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# 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:

- Documented diagnosis of moderate to severeasthma AND
- 2. 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 (b) is not being prescribed as 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)]

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- (a) Documentation of 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
    - iii. Asthma worsens upon tapering of oral corticosteroid therapy OR
    - iv. Mechanical ventilation in the past 12months OR
    - Poor symptom control indicated by Asthma Control Questionnaire (ACQ) score consistently greater than 1.5 or Asthma Control Test (ACT) score consistentlyless than 20 OR
    - vi. Forced expiratory volume in 1 second (FEV1) < 80% predicted OR FEV1/forced vital capacity (FVC) < 0.80

AND

- 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), <u>OR</u>
     Documented intolerance, FDA labeled contraindication, or hypersensitivity to ICS
     [Appendix 2: Estimated Comparative Daily Dosages for ICS in ≥ 12 years and Adults]
     AND
  - ii. ONE of the following ASTHMA CONTROLLER MEDICATION (LABA, LRTA, LAMA, AND theophylline), OR documented intolerance, FDA labeled contraindication, or hypersensitivity to all these medications (LABA, LRTA, LAMA, AND theophylline)
    - Long-acting beta-2 agonist (LABA) [e.g., salmeterol products (Serevent)formoterol (Foradil)], OR
    - Leukotriene receptor antagonist (LRTA) [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, Uniphyl, TheoChron ER,generics)

<u>OR</u>

- (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 inwithin the last 90 days. For new members to Molina Healthcare, confirm medication usein 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

**AND** 

- Prescriber attestation that the member's underlying conditions or triggers for asthma or pulmonary disease are being maximally managed AND
- Dosing requested is within the defined dosing of the FDA-approved labeling based on member's body weight 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 alabeled 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. If yes, please 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 ESOSINOPHILIC PHENOTYPE:

- Adherence to therapy at least 85% of the time as verified by the prescriber or member medication fillhistory OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation (documentation required) AND
- 2. Member has not experienced ANY of the following: Intolerable adverse effects 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]; Poor response to treatment as evidenced by physical findings and/or clinical symptoms

AND

- 3. Documentation that Cinqair (reslizumab) therapy has resulted in clinical improvement as documented by ONE or more of the following from baseline:
  - 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 wakening wheezing, sustained improvement in Asthma Control Test (ACT) scores OR
  - e. Reduction use of ICS, leukotriene or beta agonist therapy 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 (LRTA), long-acting muscarinic antagonist (LAMA), theophylline) within thepast 90 days, OR Has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL Standard therapies AND

- 5. Requested therapy is NOT prescribed for, or intended for, combination therapy or concurrent therapy with other monoclonal antibodies used to treat asthma [i.e., Xolair(omalizumab) OR other IL-5 inhibitors [benralizumab (Fasenra), mepolizumab (Nucala)] AND
- 6. Dosing requested is within the defined dosing of the FDA-approved labeling basedon member's body weight

#### **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. Consultation notes must be submitted for initial request and for continuation of treatment requests at least ONCE annually

#### **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: <u>Specialty Medication Administration Site of Care Coverage Criteria (molinamarketplace.com)</u>

# **DRUG INFORMATION**

#### **ROUTE OF ADMINISTRATION:**

Intravenous

# **DRUG CLASS:**

Interleukin-5 Antagonists (IgG4 kappa)

#### FDA-APPROVED USES:

is indicated for add-on maintenance treatment of patients with severe asthma aged18 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 Leukotriene
receptor antagonists (LTRA). Theophylline (Theo-24, Uniphyl, TheoChron ER, generics) is also a
controller agent, however, it is not as efficacious as LABAs.

# Inhaled Corticosteroids (list not all inclusive):

Beclometasone dipropionate (QVAR)
Budesonide DPI (PulmicortFlexhaler)
Budesonide nebules (Pulmicort Respules)
Ciclesonide (Alvesco)
Flunisolide (Aerospan)
Mometasonefuroate (Asmanex Twisthaler)
Mometasone furoate (Asmanex HFA\*)

*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 (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 allinclusive):

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 andrace.
- 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 3weeks of testing when asthma is in good control.

