Original Effective Date: 10/01/2016
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Last P&T Approval/Version: 10/29/2025
Next Review Due By: 10/2026
Policy Number: C9761-A

Cinqair (reslizumab)

PRODUCTS AFFECTED

Cinqair (reslizumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Severe asthma with an eosinophilic phenotype

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:
1. Documented diagnosis of moderate to severe asthma
   AND
2. Cinqair (reslizumab) is NOT being used as monotherapy for asthma (must be prescribed as add-on maintenance to be

used in combination with other medications for long-term control of asthma)
AND

3. Documentation member has eosinophilic phenotype or predominantly eosinophil-driven disease with blood eosinophil counts: ≥150 cells/microliter at initiation of therapy (within 6 weeks of request) Or ≥ 300 cells/microliter in the prior 12 months [DOCUMENTATION REQUIRED]
AND
4. Documentation member has experienced exacerbation(s) or hospitalization(s), within the last 12 months as evidenced by ANY of the following:
    i Two or more exacerbations requiring treatment with systemic corticosteroids (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months
    ii. One or more exacerbation requiring hospitalization in the past 12 months
    iii. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations
    iv. Asthma worsens upon tapering of oral corticosteroid therapy
    v. Mechanical ventilation in the past 12 months
    vi. Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistently less than 20
    vii. Forced expiratory volume in 1 second (FEV1) < 80% predicted
    viii. FEV1/forced vital capacity (FVC) < 0.80

AND

5. Documentation of adherence to ONE of the following regimens of at least 3 months (within the past 90 days) and symptoms inadequately controlled (as documented in criteria above):
    (a) Medium or High dose ICS- LABA combination product AND one additional asthma controller medication (LAMA, LTRA, Low dose azithromycin), preferably a LAMA- per GINA guideline
    OR
    (b) Medium or High dose ICS- LABA combination product AND oral corticosteroids [see Appendix for product classes]

    MOLINA REVIEWER NOTE: Verify pharmacy claims for adherence with the combination therapy above within the last 90 days. For new members to Molina Healthcare, confirm medication use in medical chart history. Non- adherence, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.
    AND
6. FOR PHYSICIAN ADMINISTERED MEDICATION REQUESTS: Documentation of trial and failure (symptoms inadequately controlled), serious side effects, or labeled contraindication to ALL preferred agents matching members diagnosis
    OR
    IF THIS IS A PHARMACY BENEFIT REQUEST FOR A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s). [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or unacceptable toxicity from the drug [e.g. symptoms of anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema), malignancy, symptoms similar to serum sickness (fever,

arthralgia, and rash); parasitic (helminth) infection, eosinophilic conditions (e.g. vasculitis rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids]
AND

3. Documentation that Cinqair (reslizumab) therapy has resulted in clinical improvement as documented by ONE or more of the following from baseline [DOCUMENTATION REQUIRED]:
   a. Improvement in lung function (increase in percent predicted FEV1 or PEF)
      OR
   b. Decreased utilization of rescue medications, decreased frequency of exacerbations (defined as worsening of asthma that requires increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)
      OR
   c. Decreased frequency of unscheduled clinic, urgent care or emergency department visits
      OR
   d. Reduction in reported symptoms: chest tightness, coughing, shortness of breath, nocturnal wakening, wheezing, sustained improvement in Asthma Control Test (ACT) scores
      OR
   e. Decreased or stopped oral treatments (including oral corticosteroids and other add on medications, if applicable), or reduced ICS-LABA dose (to at least moderate)

   MOLINA REVIEWER NOTE: For members with unclear response after initial use, see Background (GINA 2025).
   AND
4. Documentation member is currently treated and is adherent with standard therapy (e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA)) within the past 90 days

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of therapy:12 months

PRESCRIBER REQUIREMENTS:
Prescribed by, or in consultation with, a board-certified asthma specialist (allergist, immunologist, pulmonologist) or physician experienced in the management of asthma. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
3 mg/kg IV infusion over 20 to 50 minutes every 4 weeks

PLACE OF ADMINISTRATION:
The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-hospital facility-based location as per the Molina Health Care Site of Care program.

Note: Site of Care Utilization Management Policy applies for Cinqair (reslizumab). For information on site of care, see: Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Intravenous

DRUG CLASS:
Interleukin-5 Antagonists (IgG4 kappa)

FDA-APPROVED USES:
Indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype.

