaphylaxis: Initiate Xolair therapy in a healthcare setting prepared to manage anaphylaxis which can be life-threatening and observe patients for an appropriate period of time after administration.
  - Malignancy: Malignancies have been observed in clinical studies.
  - Acute Asthma Symptoms: Do not use for the treatment of acute bronchospasm or status asthmaticus.
  - Corticosteroid Reduction: Do not abruptly discontinue corticosteroids upon initiation of Xolair therapy.
  - Eosinophilic Conditions: Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids.
  - Fever, Arthralgia, and Rash: Stop Xolair if patients develop signs and symptoms similar to serum sickness.
  - Parasitic (Helminth) Infection: Monitor patients at high risk of geohelminth infection while on Xolair therapy.
  - Laboratory Tests: Serum total IgE levels increase following administration of Xolair and may persist for up to 1 year following discontinuation of Xolair.
  - Potential Medication Error Related to Emergency Treatment of Anaphylaxis: Xolair should not be used for emergency treatment of allergic reactions, including anaphylaxis.
- Contraindications:
  - Severe hypersensitivity reaction to Xolair or any ingredient of Xolair.
- Common side effects:
  - Asthma (adult and adolescent patients ≥12 years of age): arthralgia, pain (general), leg pain, fatigue, dizziness, fracture, arm pain, pruritus, dermatitis, and earache
  - Asthma (pediatric patients 6 to <12 years of age): nasopharyngitis, headache, pyrexia, upper abdominal pain, pharyngitis streptococcal, otitis media, viral gastroenteritis, arthropod bites, and epistaxis
  - Chronic Rhinosinusitis with Nasal Polyps: headache, injection site reaction, arthralgia, upper abdominal pain, and dizziness
  - IgE-Mediated Food Allergy: injection site reactions and pyrexia

- Chronic Spontaneous Urticaria: nausea, nasopharyngitis, sinusitis, upper respiratory tract infection, viral upper respiratory tract infection, arthralgia, headache, and cough

- Safety advantages or disadvantages:
  Advantages:
  - Established tolerability across indications: In asthma, CRSwNP, food allergy, and CSU trials, most adverse events were mild to moderate (e.g., headache, injection site reactions, arthralgia, fatigue).
  - Low discontinuation rates: Few patients discontinued due to adverse events, suggesting overall good tolerability.
  - Consistent safety across age groups: Pediatric, adolescent, and adult populations showed similar safety patterns, with no unique pediatric specific risks identified.
  - Predictable adverse event profile: Common reactions such as nasopharyngitis, headache, and injection site reactions are well characterized and manageable.

  Disadvantages / Risks:
  - Anaphylaxis risk: The boxed warning highlights that "anaphylaxis has occurred after the first dose of Xolair but also has occurred beyond 1 year after beginning treatment". This requires initiation in a healthcare setting and careful patient selection for self-administration.
  - Malignancy signal: Malignancies were observed in clinical studies, though a causal relationship has not been established.
  - Eosinophilic conditions: Rare but serious events such as eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and neuropathy have been reported, especially when corticosteroids are reduced.
  - Serum sickness like reactions: Fever, arthralgia, and rash resembling serum sickness may occur, requiring discontinuation.
  - Not for emergency use: Xolair is not indicated for acute bronchospasm, status asthmaticus, or emergency treatment of allergic reactions, limiting its role in acute care.
  - Uncertain long-term safety: The appropriate duration of therapy has not been established for CSU, and long-term effects remain under study.

Therapeutic alternatives

Table 9 FDA-approved indications

Drug	Indication							
	Asthma (mod. to severe)	Severe asthma	COPD	CRSwNP	CSU	EGPA	HES	IgE-mediated food allergy
Xolair (omalizumab) [21]	Yes	-	-	Yes	Yes	-	-	Yes
Cinqair (reslizumab) [22]	-	Yes*	-	-	-	-	-	-
Dupixent (dupilumab) [23]	Yes	-	Yes	Yes	Yes	-	-	-
Fasenra (benralizumab) [24]	-	Yes	-	-	-	Yes	Yes	-
Nucala (mepolizumab) [25]	-	Yes*	Yes*	Yes*	-	Yes	Yes	-
Tezspire (tezepelumab-ekko) [26]	-	Yes	-	Yes	-	-	-	-

Products may have additional FDA-approved indications not included in the table
COPD = Chronic Obstructive Pulmonary Disease
EGPA = Eosinophilic Granulomatosis with Polyangiitis
HES = Hypereosinophilic Syndrome
*Add-on maintenance treatment with eosinophilic phenotype.

