

# IL-5 Inhibitors Prior Authorization with Quantity Limit Program Summary

## POLICY REVIEW CYCLE

**Effective Date**  
03-15-2026

**Date of Origin**

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Fasenra pen	benralizumab subcutaneous soln auto-injector	30 MG/ML	M ; N ; O ; Y	N		
Nucala	mepolizumab subcutaneous solution auto-injector	100 MG/ML	M ; N ; O ; Y	N		
Nucala	mepolizumab subcutaneous solution pref syringe	100 MG/ML ; 40 MG/0.4ML	M ; N ; O ; Y	N		

## POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Fasenra pen	Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML	30 MG/ML	1	Pen	28	DAYS			
Nucala	Mepolizumab Subcutaneous Solution Auto-injector 100 MG/ML	100 MG/ML	3	Pens	28	DAYS			
Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4 ML	1	Syringe	28	DAYS			
Nucala	Mepolizumab Subcutaneous Solution Pref Syringe 100 MG/ML	100 MG/ML	3	Syringes	28	DAYS			

## CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Fasenra pen	benralizumab subcutaneous soln auto-injector	30 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Nucala	mepolizumab subcutaneous solution auto-injector	100 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Nucala	mepolizumab subcutaneous solution pref syringe	100 MG/ML ; 40 MG/0.4ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Fasenra pen	Benralizumab Subcutaneous Soln Auto-injector 30 MG/ML	30 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ;

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Nucala	Mepolizumab Subcutaneous Solution Auto-injector 100 MG/ML	100 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Nucala	Mepolizumab Subcutaneous Solution Pref Syringe	40 MG/0.4ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Nucala	Mepolizumab Subcutaneous Solution Pref Syringe 100 MG/ML	100 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p><b>Initial Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. The requested agent is eligible for continuation of therapy AND the following:</li> </ol> </li> </ol>
	<p><b>Agents Eligible for Continuation of Therapy</b></p> <p>All target agents are eligible for continuation of therapy</p>
	<ol style="list-style-type: none"> <li>1. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed <b>OR</b></li> <li>B. BOTH of the following: <ol style="list-style-type: none"> <li>1. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of severe eosinophilic asthma and BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient's diagnosis has been confirmed by ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a baseline (prior to therapy with the requested agent) blood eosinophil count of 150 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids <b>OR</b></li> <li>B. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids <b>OR</b></li> <li>C. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids <b>AND</b></li> </ol> </li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a history of uncontrolled asthma while on asthma control therapy (e.g., inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following: <ol style="list-style-type: none"> <li>1. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months <b>OR</b></li> <li>2. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months <b>OR</b></li> <li>3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered <b>OR</b></li> <li>4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li> </ol> </li> </ol> </li></ol>