Limitations of Use: CINQAIR is not indicated for:
- *treatment of other eosinophilic conditions*
- *relief of acute bronchospasm or status asthmaticus*

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX 1:
Controller medications: suppress the inflammatory causes of asthma to provide clinical control over the long term, whereas reliever medications relieve bronchoconstriction quickly. Controller medications include inhaled glucocorticoids, long-acting beta-agonists (LABAs) and Leukotriene receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyl, TheoChron ER, generics) is also a controller agent, however, it is not as efficacious as LABAs and not recommended for treatment.

Anticholinergic (LAMA)
Tiotropium bromide monohydrate (Spiriva Respimat)

Inhaled Corticosteroids (ICS) (list not all inclusive):
Beclometasone dipropionate (QVAR)
Budesonide DPI (Pulmicort Flexhaler)*
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Fluticasone propionate (ArmonAir Digihaler)
Flunisolide (Aerospan)
Mometasone furoate (Asmanex Twisthaler)
Mometasone furoate (Asmanex HFA)*
Fluticasone furoate (Arnuity Ellipta)
Fluticasone propionate (Flovent Diskus)
Fluticasone propionate (Flovent HFA)
**HFA: hydrofluoroalkane propellant metered dose inhaler*
**DPI: dry powder inhaler*

Combination Long-Acting Bronchodilator and Corticosteroid (ICS+ LABA) (list not all inclusive):
Budesonide/formoterol fumarate dihydrate (Symbicort)
Fluticasone propionate/salmeterol (Advair Diskus/ Adair HFA/ AirDuo/ AirDuo RespiClick/Wixela Inhub)
Fluticasone furoate/vilanterol (Breo Ellipta)
Mometasone furoate/formoterol fumarate dihydrate (Dulera)

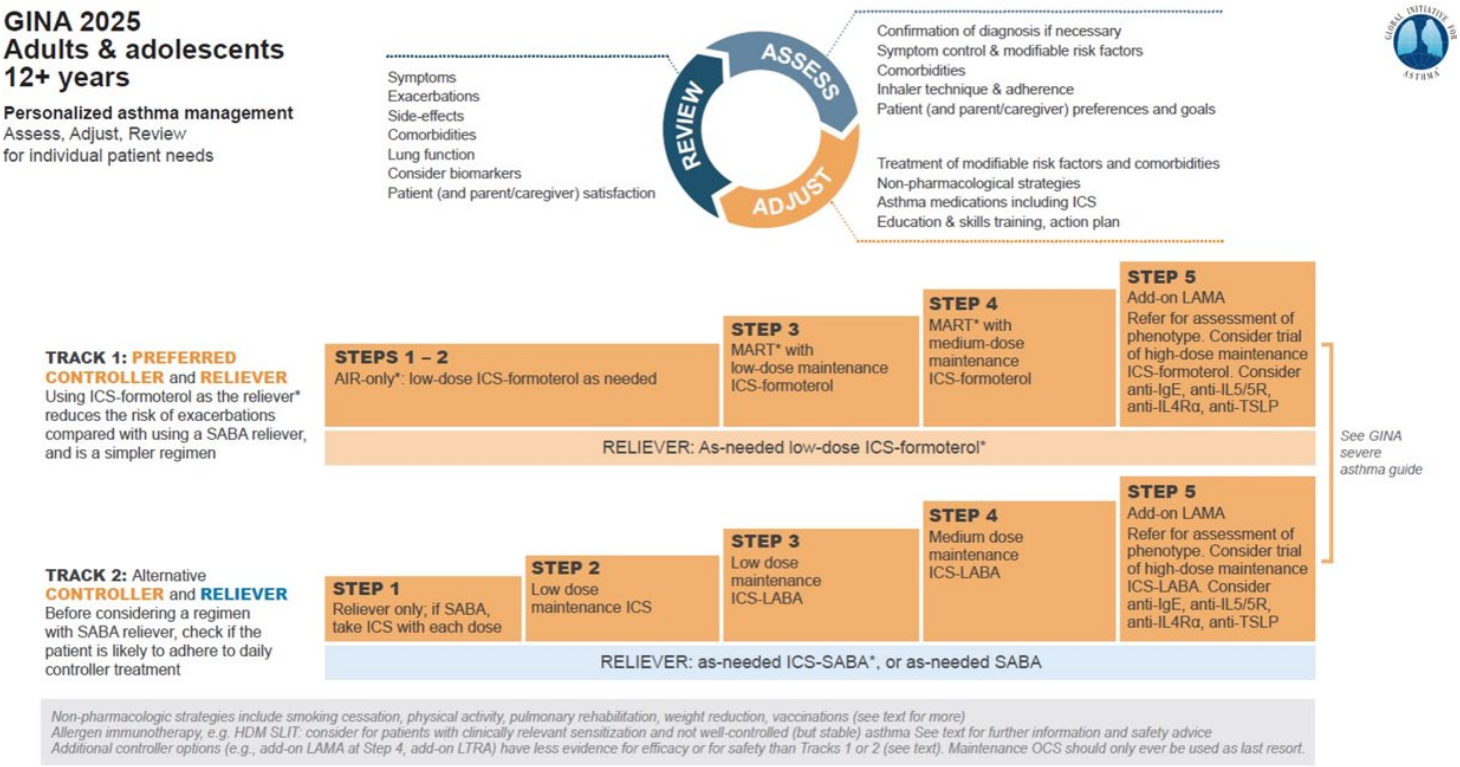
Combination Anticholinergic and Corticosteroid and long-acting bronchodilator (ICS+ LAMA+ LABA)
Fluticasone/umeclidinium/vilanterol (Trelegy Elipta)
Budesonide/glycopyrrolate/formoterol (Breztri Aerosphere)

