MetroPlus Health

Policy and Procedure

Title: UM-PT002 Monoclonal antibodies	Division: Medical Management Department: Pharmacy
Approval Date: 4/28/2023	LOB: Medicaid, HIV SNP, HARP, CHP, QHP, EP, Gold, Goldcare
Effective Date: 4/28/2023	Policy Number: UM-PT002
Review Date: 3/4/2026	Cross Reference Number:
Retired Date:	Page 1 of 14

I. POLICY DESCRIPTION:

Monoclonal antibodies - Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab-ekko), Xolair (omalizumab)

II. RESPONSIBLE PARTIES:

Medical Management Administration, Pharmacy Department, Utilization Management, Integrated Care Management, Claims Department

III. DEFINITIONS:

Cinqair, Fasenra, and Nucala are interleukin-5 (IL-5) antagonists which work by blocking IL-5 binding to the alpha chain of the IL-5 receptor complex, inhibiting IL-5 signaling, reducing the production and survival of eosinophils.

Tezspire binds to human thymic stromal lymphopoietin TSLP and blocks interaction with TSLP receptor which reduces inflammatory biomarkers and cytokines such as blood eosinophils, submucosal eosinophils, IgE, IL-5 and IL-13.

Xolair is an anti-IgE antibody which works by inhibiting the binding of IgE to the high-affinity IgE receptors on mast cells and basophils.

IV. POLICY:

The use of these monoclonal antibodies will be considered medically necessary once the following coverage criteria is met as add on maintenance treatment and approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Chart notes must be submitted to confirm diagnosis and previous treatment(s).

	Indications		Drugs			
		Cinqair	Fasenra	Nucala	Tezspire	Xolair
1	Asthma	X	X	X	X	X
2	Eosinophilic granulomatosis with polyangiitis			X		
3	Hypereosinophilic syndrome (HES)			X		
4	Chronic rhinosinusitis with nasal polyps/ Nasal Polyps			X		X
5	Chronic idiopathic urticaria					X
6	IgE-Mediated Food Allergy					X

INITIAL REQUEST:

1. Severe Asthma [Fasenra, Nucala, Tezspire, Xolair]

A. Member is ONE of the following ages:

a. Cinqair: 18 years of age or older;

OR

b. Tezspire: 12 years of age or older;

OR

c. Fasenra, Nucala, Xolair: 6 years of age or older;

AND

B. Diagnosis confirmed by chart notes as defined by ONE of the following**:**

a. Experiences asthma symptoms frequently throughout the day;

OR

b. Has nighttime awakenings ≥ 7 times per week;

OR

c. Symptoms extremely interferes with normal activity;

OR

d. Lung function is defined as FEV_1 < 60% predicted; FEV1/FVC reduced > 5%;

OR

e. Individual experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year;

OR

f. Individual experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year

AND

C. Member has ONE of the following documented lab work:

a. Cinqair: Baseline blood eosinophil count of at least 400 cells per microliter;

OR

b. Fasenra, Nucala: Baseline baseline blood eosinophil count of at least 150 cells;

OR

c. Xolair: Baseline immunoglobulin E (IgE) level ≥ 30 IU/mL

AND

D. Member has documented adherence to asthma medications at optimized doses for sufficient treatment length (Medication adherence is defined as > 80% PDC, **MUST** be confirmed by paid claim or chart documentation) for ONE of the following:

a. 12 months of high-dose Inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long acting $beta_2$-agonist [LABA], or a leukotriene receptor antagonist (LTRA), or

sustained-release theophylline), unless the patient is intolerant of or has a known contraindication to these agents;
OR

b. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a LABA, or LTRA, or theophylline), unless the patient is intolerant of or has a known contraindication to these agents;

AND

E. Member will not use immunomodulators concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Xolair);

AND

F. Authorization is for no more than 6 months

2. Eosinophilic granulomatosis with polyangiitis [Nucala]

A. Member is 18 years of age or older;

AND

B. Member has a history or the presence of an eosinophil count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10%;

AND

C. Member has at least TWO of the following disease characteristics of EGPA:

- **a.** Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration, or eosinophil-rich granulomatous inflammation;
- **b.** Neuropathy, mono or poly (motor deficit or nerve conduction abnormality);
- **c.** Pulmonary infiltrates, non-fixed; sino-nasal abnormality;
- **d.** Cardiomyopathy (established by echocardiography or magnetic resonance imaging);
- **e.** Glomerulonephritis (hematuria, red cell casts, proteinuria);
- **f.** Alveolar hemorrhage (by bronchoalveolar lavage);
- **g.** Palpable purpura;
- **h.** Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinease 3)

AND

D. Member has tried ONE of the following for at least 3 months (unless intolerant or contraindicated): azathioprine, methotrexate or mycophenolate;

AND

E. Member has had at least one relapse (requiring increase in oral corticosteroids dose, initiation/increased dose of immunosuppressive therapy or hospitalization) within 2 years prior to starting treatment with Nucala or has a refractory disease;

