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 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 or predominantly eosinophil-driven disease also described as "airway eosinophilia"

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.

A. SEVERE ASTHMA WITH EOSINOPHILIC PHENOTYPE:

1. Documented diagnosis of moderate to severe asthma
AND
2. Prescriber attests or clinical reviewer has found that Cinqair (reslizumab) is NOT being prescribed as:
 - (a) 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

Drug and Biologic Coverage Criteria

(b) Concurrent therapy with other monoclonal antibodies used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [benralizumab (Fasenra), mepolizumab (Nucala)] OR IL-4 agonist Dupixent (dupilumab) OR Anti-TSLP Tezspire (Tezepelumab-ekko)]
AND

3. Documentation of one of the following [DOCUMENTATION REQUIRED]:

(a) 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

OR

(b) Member has experienced exacerbation(s) or hospitalization(s), within the last 12 months documented by any of the following:

- i. TWO (2) or more exacerbations requiring treatment with systemic corticosteroid (intramuscular, intravenous, or oral) despite the use of high-dose inhaled corticosteroids in the past 12 months **OR**
- ii. Two-fold increase or greater in the dose of systemic corticosteroid treatment for asthma exacerbations **OR**
- iii. Asthma worsens upon tapering of oral corticosteroid therapy **OR**
- iv. Mechanical ventilation in the past 12 months **OR**
- v. 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 **OR**
- vi. Forced expiratory volume in 1 second (FEV1) < 80% predicted **OR**
- vii. FEV1/forced vital capacity (FVC) < 0.80

AND

4. Symptoms inadequately controlled (as documented in criteria above) by the following adherent regimen of at least 3 months (within the past 90 days): (a) or (b)

(a) COMBINATION THERAPY of high-dose inhaled corticosteroid (ICS) **AND** an asthma controller medication with or without oral corticosteroid:

- i. Maximally tolerated dose of inhaled ICS (appropriately adjusted for age), OR Documented serious side effects, FDA labeled contraindication, or hypersensitivity to ICS [Appendix 2: Suggested total daily dosages for inhaled corticosteroids (ICS) in adults and adolescents (12 years and older) **AND**
- ii. ONE of the following ASTHMA CONTROLLER MEDICATION (LABA, LTRA, LAMA, AND theophylline), OR documented serious side effects, FDA labeled contraindication, or hypersensitivity to all these medications (LABA, LTRA, LAMA, AND theophylline)
 - Long-acting beta-2 agonist (LABA) [e.g., salmeterol products (Serevent) formoterol (Foradil)], **OR**
 - Leukotriene receptor antagonist (LTRA) [e.g., montelukast (Singulair); zafirlukast (Accolate); zileuton (Zyflo)], **OR**
 - Long-acting muscarinic antagonist (LAMA) [e.g., tiotropium bromide inhalation spray (Spiriva, Respimat)], **OR**
 - Theophylline (Theo-24, Uniphyll, TheoChron ER, generics)

OR

(b) Combination ICS/LABA at maximum recommended doses or maximally tolerated dose [i.e., fluticasone/salmeterol (Advair), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort); fluticasone/vilanterol (Breo Ellipta)]

MOLINA REVIEWER: Verify pharmacy claims for compliance with the combination therapy above within the last 90 days. For new members to Molina Healthcare, confirm medication use in medical chart history. Non-compliance, which can be documented by review of the prescription fill history, would not constitute therapeutic failure.

AND

5. Prescriber attestation that IF 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

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AND

6. Prescriber attestation that the member's underlying conditions or triggers for asthma or pulmonary disease are being maximally managed
AND
7. Documentation of member's current weight (within the last 30 days)
AND
8. FOR MEDICAL BENEFIT CLAIMS (i.e., HCPC billing by a prescriber) REQUESTS: Member has tried (30 days minimum) and failed (symptoms inadequately controlled) or has a labeled contraindication to ALL of the following preferred agents matching members diagnosis; Dupixent® (dupilumab), Fasenra® (benralizumab), Nucala (mepolizumab), Xolair (omalizumab)
OR
IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT PHARMACY REQUEST:
Documentation of trial/failure of or intolerance 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) from pre-treatment baseline 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 waking 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 2022).

