

Clinical Policy: Reslizumab (Cinqair)

Reference Number: CP.PHAR.223

Effective Date: 05.16

Last Review Date: 02.19

Line of Business: Commercial, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Reslizumab (Cinqair[®]) is a humanized interleukin-5 antagonist monoclonal antibody (IgG1 kappa).

FDA Approved Indication(s)

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

Limitation(s) of use: Cinqair is not indicated for treatment of other eosinophilic conditions. Cinqair is not indicated for the relief of acute bronchospasm or status asthmaticus.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Cinqair is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Severe Asthma (must meet all):

1. Diagnosis of asthma;
2. Member has an absolute blood eosinophil count ≥ 400 cells/mcL within the past 3 months;
3. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
4. Age ≥ 18 years;
5. Member has experienced ≥ 2 exacerbations within 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid (ICS) plus either a long acting beta-2 agonist (LABA) or leukotriene modifier (LTRA) if LABA contraindication/intolerance):
 - a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid);
 - b. Urgent care visit or hospital admission;
 - c. Intubation;
6. Cinqair is prescribed concomitantly with an ICS plus either a LABA or LTRA;
7. Dose does not exceed 3 mg/kg once every 4 weeks.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Severe Asthma (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus either an LABA or LTRA;
3. Member is responding positively to therapy (examples may include but are not limited to a reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume₁ over one second) since baseline; reduction in the use of rescue therapy);
4. If request is for a dose increase, new dose does not exceed 3 mg/kg once every 4 weeks.

Approval duration:

Medicaid – 12 months

Commercial – 6 months or member’s renewal period, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial and CP.PMN.53 for Medicaid or evidence of coverage documents;

- B.** Acute bronchospasm or status asthmaticus.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

GINA: Global Initiative for Asthma

ICS: inhaled corticosteroid

FDA: Food and Drug Administration

LABA: long-acting beta-agonist

LTRA: leukotriene modifier

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ICS (medium – high dose)		
Qvar [®] (beclomethasone)	> 200 mcg/day 40 mcg, 80 mcg per actuation 1-4 actuations BID	4 actuations BID
budesonide (Pulmicort [®])	> 400 mcg/day 90 mcg, 180 mcg per actuation 2-4 actuations BID	2 actuations BID
Alvesco [®] (ciclesonide)	> 160 mcg/day 80 mcg, 160 mcg per actuation 1-2 actuations BID	2 actuations BID
Aerospan [®] (flunisolide)	> 320 mcg/day 80 mcg per actuation 2-4 actuations BID	2 actuations BID
Flovent [®] (fluticasone propionate)	> 250 mcg/day 44-250 mcg per actuation 2-4 actuations BID	2 actuations BID
Arnuity Ellipta [®] (fluticasone furoate)	200 mcg/day 100 mcg, 200 mcg per actuation 1 actuation QD	1 actuation QD
Asmanex [®] (mometasone)	>220 mcg/day HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation 1-2 actuations QD to BID	2 inhalations BID
LABA		
Serevent [®] (salmeterol)	50 mcg per dose 1 inhalation BID	1 inhalation BID
Combination products (ICS + LABA)		
Dulera [®] (mometasone/formoterol)	100/5 mcg, 200/5 mcg per actuation 2 actuations BID	4 actuations per day
Breo Ellipta [®] (fluticasone/vilanterol)	100/25 mcg, 200/25 mcg per actuation 1 actuation QD	1 actuation QD
Advair [®] (fluticasone/salmeterol)	Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation 1 actuation BID	1 actuation BID
fluticasone/salmeterol (Airduo RespiClick [®])	55/13 mcg, 113/14 mcg, 232/14 mcg per actuation 1 actuation BID	1 actuation BID
Symbicort [®] (budesonide/formoterol)	80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation 2 actuations BID	2 actuations BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
LTRA		
montelukast (Singulair [®])	4 to 10 mg PO QD	10 mg per day
zafirlukast (Accolate [®])	10 to 20 mg PO BID	40 mg per day
zileuton ER (Zyflo [®] CR)	1200 mg PO BID	2400 mg per day
Zyflo [®] (zileuton)	600 mg PO QID	2400 mg per day
Oral corticosteroids		
dexamethasone (Decadron [®])	0.75 to 9 mg/day PO in 2 to 4 divided doses	Varies
methylprednisolone (Medrol [®])	40 to 80 mg PO in 1 to 2 divided doses	Varies
prednisolone (Millipred [®] , Orapred ODT [®])	40 to 80 mg PO in 1 to 2 divided doses	Varies
prednisone (Deltasone [®])	40 to 80 mg PO in 1 to 2 divided doses	Varies