Module	Clinical Criteria for Approval
	<p style="text-align: center;">B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma within the past 12 months <b>OR</b></p> <p>B. The patient has a diagnosis of chronic obstructive pulmonary disease (COPD) AND ALL of the following:</p> <ol style="list-style-type: none"> <li>1. The requested agent is FDA labeled or compendia supported for COPD <b>AND</b></li> <li>2. The patient's diagnosis was confirmed by spirometry with a post-bronchodilator FEV1/FVC ratio less than 0.7 <b>AND</b></li> <li>3. The patient has an eosinophilic phenotype defined by a baseline (prior to therapy with the requested agent) blood eosinophil count of 300 cells/microliter or higher <b>AND</b></li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a history of inadequately controlled COPD while on COPD inhaled maintenance therapy as demonstrated by ONE of the following: <ol style="list-style-type: none"> <li>1. Frequent COPD exacerbations (i.e., 2 or more moderate exacerbations) requiring one or more courses of systemic corticosteroids within the past 12 months <b>OR</b></li> <li>2. A severe COPD exacerbation requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months <b>OR</b></li> </ol> </li> <li>B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of COPD within the past 12 months <b>OR</b></li> </ol> </li> </ol> <p>C. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) and ALL of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has ONE of the following:[medical records including lab results are required]: <ol style="list-style-type: none"> <li>A. Baseline (prior to therapy for the requested indication) blood eosinophil count greater than or equal to 1000 cells/microliter <b>OR</b></li> <li>B. Baseline (prior to therapy for the requested indication) blood eosinophil level greater than or equal to 10% eosinophils on white blood cell differential count <b>AND</b></li> </ol> </li> <li>2. The patient has a history or presence of asthma <b>AND</b></li> <li>3. The patient does NOT have severe disease with organ- or life-threatening manifestations (e.g., alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, limb/digit ischemia) <b>AND</b></li> <li>4. ONE of the following: <ol style="list-style-type: none"> <li>A. BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient is currently treated within the past 90 days with oral corticosteroid (OCS) therapy for at least 4 weeks <b>AND</b></li> <li>2. The patient will be using oral corticosteroid (OCS) therapy in combination with the requested agent <b>OR</b></li> </ol> </li> <li>B. The patient has an intolerance or hypersensitivity to ONE oral corticosteroid (OCS) used in the treatment of EGPA <b>OR</b></li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<ul style="list-style-type: none"> <li>C. The patient has an FDA labeled contraindication to ALL oral corticosteroids <b>AND</b></li> <li>5. The patient will be using the requested agent for ONE of the following: <ul style="list-style-type: none"> <li>A. Treatment of relapsing or refractory disease <b>OR</b></li> <li>B. Treatment for maintenance of disease remission <b>OR</b></li> </ul> </li> <li>D. The patient has a diagnosis of hypereosinophilic syndrome (HES) and ALL of the following: <ul style="list-style-type: none"> <li>1. The requested agent is FDA labeled or compendia supported for HES <b>AND</b></li> <li>2. The patient has had a diagnosis of HES for at least 6 months <b>AND</b></li> <li>3. The patient's diagnosis of HES was confirmed by BOTH of the following: <ul style="list-style-type: none"> <li>A. The patient has ONE of the following: <ul style="list-style-type: none"> <li>1. Peripheral blood eosinophil count of 1000 cells/microliter or greater <b>OR</b></li> <li>2. Percentage of eosinophils in bone marrow section exceeding 20% of all nucleated cells <b>OR</b></li> <li>3. Marked deposition of eosinophil granule proteins found <b>OR</b></li> <li>4. Tissue infiltration by eosinophils that is extensive in the opinion of a pathologist <b>AND</b></li> </ul> </li> <li>B. There has been evaluation of hypereosinophilia-related organ involvement (e.g., fibrosis of lung, heart, digestive tract, skin; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritus, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) <b>AND</b></li> </ul> </li> <li>4. The patient does NOT have an identifiable non-hematologic secondary (reactive) cause of HES (e.g., infection [e.g., HIV infection or parasitic helminth infection], allergy/atopy, medications [e.g., drug hypersensitivity], collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma [e.g., non-hematologic malignancy]) <b>AND</b></li> <li>5. The patient does NOT have FIP1L1-PDGFR<math>\alpha</math>-positive disease <b>AND</b></li> <li>6. The patient has a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) <b>AND</b></li> <li>7. The patient has ONE of the following: <ul style="list-style-type: none"> <li>A. Tried and had an inadequate response to ONE of the following: <ul style="list-style-type: none"> <li>1. Oral corticosteroid (OCS) therapy <b>OR</b></li> <li>2. Hydroxyurea <b>OR</b></li> <li>3. Interferon-<math>\alpha</math> <b>OR</b></li> <li>4. Another immunosuppressive agent (e.g., cyclosporine, methotrexate) <b>OR</b></li> </ul> </li> <li>B. An intolerance or hypersensitivity to ONE oral corticosteroid, hydroxyurea, interferon-<math>\alpha</math>, or immunosuppressive agent (e.g., cyclosporine, methotrexate) used in the treatment of HES <b>OR</b></li> <li>C. An FDA labeled contraindication to hydroxyurea, interferon-<math>\alpha</math>, and ALL oral corticosteroids and</li> </ul> </li> </ul> </li> </ul>