Leukotriene receptor antagonist (LTRA) (list not all inclusive):
Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)

APPENDIX 2:
- FEV1 (forced expiratory volume in 1 second): A measure of airway obstruction determined using spirometry. Individual FEV1 values are compared to predicted values based on age, height, sex and race.
- PEF (peak expiratory flow): PEF is often described as a percent of personal best measurement.

Personal best PEF is the highest PEF value attained after 2 to 3 weeks of testing when asthma is in good control.

APPENDIX 3: Managing Asthma in Adults and Adolescents 12+ Years



ABBREVIATIONS: AIR: anti-inflammatory reliever; HDM: house dust mite; ICS: inhaled corticosteroid; Ig: immunoglobulin; IL: interleukin; LABA: long-acting beta2-agonist; LAMA: long-acting muscarinic antagonist; LTRA: Leukotriene Receptor Antagonist; MART: maintenance-and-reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta2-agonist; SLIT: sublingual immunotherapy; TSLP: thymic stromal lymphopoietin
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2025. Available from: www.ginasthma.org

APPENDIX 4: SUGGESTED TOTAL DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) IN ADULTS AND ADOLESCENTS (12 years and older):

Inhaled Corticosteroid	Low Dose ICS (mcg)	Medium Dose ICS (mcg)	High Dose ICS (mcg)
Beclometasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclometasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400	>400-800	>800
Ciclesonide (pMDI, extrafine particle, HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	100-200	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	>250-500	>500
Mometasone furoate (DPI)	Depends on DPI device – see product information		

Mometasone furoate (pMDI, standard particle, HFA)	200-400	200-400	>400

Reference: Box 4-2. Low, medium and high daily metered doses of inhaled corticosteroids (alone or with LABA) Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention,2025. Available from: www.ginasthma.org

APPENDIX 5: Blood Eosinophil Levels

Earlier studies with reslizumab indicate that eosinophilic asthma can be characterized by a sputum eosinophil count of ≥3% and that reslizumab is expected to benefit patients with asthma with sputum eosinophil count of ≥3%. The sponsor chose blood eosinophil as a surrogate of sputum eosinophilia because of the ease of obtaining in clinical practice. The sponsor selected ≥400 cells/μL as the threshold based on a secondary analysis of datasets from asthma patients that indicated blood eosinophil count of ≥400 cells/μL had a high positive predictive value for the presence of sputum eosinophils of ≥3%, and a count of <400 cells/μL identified the majority of patients without sputum eosinophilia. It should be noted that a definitive threshold value of eosinophilia has not been defined.