AND

4. Member is currently treated and is compliant with standard therapy (e.g., inhaled corticosteroids, long-acting beta-2 agonist (LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline) within the past 90 days
AND
5. Prescriber attests or clinical reviewer has found that requested therapy is NOT prescribed for, or intended for, combination therapy or concurrent therapy with other monoclonal antibodies

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used to treat asthma [i.e., Xolair (omalizumab) OR other IL-5 inhibitors [benralizumab (Fasenra), mepolizumab (Nucala)] OR IL-4 agonist Dupixent (dupilumab) OR Anti-TSLP Tezspire (Tezepelumab-ekko)]
AND

6. Documentation of member's current weight (within the last 30 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 or 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 onsite of care, see: [Specialty Medication Administration Site of Care Coverage Criteria \(molinamarketplace.com\)](https://www.molinamarketplace.com/specialty-medication-administration-site-of-care-coverage-criteria)

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:

- 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

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Drug and Biologic Coverage Criteria

Leukotriene receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyll, TheoChron ER, generics) is also a controller agent, however, it is not as efficacious as LABAs.

Inhaled Corticosteroids (list not all inclusive):

| | |
|--|--|
| <i>Beclometasone dipropionate (QVAR)</i> | <i>Fluticasone furoate (Arnuity Ellipta)</i> |
| <i>Budesonide DPI (Pulmicort Flexhaler)</i> | <i>Fluticasone propionate (Flovent Diskus)</i> |
| <i>Budesonide nebulas (Pulmicort Respules)</i> | <i>Fluticasone propionate (Flovent HFA)</i> |
| <i>Ciclesonide (Alvesco)</i> | |
| <i>Flunisolide (Aerospan)</i> | |
| <i>Mometasone furoate (Asmanex Twisthaler)</i> | |
| <i>Mometasone furoate (Asmanex HFA*)</i> | |

*HFA: hydrofluoroalkane propellant metered dose inhaler

*DPI: dry powder inhaler

Combination Long-Acting Bronchodilator and Corticosteroid (list not all inclusive):

Budesonide/formoterol (Symbicort)
Fluticasone/salmeterol (Advair Diskus)
Fluticasone/salmeterol (Advair HFA)
Fluticasone/vilanterol (Breo Ellipta)
Mometasone/formoterol (Dulera)

Leukotriene receptor antagonist (LTRA) (list not all inclusive):

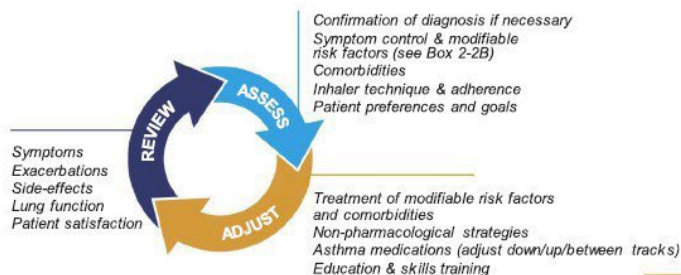
Montelukast (Singulair), Zafirlukast (Accolate), Zileuton (Zyflo)

- 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.

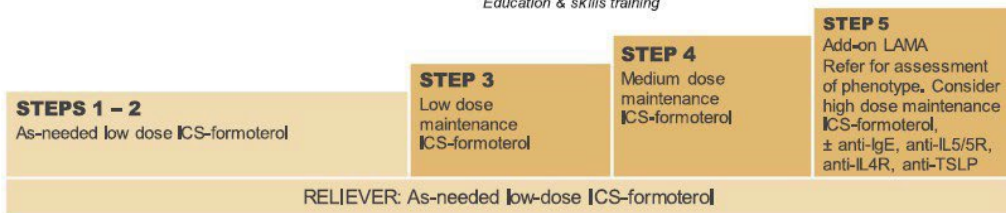
APPENDIX 1: Managing Asthma in Adults and Adolescents 12+ Years

Adults & adolescents 12+ years

Personalized asthma management
Assess, Adjust, Review
for individual patient needs

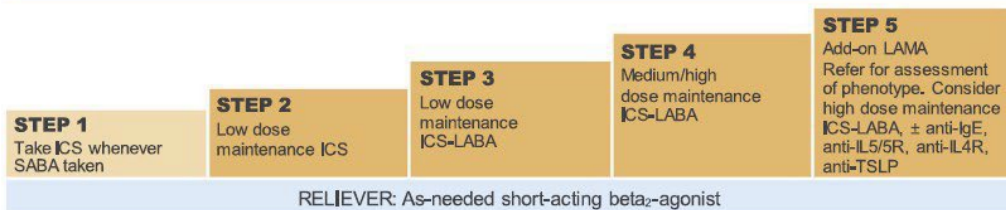


CONTROLLER and PREFERRED RELIEVER
(Track 1). Using ICS-formoterol as reliever reduces the risk of exacerbations compared with using a SABA reliever



