

Cinqair® (reslizumab)



When requesting Cinqair® (reslizumab), the individual requiring treatment must be diagnosed with an FDA-approved indication and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-approved Indication

Cinqair is indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype.

Coverage Guidelines

Severe Asthma with an Eosinophilic Phenotype

Initial authorization:

The individual must meet **all** of the following criteria for approval:

- Has a blood eosinophil count of greater than or equal to 400 cells per microliter within the previous 4 weeks *or* within 4 weeks prior to treatment with any anti-interleukin-5 therapy (e.g., Fasenra, Nucala);
- Has received at least 3 consecutive months of the following combination therapy:
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND an anti-interleukin-5 therapy (e.g., Fasenra, Nucala)
 - OR
 - o An inhaled corticosteroid (ICS) [e.g., Flovent Diskus/HFA, Arnuity, Ellipta, Qvar/Qvar RediHaler]; AND at least one additional asthma controller/maintenance medication (e.g., inhaled long-acting beta₂ agonist (LABA) [e.g., Serevent Diskus]; inhaled long-acting muscarinic antagonist (LAMA) [e.g., Spiriva]; leukotriene receptor antagonist (LTRA) [e.g., montelukast, zafirlukast]; theophylline)
 - OR
 - o A combination inhaler containing both an inhaled corticosteroid and a long-acting beta₂ agonist (e.g., Symbicort, Advair, Dulera)
- Patient's asthma is uncontrolled defined by ONE of the following:
 - o Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; OR
 - o Has experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year; OR
 - o Has a forced expiratory volume in 1 second (FEV₁) less than 80% predicted; OR
 - o Has an FEV₁/forced vital capacity (FVC) less than 0.80; OR
 - o Asthma worsens upon tapering of oral corticosteroids therapy;
- Is 18 years of age or older; AND
- Cinqair is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

Reauthorization:

The individual must meet **all** of the following criteria for approval:

- Has already received at least 6 months of Cinqair therapy (*NOTE: Patients who have received less than 6 months of therapy or those who are restarting therapy with Cinqair should be considered under initial criteria*);
- Continues to receive therapy with one inhaled corticosteroid (ICS) or one ICS-containing combination inhaler (e.g., Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity); AND
- Has responded to Cinqair therapy (e.g., decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency room visits, or physician visits due to asthma; decreased requirement for oral corticosteroids therapy).

Approval duration (initial): 6 months

Approval duration (renewal): 12 months

Dosing Guidelines

Approve 3 mg/kg administered intravenously once every 4 weeks.

References

1. Cinqair® injection for intravenous use [prescribing information]. Frazer, PA: Teva Respiratory, LLC; February 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicenter, parallel, double-blind, randomized, placebo-controlled, phase 3 trials. *Lancet Respir Med*. 2015;3:355-366.
3. Bjerner L, Lemiere C, Maspero J, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil levels: a randomized phase 3 study. *Chest*. 2016;150(4):789-798.
4. Corren J, Weinstein S, Janka L, et al. Phase 3 study of reslizumab in patients with poorly controlled asthma: effects across a broad range of eosinophil counts. *Chest*. 2016;150(4):799-810.
5. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2019. Available at: <http://www.ginasthma.org>. Accessed on January 30, 2020.
6. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43:343-373.
7. Xolair® subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; December 2020.
8. Prussin C, James SP, Huber MM, et al. Pilot study of anti-IL-5 in eosinophilic gastroenteritis. *J Allergy Clin Immunol*. 2003;111:S275.
9. Spergel JM, Rothenberg ME, Collins MH, et al. Reslizumab in children and adolescents with eosinophilic esophagitis: results of a double-blind, randomized, placebo-controlled trial. *J Allergy Clin Immunol*. 2012;129(2):456-463.
10. Klion AD, Law MA, Noel P, et al. Safety and efficacy of the monoclonal anti-interleukin-5 antibody SCH55700 in the treatment of patients with hypereosinophilic syndrome. *Blood*. 2004;103(8):2939-2941.
11. Gevaert P, Lang-Loidolt D, Lackner A, et al. Nasal IL-5 levels determine the response to anti-IL-5 treatment in patients with nasal polyps. *J Allergy Clin Immunol*. 2006;118(5):1133-1141.
12. Weinstein SF, Katial RK, Bardin P, et al. Effects of reslizumab on asthma outcomes in a subgroup of eosinophilic asthma patients with self-reported chronic rhinosinusitis with nasal polyps. *J Allergy Clin Immunol Pract*. 2019;7(2):589-596.
13. Shomali W, Gotlib J. World Health Organization-defined eosinophilic disorders: 2019 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2019;94(10):1149-1167.
14. Brusselle G, Germinaro M, Weiss S, et al. Reslizumab in patients with inadequately controlled late-onset asthma and elevated blood eosinophils. *Pulm Pharmacol Ther*. 2017;43:39-45.
15. Coffey F, Fajt ML, Acho M, et al. Successful treatment of corticosteroid-refractory hypereosinophilia with reslizumab. *J Investig Allergol Clin Immunol*. 2019;29(3):241-242.

16. Kent BD, d'Ancona G, Fernandes M, et al. oral corticosteroid-sparing effects of reslizumab in the treatment of eosinophilic granulomatosis with polyangiitis. *ERJ Open Res.* 2020;6(1):eCollection.
17. Markowitz JE, Jobe L, Miller M, et al. Safety and efficacy of reslizumab for children and adolescents with eosinophilic esophagitis treated over nine years. *J Pediatr Gastroenterol Nutr.* 2018;66(6):893-897.
18. Mukherjee M, Aleman Paramo F, Kjarsgaard M, et al. Weight-adjusted intravenous reslizumab in severe asthma with inadequate response to fixed-dose subcutaneous mepolizumab. *Am J Respir Crit Care Med.* 2018;197(1):38-46.
19. Murphy K, Jacobs J, Bjermer L, et al. Long-term safety and efficacy of reslizumab in patients with eosinophilic asthma. *J Allergy Clin Immunol Pract.* 2017;5(6):1572-1581.
Perez de Llano LA, Cosio BG, Domingo C, et al. Efficacy and safety of reslizumab in patients with severe asthma with inadequate response to omalizumab: a multicenter, open-label pilot study. *J Allergy Clin Immunol Pract.* 2019;7(7):2277-2283.