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Asthma is a heterogeneous syndrome that might be better described as a constellation of phenotypes, each with distinct cellular and molecular mechanisms, rather than as a singular disease. One of these phenotypes is eosinophilic asthma. Eosinophilic asthma is a sub phenotype of severe asthma characterized by elevated sputum and blood eosinophil levels as well as increased asthma severity, atopy, late-onset disease, and steroid refractoriness. Severe asthma is defined as “asthma that requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller and/or systemic corticosteroids to prevent it from becoming ‘uncontrolled’ or which remains ‘uncontrolled’ despite this therapy.” Several biomarkers including blood eosinophilic counts and sputum eosinophilic counts are used in diagnosing severe asthma with an eosinophilic phenotype. Development of eosinophilic inflammation is dependent on the biological activity of Interleukin-5 (IL-5), an inflammatory cytokine. IL-5 is responsible for growth, differentiation, recruitment, activation, and survival of eosinophils. Nucala (mepolizumab), Cinqair (reslizumab), and Fasenra (benralizumab), IL- 5 antagonist monoclonal antibodies, antagonize the IL-5/eosinophil inflammatory pathway. Nucala and Cinqair binds to IL-5, and Fasenra binds directly through the IL-5 surface receptors on eosinophils. Similar to other severe forms of asthma, the Gold Standard/International Guidelines treatment for severe asthma, including eosinophilic asthma, is high dose ICS plus a long-acting beta- 2 agonist (LABA), leukotriene modifier or theophylline and/or continuous systemic corticosteroids as background therapy. Cinqair (reslizumab), Fasenra (benralizumab), and Nucala (mepolizumab) are FDA indicated for severe eosinophilic asthma.

Cinqair (reslizumab)

- The second IL-5 monoclonal antibody to be approved in the U.S. Nucala (mepolizumab) was approved for the same indication in 2015 and was the first FDA-approved biologic agent that targets IL-5, which regulates the function of eosinophils.
- FDA approved in combination with other asthma medications for maintenance treatment of severe asthma in patients ≥ 18 years old who have history of exacerbations despite receiving their current asthma medications
- Not indicated for the relief of eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.
- Administered via IV infusion only [while Nucala (mepolizumab) and Fasenra (benralizumab) are both administered subcutaneously].
- FDA approval of reslizumab for the treatment of severe asthma with elevated level of blood eosinophils was based on the results of four Phase 3 trials (two 52-week and two 16-week trials) comparing reslizumab and placebo.

- In pivotal trials, an eosinophil phenotype was defined as a peripheral blood absolute eosinophil count of 400/microL or greater, although the threshold required for patients on systemic glucocorticoids is not clear. The primary endpoint of two of the trials was frequency of asthma exacerbations, which was significantly decreased with reslizumab therapy compared to placebo. In these studies, reslizumab reduced asthma exacerbations by approximately 50 percent and demonstrated an improvement in forced expiratory volume in one second (FEV1), except for in patients with baseline eosinophil <400 cells/μL.
- Demonstrated a modest reduction in clinical exacerbation in patients with hyper-eosinophilic asthma inadequately controlled with a LABA and ICS. Its use is limited to patients not adequately controlled with an optimized regimen that includes a LABA and ICS.

Global Initiative for Asthma (GINA, 2024)
Add-on biologic therapy: options recommended by GINA for patients with uncontrolled severe asthma despite optimized maximal therapy include:

- Add-on anti-immunoglobulin E treatment (omalizumab [Xolair]) for patients age ≥ 6 years with **severe allergic asthma** (Evidence A)
- Add-on anti-interleukin- 5/5R treatment (SC mepolizumab [Nucala] for patients age ≥ 6 years; IV reslizumab [Cinqair] for ages ≥18 years or SC benralizumab [Fasenra] for ages ≥12 years), with **severe eosinophilic asthma** (Evidence A)
- Add-on anti-interleukin-4Rα treatment (SC dupilumab [Dupixent]) for patients aged ≥ 6 years with **severe eosinophilic/type 2 asthma** or for **patients requiring treatment with maintenance OCS** (Evidence A)
- Add-On anti-thymic stromal lymphopoietin (anti TSLP) treatment (subcutaneous tezepelumab [Tezspire]) for patients aged ≥12 years with **severe asthma** (Evidence A)
- Suggested initial trial of add-on anti-IL5 for severe eosinophilic asthma is at least 4 months. At that point, response to initial trial of add-on therapy should be reviewed. There are no well-defined criteria for good response, but exacerbations, symptom control, lung function, side effects, treatment intensity, and patient satisfaction should be considered. If the response is unclear, consider extending the trial to 6-12 months. If there is no response, stop the biologic therapy and consider switching to a different targeted therapy, if available.

No significant changes in 2025.