AND

F. Authorization is for no more than 6 months

3. Hypereosinophilic syndrome (HES) [Nucala]

A. Member is 12 years of age or older;

AND

B. ONE of the following:

a. Member does not have HES secondary to a non-hematologic cause (e.g., drug hypersensitivity, parasitic helminth infection, [human immunodeficiency virus] HIV infection, non-hematologic malignancy);

OR

b. Member does not have FIP1L1-PDGFRA kinase-positive HES;

AND

C. Member has a history or presence of a blood eosinophil count of at least 1000 cells per microliter;

AND

D. Member has been on a stable dose of HES therapy for at least 4 weeks (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy);

AND

E. Member has experienced at least two HES flares within the past 12 months;

AND

F. Authorization is for no more than 6 months

4. Chronic rhinosinusitis with nasal polyps/ Nasal Polyps[Nucala, Xolair]

A. Member is 18 years of age or older;

AND

B. For Xolair, member has a baseline IgE level ≥ 30 IU/mL;

AND

C. Member has had a bilateral nasal endoscopy or anterior rhinoscopy showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril;

AND

D. Member has nasal blockage plus ONE additional symptom for at least 6 months:

a. Rhinorrhea (anterior/posterior);

OR

b. Reduction or loss of smell;

OR

c. Facial pain or pressure;

AND

E. Member has documented recent history (within 12 months) of taking at least 3 of the following topical intranasal agents for at least 3 months each: flunisolide, fluticasone, budesonide, triamcinolone acetonide;

AND

F. Member meets ONE of the following:

a. Member has received at least one course of treatment with systemic cortiscoteroid in the previous 2 years (unless intolerant or contraindicated);
OR
b. Member has had prior surgery for nasal polyps

AND

G. Member will be using a daily intranasal corticosteroid while being treated with Nucala/Xolair, unless contraindicated or not tolerated;

AND

H. Authorization is for no more than 6 months

5. Chronic idiopathic urticaria [Xolair]

A. Member is 12 years of age or older;

AND

B. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis);

AND

C. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks almost every day;

AND

D. Member has tried/failed or has history of contradiction or intolerance of ALL of the following regimen for at least 2 months each:

a. At least two second generation H1-antihistamines [e.g., Allegra (fexofenadine), Claritin (loratadine), Zyrtec (cetirizine)];

AND

b. Titrate at least two second generation H1-antihistamine to FOUR times normal dose;

AND

c. A combination: One second generation H1-antihistamine and One of the following:

i. A Different second generation H1-antihistamine (Titrated to FOUR times the normal dose);

OR

ii. A 1 st generation antihistamine to be taken at bedtime;

OR

iii. Leukotriene modifier [e.g., Singulair (montelukast)];

AND

E. Member does not have known hypersensitivity to Xolair or any of its excipients;

AND

F. Authorization is for no more than 6 months

6. IgE-Mediated Food Allergy [Xolair]

A. Member is 1 year of age or older**;**

AND

B. Member has confirmed diagnosis of IgE-mediated food allergy as demonstrated by a clinical history of IgE-mediated allergy to one or more foods that meet ALL of the following:

a. Member demonstrated signs and symptoms of a significant systemic allergic reaction;

AND

b. System allergic reaction occurred shortly after a known ingestion of the food;

AND

c. Member's prescriber concluded that reaction warranted a prescription for an epinephrine auto-injector;

AND

C. Member meets ALL of the following:

a. Positive skin prick test response to one or more foods;

AND

b. Positive in vitro test for IgE to one or more foods;

AND

D. Member has baseline IgE levels ≥ 30 IU/mL;

AND

E. Xolair is being used in conjunction to a diet that avoids food allergens;

AND

F. Member has been prescribed an epinephrine auto-injector for treating emergency allergic reactions;

AND

G. Authorization is for no more than 6 months

RENEWAL REQUEST:

1. Severe Asthma [Cinqair, Fasenra, Nucala, Tezspire, Xolair]

A. Initial conditions of coverage have been met;

AND

B. Member achieved or maintained a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when any of the following is met confirmed by clinical chart notes;

AND

C. ONE of the following reduction in the frequency and/or severity of symptoms and exacerbations:

a. A reduction in the frequency and/or severity of symptoms and exacerbations;

OR

b. A reduction in the daily maintenance oral corticosteroid dose;

AND

D. Authorization is for no more than 12 months

2. Eosinophilic granulomatosis with polyangiitis [Nucala]

A. Initial conditions of coverage have been met;

AND

B. Member is 18 years of age or older**;**

AND

C. Member has beneficial response to treatment with Nucala as demonstrated by ONE of the following:

a. A reduction in the frequency of relapses;

OR

b. A reduction in the daily oral corticosteroid dose;

OR

c. No active vasculitis;

AND

D. Authorization is for no more than 12 months

3. Hypereosinophilic syndrome (HES) [Nucala]

A. Initial conditions of coverage have been met;

AND

B. Member is 12 years of age or older;

AND

C. Member has experienced a reduction in HES flares since starting treatment with Nucala;

AND

D. Member will not use Nucala as monotherapy;

AND

E. Authorization is for no more than 12 months

4. Chronic rhinosinusitis with nasal polyps/ Nasal Polyps [Nucala, Xolair]

A. Initial conditions of coverage have been met;

AND

B. Member is 18 years of age or older;

AND

C. Member achieved or maintained a positive clinical response therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use) confirmed by clinical chart notes;