[21] U.S. Food & Drug Administration. *Xolair (omalizumab) Prescribing Information.* Genentech, Inc., Revised 2/2024. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5245lbl.pdf
[22] U.S. Food & Drug Administration. *Cinqair (reslizumab) Prescribing Information.* Teva Respiratory, LLC, Revised 1/2019. https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/0761033s010lbl.pdf
[23] U.S. Food & Drug Administration. *Dupixent (dupilumab) Prescribing Information.* Regeneron Pharmaceuticals, Inc., Revised 4/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761055s074lbl.pdf
[24] U.S. Food & Drug Administration. *Fasenra (benralizumab) Prescribing Information*. AstraZeneca AB, Revised 5/2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2026/761070s023lbl.pdf
[25] U.S. Food & Drug Administration. *Nucala (mepolizumab) Prescribing Information.* GlaxoSmithKline LLC, Revised 8/2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761122s022lbl.pdf
[26] U.S. Food & Drug Administration. *Tezspire (tezepelumab-ekko) Prescribing Information.* AstraZeneca AB, Revised 10/2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761224s006lbl.pdf

Table 10 Summary of key clinical trials - asthma

Asthma study drug/number	Xolair Trial 1	Cinqair Study 1	Dupixent QUEST trial	Fasenra SIROCCO trial	Nucala MENSA trial	Tezspire NAVIGATOR trial
Population	Adults & adolescents (moderate–severe allergic asthma, IgE 30–700 IU/mL)	Adults ≥18 yrs, eosinophilic asthma	adults, ICS-dependent asthma & ≥ 1 controller meds	≥12yrs, severe eosinophilic asthma	≥12 yrs, severe eosinophilic asthma	≥12 yrs, severe asthma (all phenotypes)
Treatment	SC inj q2–4 wks, dose based on weight & IgE	IV infusion 3 mg/kg q4 wks	SC inj 200–300 mg q2 wks	SC inj 30 mg q4 wks ×3, then q8 weeks	SC inj 100 mg q4 wks	SC inj 210 mg q4 wks
Size	268	245	277	267	194	528
Exacerbation Rate (per year)	0.91	0.90	0.40	0.74	0.83	0.93
Rate Ratio vs. placebo (95% CI)	0.57 (0.45-0.72)	0.5 (0.37–0.67)	0.33 (0.23–0.45)	0.49 (0.37–0.64)	0.47 (0.35–0.64)	0.44 (0.37–0.53)

Table 11 Strengths, dosing & route

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
Xolair	SC every 2-4 weeks	Asthma[i]: 75-375mg q2 or 4wks CRSwNP and IgE-Mediated food allergy[*]: 75-600mg SC q2 or 4wks CSU: 150 or 300mg SC q4wks	Injection (single-dose prefilled syringe): 75mg/0.5mL, 150mg/mL, 300mg/2mL solution Injection (single-dose prefilled autoinjector): 75mg/0.5mL, 150mg/mL, 300mg/2mL solution Injection (single-dose vial for reconstitution): 150mg lyophilized powder
Cinqair	IV infusion every 4 weeks	3mg/kg once q4wks infused over 20-50 minutes	Injection (single-use vials): 100 mg/10 mL (10 mg/mL) solution

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
Dupixent	SC: AD (adults), CRSwNP, Prurigo Nodularis, COPD, Bullous Pemphigoid: q2wks AD (6 mths-5yo): q4wks AD (6yo-17yo): q4wks (15-30kg); q2w (30kg+) Asthma (adults & 12yo+): q2wks Asthma (6yo-11yo): q4w (15-30kg); q2wks (30kg+) Eosinophilic Esophagitis (adults + 1yo+): q2wks (15-40kg); qwk (40kg+) CSU (adults): q2wks; (2-5yo) q4wks; (6-17yo) q4wks (15-30kg); q2wks (30kg+) Allergic Fungal Rhinosinusitis (adults): q2wks; (6-17yo) q4wks (15-30kg); q2wks (30kg+)	AD (adults): initial 600mg, then 300mg q2wks AD (6mths-5yo): 200mg q4wks (5-<15kg); 300mg q4wks (15-<30kg) AD (6-17yo) and asthma and co-morbid moderate to severe AD (6-11yo): 600mg, then 300mg q4wks (15-<30kg); 400mg, then 200mg q2wks (30-<60kg); 600mg, then 300mg q2wks (60kg+) Asthma (adults & 12yo+): 400mg, then 200mg q2wks OR 600mg, then 300mg q2wks Patients w/ oral corticosteroid-dependent asthma or w/ co-morbid moderate to severe AD, CRSwNP, or AFRS[ii]: 600mg, then 300mg q2wks Asthma (6-11yo): 300mg q4wks (15-<30kg); 200mg q2wks (30kg+) CRSwNP (adults & 12yo+): 300mg q2wks EE (adults & 1yo+): 200mg q2wks (15-<30kg); 300mg q2wks (30-<40kg); 300mg qwk (40kg+) PN (adults): 600mg, then 300mg q2wks COPD (adults): 300mg q2wks CSU (adults): 600mg, then 300mg q2wks; (2-5yo[iii]) 200mg q4wks (5-<15kg); 300mg q4wks (15-<30kg); (6-17yo) 600mg, then 300mg q4wks (15-<30kg); 400mg, then 200mg q2wks (30-<60kg); 600mg, then 300mg q2wks (60kg+)	Injection (single dose prefilled syringe): 300mg/2mL, 200mg/1.14mL Injection (single-dose prefilled pen): 300mg/2mL, 200mg/1.14mL