See GINA severe asthma guide

CONTROLLER and ALTERNATIVE RELIEVER
(Track 2). Before considering a regimen with SABA reliever, check if the patient is likely to be adherent with daily controller



Other controller options for either track (limited indications, or less evidence for efficacy or safety)

| | | | | |
|--|--|---|--|--|
| | Low dose ICS whenever SABA taken, or daily LTRA, or add HDM SLIT | Medium dose ICS, or add LTRA, or add HDM SLIT | Add LAMA or LTRA or HDM SLIT, or switch to high dose ICS | Add azithromycin (adults) or LTRA. As last resort consider adding low dose OCS but consider side-effects |
|--|--|---|--|--|

GINA 2022, Box 3-5A

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ABBREVIATIONS: HDM: house dust mite; ICS: inhaled corticosteroid; LABA: long-acting beta₂-agonist; LAMA: long-acting muscarinic antagonist; LTRA: Leukotriene Receptor Antagonist; OCS: oral corticosteroids; SABA: short-acting beta₂-agonist; SLIT: sublingual immunotherapy
REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2022. Available from: www.ginasthma.org

APPENDIX 2: 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 (DIP, 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 |
| Fluticasone propionate (DPI) | 100-250 | >250-500 | >500 |
| Fluticasone propionate (pMDI, standard particle, HFA) | 100-250 | >250-500 | >500 |
| Mometasone furoate (pMDI, standard particle, HFA) | 200-400 | 200-400 | >400 |

*-Reference: Box 3-6. 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, 2022. Available from:
www.ginasthma.org*

APPENDIX 3: Blood Eosinophil Levels

Earlier studies with reslizumab indicate that eosinophilic asthma can be characterized by a sputum eosinophil count of $\geq 3\%$ and that reslizumab is expected to benefit patients with asthma with sputum eosinophil count of $\geq 3\%$. 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 $\geq 3\%$, 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

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Drug and Biologic Coverage Criteria

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/ μ L.
- 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, 2022)

- Provides a stepwise approach to asthma management, adjusting treatment in a continuous cycle of assessment, treatment, and review of the patient's response as it relates to symptom control, future risk of exacerbations, and side effects
- Cinqair (reslizumab) is recommended as add-on for patients ≥ 18 years old with severe eosinophilic asthma uncontrolled with step 4-5 treatment (GINA Evidence A). Higher blood eosinophil levels, more exacerbations in the previous year, adult-onset asthma, nasal polyposis, maintenance oral corticosteroids at baseline, and low lung function may predict a good asthma response to Cinqair.
- Anti-IL-5 therapy with mepolizumab is recommended in patients 6 years and older and benralizumab is recommended in patients 12 years and older with severe eosinophilic asthma that is uncontrolled despite optimized doses of inhaled corticosteroids (ICSs) plus long-acting beta-agonists (LABAs) with or without other controller drugs (e.g., long-acting muscarinic antagonist, leukotriene receptor antagonist, theophylline). All patients should have access to a reliever medication (SABA or low-dose ICS-formoterol) for as-needed symptom control.
- Phenotype-guided add-on treatment:
 - Patients with severe asthma, uncontrolled on Step 4 treatment, may benefit from phenotyping into categories such as severe allergic, aspirin-exacerbated or eosinophilic asthma
 - Patients > 6 years with severe allergic asthma with elevated IgE levels may benefit from omalizumab (anti-IgE) therapy (Evidence A)

Drug and Biologic Coverage Criteria

- Those with severe eosinophilic asthma may benefit from anti-IL5 therapy (subcutaneous mepolizumab (Nucala) > 6 years; intravenous reslizumab (Cinqair) > 18 years) or anti-IL receptor therapy (subcutaneous benralizumab (Fasenra) > 12 years) (Evidence A)
- LTRAs may be helpful of patients found to be aspirin sensitive (Evidence B)
- 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.

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 β 2-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

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 \geq 400 cells/microliter despite medium to high dose inhaled corticosteroid (ICS) therapy.

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

| HCPCS CODE | DESCRIPTION |
|-------------------|----------------------------|
| J2786 | injection, reslizumab, 1mg |

AVAILABLE DOSAGE FORMS:

Cinqair SOLN 100MG/10ML

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Drug and Biologic Coverage Criteria

| SUMMARY OF REVIEW/REVISIONS | DATE |
|--|----------------------------|
| 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 |
| | |