European Respiratory Society (ERS)/American Thoracic Society (ATS)

- The guidelines recommend “While the anti-IL5 antibody, mepolizumab, was not beneficial in unselected adult patients with moderate asthma, when studied in severe asthma patients with persistent sputum eosinophilia, two anti- IL-5 antibodies, mepolizumab and reslizumab, have been shown to decrease exacerbations and oral corticosteroid use, as well as improve symptoms and lung function to varying degrees.”
- Asthma is classified as severe when it requires treatment with high-dose inhaled corticosteroids plus a second asthma controller therapy (e.g., long-acting β2-agonist), and/or systemic corticosteroids to prevent asthma from becoming or remaining uncontrolled despite this therapy.
  - Although there are no widely accepted definitions for specific asthma phenotypes, an eosinophilic phenotype (i.e., eosinophilic asthma) is generally characterized by blood and sputum eosinophilia and eosinophilic inflammation, recurrent exacerbations, and, frequently, responsiveness to corticosteroids.
  - Sputum eosinophil counts are used as a reliable biomarker for eosinophilic lung inflammation; ATS and ERS currently recommend treatment of severe asthma guided by sputum eosinophil counts in addition to clinical criteria in adults, and treatment guided by clinical criteria alone in pediatric patients. However, sputum eosinophil counts are difficult to use in routine practice because testing must be performed in specialized centers experienced in using the technique.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cinqair (reslizumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Cinqair (reslizumab) include: known hypersensitivity to reslizumab or any of its excipients (sodium acetate, acetic acid, sucrose sodium acetate trihydrate, and sucrose) or previous anaphylactic reaction to reslizumab, treatment of other eosinophilic conditions, or for the relief of acute bronchospasm or status asthmaticus.

Exclusions/Discontinuation:

If the member is a smoker, the member has been counseled regarding the benefits of smoking cessation and/or connected with a program to support smoking cessation.
Underlying conditions or triggers for asthma or pulmonary disease must be maximally managed.
Do not use concurrently with any of the following: Xolair (omalizumab) OR other IL-5 inhibitors [benralizumab (Fasenra), mepolizumab (Nucala)] OR IL-4 antagonist Dupixent (dupilumab) OR Anti-TSLP Tezspire (Tezepelumab-ekko).

OTHER SPECIAL CONSIDERATIONS:

Cinqair (reslizumab) has a black box warning for anaphylaxis and should only administered by a healthcare professional. Patients should be observed for an appropriate period of time after reslizumab administration by a health care professional prepared to manage anaphylaxis. Anaphylaxis has been observed with reslizumab infusion in 0.3% of patients in placebo-controlled clinical studies. Anaphylaxis was reported as early as the second dose of reslizumab. Anaphylaxis can be life-threatening.
No drug interaction studies have been performed. Based on in vitro data, drug interactions involving cytochrome P450 (CYP-450) 1A2, 2B6, and 3A4 are unlikely.
Safety of concurrent use of Nucala, Cinqair, Fasenra, and Dupixent with other monoclonal antibodies used to treat inflammation (TNF-inhibitors, interleukin antagonists, etc.) has not been established.
In pivotal trials, an eosinophil phenotype was defined as a peripheral blood eosinophil count of 400/microL or greater, although the threshold required for patients on systemic glucocorticoids is not clear. Three of the four pivotal studies (all except Study 4) required patients to have blood eosinophil levels ≥ 400 cells/microliter despite medium to high dose inhaled corticosteroid (ICS) therapy.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J2786	Injection, reslizumab, 1 mg

AVAILABLE DOSAGE FORMS:

Cinqair SOLN 100MG/10ML single-use vial

REFERENCES

1. Cinqair (reslizumab) injection, for intravenous use [prescribing information]. West Chester, PA: Teva Respiratory, LLC; February 2020.

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3. Bjermer L, Lemiere C, Maspero J, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil levels: a randomized phase 3 study. Chest. 2016;150:789- 798.
4. Corren J, Weinstein S, Janka L, et al. A randomized phase 3 study of reslizumab efficacy in relation to blood eosinophil levels in patients with moderate to severe asthma. Eur Respir J. 2014;44(Suppl58):4673.
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13. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org
14. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2024. Available from: www.ginasthma.org
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Contraindications/Exclusions/Discontinuation References	Q4 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Required Medical Information Continuation of Therapy Appendix References	Q4 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Appendix Background References	Q4 2023

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Appendix Background Contraindications/Exclusions/Discontinuation Other Special Considerations References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file