#### APPENDIX 1: Managing Asthma in Youths > 12 years of age and adults

#### STARTING TREATMENT

#### in adult and adolescents with a diagnosis of asthma

Track 1 is preferred if the patient is likely to be poorly adherent with daily controller ICS-containing therapy is recommended eve if symptoms are infrequent, as it reduces the risk of severe exacerbations and need for OCS Short course OCS Daily Symptoms, may also be need for patients or waking with asthma once a presenting with Symptoms most week or more. severely days, or waking uncontrolled asthma and low lung Symptoms less with asthma once function **FIRST START** than 4-5 days a a week or more, STEP 5 **ASSESS:** HERE IF: Add-on LAMA STEP 4 Refer for phenotypic Medium dose STEP 3 assessment + anti-lgE anti-IL5/5R, anti-IL4R **CONTROLLER** and maintenance ICS-formoterol STEP 1 - 2 Low dose PREFERRED RELIEVER (Track Confirm diagnosis As-needed low dose ICS-formoterolt maintenance Consider high dose 1), Using ICS-formoterol as ICS-formoterol ICS-formoterol Symptom control reliever reduces the risk of and modifiable risk exacerbations compared with factors, including RELIEVER: As-needed low-dose ICS-formoterol using a SABA reliever lung function Comorbidities Short course OCS Inhaler technique Daily Symptoms, may also be need for patients and adherence or waking with Patient preferences asthma once a presenting with Symptoms most severely uncontrolled asthma and goals days, or waking with asthma once Symptoms twice and low lung **START** function a mont or more, but less than 4-5 HERE IF: Symptoms less a week or more, than twice a STEP 5 fays a week month Add-on LAMA STEP 4 Refer for phenotypic **CONTROLLER** and Medium/high dose STEP 3 assessment + anti-lgE anti-lL5/5R, anti-lL4R **ALTERNATIVE RELIEVER** maintenance ICS-STEP 2 Low dose (Track 2). Before considering LABA maintenance Low dose Consider high dose a regimen with SABA reliever, ICS-LABA maintenance ICS Take ICS whenever ICS-LABA check if the patient is likely to SABA taken be adherent with daily controller therapy RELIEVER: As-needed short-acting ß2-agonist

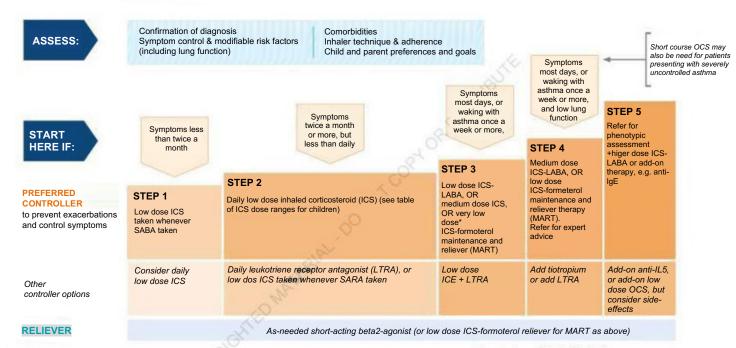
ICS: inhaled corticosteroid; LABA: long-acting beta<sub>2</sub>-agonist; LAMA: long-acting muscarinic antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA; short-acting beta<sub>2</sub>-agonist

NOTE: Alphabetical order is used when more than one treatment option is listed within either preferred or alternative therapy. ABBREVIATIONS: ICS, inhaled corticosteroid; LABA, inhaled long-acting beta2-agonist; Leukotriene Receptor Antagonists (LTRAs), SABA, inhaled short-acting beta2-agonist

REFERENCE: Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2021. Available from www.ginasthma.org

#### STARTING TREATMENT

Children 6-11 years with a diagnosis of asthma



<sup>\*</sup>Very low dose: BUD-FORM 100/6 mcg †Low dose: BUD-FORM 200/6 mcg (metered doses).