AND

D. Authorization is for no more than 12 months

5. Chronic idiopathic urticaria [Xolair]

A. Initial conditions of coverage have been met;
AND
B. Member is 12 years of age or older;
AND
C. Member achieved or maintained a positive clinical response confirmed by clinical chart notes;
AND
D. Authorization is for no more than 12 months

6. IgE-Mediated Food Allergy [Xolair]

A. Initial coverage have been met**;**
AND
B. Member is 1 year of age or older;
AND
C. Member achieved or maintained a positive clinical response confirmed by clinical chart notes;
AND
D. Authorization is for no more than 12 months

V. LIMITATIONS/ EXCLUSIONS:

The use of Nucala, Fasenra, Tezspire and Xolair is considered to be experimental and investigational if prescribed for indications that have not been approved by the FDA and will not be covered under this policy

VI. APPLICABLE PROCEDURE CODES:

CPT	Description
J0517	Injection, benralizumab, 1 mg (Fasenra)
J2182	Injection, mepolizumab, 1 mg (Nucala)
J2356	Injection, tezepelumab-ekko, 1 mg (Tezspire)
J2357	Injection, omalizumab, 5 mg (Xolair)
J2786	Injection, reslizumab, 1 mg (Cinqair)

VII. APPLICABLE DIAGNOSIS CODES:

CODE	Description
D72.110	Idiopathic hypereosinophilic syndrome
D72.111	Lymphocytic Variant Hypereosinophilic Syndrome

D72.118	Other hypereosinophilic syndrome
D72.119	Hypereosinophilic syndrome , unspecified
J01.00	Acute maxillary sinusitis, unspecified
J01.01	Acute recurrent maxillary sinusitis
J01.10	Acute frontal sinusitis, unspecified
J01.11	Acute recurrent frontal sinusitis
J01.20	Acute ethmoidal sinusitis, unspecified
J01.21	Acute recurrent ethmoidal sinusitis
J01.30	Acute sphenoidal sinusitis, unspecified
J01.31	Acute recurrent sphenoidal sinusitis
J01.40	Acute pansinusitis, unspecified
J01.41	Acute recurrent pansinusitis
J01.80	Other acute sinusitis
J01.81	Other acute recurrent sinusitis
J01.90	Acute sinusitis, unspecified
J01.91	Acute recurrent sinusitis, unspecified
J32.0	Chronic maxillary sinusitis
J32.1	Chronic frontal sinusitis
J32.2	Chronic ethmoidal sinusitis
J32.3	Chronic sphenoidal sinusitis
J32.4	Chronic pansinusitis
J32.8	Other chronic sinusitis
J32.9	Chronic sinusitis, unspecified
J33.0	Polyp of nasal cavity
J33.9	Nasal polyp, unspecified
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J45.901	Unspecified asthma with (acute) exacerbation
J45.902	Unspecified asthma with status asthmaticus
J45.909	Unspecified asthma, uncomplicated
J45.998	Other asthma
M30.1	Polyarteritis with lung involvement
M31.30	Wegener's granulomatosis without renal involvement
M31.31	Wegener's granulomatosis with renal involvement
J45.40	Moderate persistent asthma, uncomplicated

J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
L50.1	Idiopathic urticaria
Z91.010	Allergy To Peanuts
Z91.011	Allergy To Milk Products
Z91.012	Allergy To Eggs
Z91.013	Allergy To Seafood
Z91.014	Allergy To Mammalian Meats
Z91.018	Allergy To Other Foods

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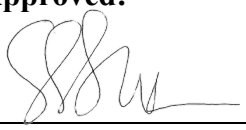
REVISION LOG:

REVISIONS	INITIAL	DATE
Creation date	SC	4/28/2023
Annual review	JL	3/4/2026

Approved:	**Date:**	**Approved:**	**Date:**
Suzana Patel	3/12/26		03.12.2026
Suzana Patel, PharmD **Senior Director of Pharmacy**		**Sanjiv Shah, MD** **Chief Medical Officer**	

Medical Guideline Disclaimer:

 The treating physician or primary care provider must submit MetroPlus Health Plan clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, Metroplus Health Plan will not be able to properly review the request for prior authorization. The clinical review criteria expressed in this policy reflects how MetroPlus Health Plan determines whether certain services or supplies are medically necessary. MetroPlus Health Plan established the clinical review criteria based upon a review of currently available clinical information(including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). MetroPlus Health Plan expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered andor paid for by MetroPlus Health Plan, as some programs exclude coverage for services or supplies that MetroPlus Health Plan considers medically necessary. If there is a discrepancy between this guidelines and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication.

MetroPlus HealthPlan has adopted the herein policy in providing management, administrative and other services to our members, related to health benefit plans offered by our organization.