Drug	Route & schedule	Starting & maintenance dose(s)	Marketed strengths / pens
		BP (adults): 600mg, then 300mg q2wks AFR (adults): 300mg q2wks; (6-17yo) 300mg q4wks (15-<30kg); 200mg q2wks (30-<60kg); 300mg q2wks (60kg+)	
Fasenra	Asthma: SC q4wks x 3 doses, then q8wks EGPA & HES: SC q4wks	Asthma (adults & 12yo+): 30mg q4wks x first 3 doses, then once q8wks thereafter; (6-11yo) 10mg q4wks x first 3 doses, then once q8wks thereafter (<35kg); 30mg q4wks x first 3 doses, then once q8wks thereafter (35kg+) EGPA & HES: 30mg q4wks	Injection (single dose prefilled syringe): 10mg/0.5mL, 30mg/mL Injection (single-dose autoinjector): 30mg/mL
Nucala	SC q4wks	Severe asthma (12yo+): 100mg SC once q4wks Severe asthma (6-11yo): 40mg SC once q4wks CRSwNP & COPD: 100mg SC once q4wks EGPA & HES: 300mg SC once q4wks	Injection (single-dose prefilled syringe): 40mg/0.4mL, 100mg/mL Injection (single-dose prefilled autoinjector): 100mg/mL Injection (single-dose vial for reconstitution): 100mg lyophilized powder
Tezspire	SC q4wks	210mg SC once q4wks	Injection (single-dose glass vial): 210mg/1.91mL solution Injection (single-dose pre-filled syringe): 210mg/1.91mL solution Injection (single-dose pre-filled pen): 210mg/1.91mL solution

[i] Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg).
[ii] For pediatric patients 12 years to 17 years of age (>60 kg) and adults with AFRS.
[iii] For pediatric patients 2 years to 5 years of age with CSU, no initial loading dose is recommended.

Table 12 Safety & therapeutic considerations

Drug	Boxed warning	Notable warnings/precautions (selected)
Xolair (omalizumab)	anaphylaxis	malignancy, corticosteroid reduction, eosinophilic conditions, serum sickness symptoms
Cinqair (reslizumab)	anaphylaxis	malignancy, corticosteroid reduction, parasitic (helminth) infections
Dupixent (dupilumab)	none	hypersensitivity reactions, conjunctivitis, keratitis, and blepharitis, eosinophilic conditions, corticosteroid dosage reduction, psoriasis, arthralgia and psoriatic arthritis, parasitic (helminth) infections, live vaccines
Fasenra (benralizumab)	none	hypersensitivity reactions, corticosteroid dosage reduction, parasitic (helminth) infections
Nucala (mepolizumab)	none	hypersensitivity reactions, herpes zoster infections, corticosteroid dosage reduction, parasitic (helminth) infections
Tezspire (tezepelumab-ekko)	none	hypersensitivity reactions, corticosteroid dosage reduction, parasitic (helminth) infections, live vaccines

Clinical Benefits and Disadvantages

The considerations below reflect guideline- and label-level information for the five board-selected therapeutic alternatives only. Consistent with the limitation noted for the trial data elsewhere in this document, these benefits and disadvantages are not derived from head-to-head efficacy comparisons and should not be read as implying one agent is more effective than another.

Table 13 Clinical benefits and disadvantages

Drug	Clinical benefits	Clinical disadvantages
Xolair	Broadest indication profile	Boxed warning for anaphylaxis; weight/IgE-based dosing for several indications
Cinqair	Effective in type 2 inflammatory disease; improves asthma and nasal polyps; self-administration	Not approved for food allergy

Drug	Clinical benefits	Clinical disadvantages
Dupixent	Proven efficacy in eosinophilic disease; reduces oral corticosteroid use	Requires eosinophilic phenotype
Fasenra	Every-8-week maintenance dosing	Not approved for CRSwNP, CSU, or food allergy
Nucala	Effective for selected patients	Infusion-only administration; limited utilization
Tezspire	Effective regardless of eosinophil count	Asthma indication only