BUD-FORM: budesonide-formoterol; ICS: inhaled corticosteroid; LABA: long-acting beta<sub>2</sub>-agonist; LTRA: leukotriene receptor antagonist; MART: maintenance and reliever therapy with ICS-formoterol; OCS: oral corticosteroids; SABA: short-acting beta<sub>2</sub>-agonist

# APPENDIX 2: ESTIMATED COMPARATIVE DAILY DOSAGES for INHALED CORTICOSTEROIDS (ICS) in YOUTH ≥12 YEARS of AGE and ADULTS:



Drug	Low Daily Dose Adult	Medium Daily Dose Adult	High Daily Dose Adult
Beciomethasone HFA 40 o 80 mcg/puff	80-240 mcg	>240-80 mcg	>480 mcg
Budesonide DPI 90, 180, or 200 mcg/inhalation	180-600 mcg	>600-1,200 mcg	>1,200 mcg
Flunisolide 250 mcg/puff	500-1,000 mcg	>1,000-2,000 mcg	>2,000 mcg
Flunisolide HFA 80 mcg/puff	320 mcq	>320-640 mcg	>640 mcg
Fluticasone HFA/MDI: 44, 110 or 220 mcg/puff	88-264 mcg	>264-440 mcg	>440 mcg
<b>DPI:</b> 50, 100 or 250 mcg/inhalation	100-300 mcg	>300-500 mcg	>500 mcg
Mometasone DPI 200 mcg/inhalation	200 mcg	400 mcg	>400 mcg
Triamcinolone acetonide 75 mcg/puff	300-750 mcg	>750-1,500 mcg	>1,500 mcg

Reference: Section 4, Stepwise Approach for Managing Asthma in Youths ≥12 Years of Age and Adults Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute(US); 2007 Aug.

# **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  $\geq 400$  cells/ $\mu$ L as the threshold based on a secondary analysis of datasets from asthma patients that indicated blood eosinophil count of  $\geq 400$  cells/ $\mu$ L had a high positive predictive value for the presence of sputum eosinophils of  $\geq 3\%$ , and a count of < 400 cells/ $\mu$ L 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 aneosinophilic 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), Cingair (reslizumab), and Fasenra (benralizumab), IL- 5 antagonist monoclonal antibodies, antagonize thelL-5/eosinophil inflammatory pathway. Nucala and Cingair binds to IL-5, and Fasenra binds directly through the IL-5surface 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 firstFDA-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.</p>
- 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, 2021)

- 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 sideeffects
- Cinqair (reslizumab) is recommended as add-on for patients ≥ 18 years old with severe eosinophilic asthma uncontrolled with step 4 treatment (GINA Evidence A) Higher blood eosinophil levels, more exacerbations in the previous year, adult-onset asthma, nasal polyposis, and maintenance oral corticosteroids at baseline may predict a good asthma response to Cinqair
- Anti–IL-5 therapy (mepolizumab, reslizumab) 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 short-acting beta2-agonist
  (SABA) 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, aspirinexacerbated or eosinophilic asthma
  - Patients > 6 years with severe allergic asthma with elevated IgE levels may benefit from omalizumab (anti-IgE) therapy (Evidence A)
  - Those with severe eosinophilic asthma may benefit from anti-IL5 therapy (subcutaneous mepolizumab (Nucala) > 12 years; intravenousreslizumab (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

# A) 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; Severe hypersensitivity reaction to reslizumab or any of its excipients (glacial acetic acid, 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: 1) Concurrent Respiratory Disease: Presence of a clinically important lung condition other than asthma; 2) Concurrent use with Xolair (omalizumab) NOTE: If currently treated with Xolair(omalizumab), then Xolair (omalizumab) must be discontinued when starting Cinqair (reslizumab); 3)Concurrent use with other IL-5 inhibitors [Nucala (mepolizumab), Fasenra (benralizumab)]; 4) Known or suspected infection; Helminth infections NOTE: Members with pre-existing helminth infections should undergo treatment of the infection prior to initiation of reslizumab therapy. It is unknown if reslizumab will influence a patient's response against parasitic infections (patients with known parasitic infections were excluded from the clinical trials), AND 5) Non-FDA approved indications [includes: urticaria and other eosinophilic conditions; severe allergic asthma without documentation of severe eosinophilia]; Aspirin- exacerbated respiratory disease (AERD); Eosinophilic granulomatosis with polyangiitis (EGPA; Churg- Strauss syndrome); Hyper eosinophilic syndromes (other than severe eosinophilic asthma as indicated), including: Angiolymphoid hyperplasia, Atopic dermatitis, Eosinophilic esophagitis, Nasal polyposis, Acute bronchospasm and/or status asthmaticus

#### **OTHER SPECIAL CONSIDERATIONS:**

Cinqair (reslizumab) 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. Anaphylaxiscan 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**

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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