

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

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7. Xolair® subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; December 2020.
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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.
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