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): hypersensitivity
- Boxed warning(s): none reported

Appendix D: General Information

- Cinqair is not indicated for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.
- Asthma exacerbations (primary endpoint) was defined as 1) use of systemic steroid, or \geq 2-fold increase in the use of ICS for 3 or more days; 2) asthma related emergency treatment by nebulizer, a visit to the emergency department (ED) or asthma related hospitalization.
- Controller medications are: inhaled glucocorticoids (Flovent, Pulmicort, Qvar, Asmanex), long-acting beta-agonists (LABAs) such as salmeterol, formoterol, or vilanterol, and antileukotriene agents (montelukast [Singulair], zafirlukast [Accolate] or Zyflo [zileuton]). Theophylline is also a controller agent; however, it is not as efficacious as LABAs.
- Patients could potentially meet criteria for both Xolair[®] and Cinqair. The combination has not been studied. Approximately 30% of patients in the Nucala[®] study also were candidates for therapy with Xolair.
- Positive response to therapy for asthma may include reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, or reduction in the use of rescue therapy.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Severe asthma	3 mg/kg IV every 4 weeks Cinqair should be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis.	3 mg/kg every 4 weeks

VI. Product Availability

Single-use vial: 100 mg/10 mL solution

VII. References

1. Cinqair prescribing information. Frazer, PA: Teva Pharmaceutical Industries Ltd.; May 2016. Available at <http://www.cinqair.com/pdf/PrescribingInformation.pdf>. Accessed October 23, 2018.
2. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at <http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines>. Accessed November 2017.
3. Corren J, Weinstein S, Janka L, Zangrilli J, Garin M. 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.
4. Maselli DJ, Velez MI, Rogers L. Reslizumab in the management of poorly controlled asthma: The data so far. *Journal of Asthma and Allergy*. August 31, 2016; 9: 155-162.
5. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: <http://www.clinicalpharmacology.com>. Accessed October 23, 2018.
6. Global Initiative for Asthma: Global strategy for asthma management and prevention (2018 update). Available at: <https://ginasthma.org/2018-gina-report-global-strategy-for-asthma-management-and-prevention/>. Accessed November 13, 2018.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J2786	Injection, reslizumab, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy developed.	05.16	05.16
An absolute blood eosinophil count ≥ 400 cells/mcL is added. Controller trial requirements are edited in the initial and renewal criteria and a smoking cessation line item is added. The	03.17	04.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
contraindication/hypersensitivity black box warning of anaphylaxis is not included. Efficacy statement is added to renewal criteria. Approval durations changed to 6 and 12 months.		
1Q18 annual review: - Combined Medicaid and Commercial policies - No significant changes from previously approved corporate policy - Removed smoking cessation program requirements from existing Medicaid policy as this cannot be enforced. - Added “Acute bronchospasm or status astmaticus” to section III as indications for which coverage is not authorized per PI - References reviewed and updated	11.07.17	02.18
1Q 2019 annual review: modified ICS requirement to include medium dose ICS per GINA 2018 recommendations; added option for immunologist prescribing; references reviewed and updated.	10.11.18	02.19

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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