Module	Clinical Criteria for Approval
	<p style="text-align: center;">immunosuppressive agents (e.g., cyclosporine, methotrexate) used in the treatment of HES <b>OR</b></p> <p>E. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) <b>AND ALL</b> of the following:</p> <ol style="list-style-type: none"> <li>1. The requested agent is FDA labeled or compendia supported for CRSwNP <b>AND</b></li> <li>2. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): <ol style="list-style-type: none"> <li>A. Nasal discharge (rhinorrhea or post-nasal drainage)</li> <li>B. Nasal obstruction or congestion</li> <li>C. Loss or decreased sense of smell (hyposmia)</li> <li>D. Facial pressure or pain <b>AND</b></li> </ol> </li> <li>3. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks <b>AND</b></li> <li>4. The patient's diagnosis was confirmed by ONE of the following: <ol style="list-style-type: none"> <li>A. Anterior rhinoscopy <b>OR</b></li> <li>B. Nasal endoscopy <b>OR</b></li> <li>C. Computed tomography (CT) of the sinuses <b>AND</b></li> </ol> </li> <li>5. The patient has ONE of the following: <ol style="list-style-type: none"> <li>A. Tried and had an inadequate response to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) after at least a 4-week duration of therapy <b>OR</b></li> <li>B. An intolerance or hypersensitivity to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) <b>OR</b></li> <li>C. An FDA labeled contraindication to ALL intranasal corticosteroids <b>OR</b></li> </ol> </li> </ol> <p>F. The patient has another FDA labeled indication for the requested agent and route of administration <b>AND</b></p> <ol style="list-style-type: none"> <li>2. If the patient has an FDA labeled indication, then ONE of the following: <ol style="list-style-type: none"> <li>A. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>B. There is support for using the requested agent for the patient's age for the requested indication <b>OR</b></li> </ol> </li> <li>C. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>AND</b></li> </ol> <p>2. If the patient has a diagnosis of severe eosinophilic asthma, then ALL of the following:</p> <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient is NOT currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) <b>AND</b> is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months <b>AND</b> has been adherent for 90 days within the past 120 days [chart notes required] <b>OR</b></li> <li>2. The patient is currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) <b>AND</b> ONE of the following [chart notes required]: <ol style="list-style-type: none"> <li>A. The patient is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms <b>AND</b> has been adherent for 90 days within the past 120 days <b>OR</b></li> <li>B. The patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months <b>AND</b> has been adherent for 90 days within the past 120 days <b>OR</b></li> </ol> </li> <li>3. The patient has an intolerance or hypersensitivity to ONE inhaled corticosteroid <b>OR</b></li> <li>4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids <b>AND</b></li> </ol> </li> <li>B. ONE of the following:</li> </ol>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>1. The patient is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following [chart notes required]: <ol style="list-style-type: none"> <li>A. A long-acting beta-2 agonist (LABA) <b>OR</b></li> <li>B. A long-acting muscarinic antagonist (LAMA) <b>OR</b></li> <li>C. A leukotriene receptor antagonist (LTRA) <b>OR</b></li> <li>D. Theophylline <b>OR</b></li> </ol> </li> <li>2. The patient has an intolerance or hypersensitivity to ONE long-acting beta-2 agonist (LABA), a long-acting muscarinic antagonist (LAMA), a leukotriene receptor antagonist (LTRA), or theophylline <b>OR</b></li> <li>3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) <b>AND</b> <ol style="list-style-type: none"> <li>C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent <b>AND</b></li> </ol> </li> <li>3. If the patient has a diagnosis of chronic obstructive pulmonary disease (COPD), then ALL of the following: <ol style="list-style-type: none"> <li>A. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient is currently treated with an inhaled corticosteroid (ICS) for at least 3 months AND has been adherent for 90 days within the past 120 days [chart notes required] <b>OR</b></li> <li>2. The patient has an intolerance or hypersensitivity to ONE inhaled corticosteroid <b>OR</b></li> <li>3. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids <b>AND</b></li> </ol> </li> <li>B. The patient is currently treated with a long-acting muscarinic antagonist (LAMA) AND a long-acting beta-2 agonist (LABA) used in combination (LAMA/LABA dual therapy) for at least 3 months AND has been adherent for 90 days within the past 120 days [chart notes required] <b>AND</b></li> <li>C. The patient will continue COPD inhaled maintenance therapy (i.e., ICS/LAMA/LABA triple therapy, LAMA/LABA dual therapy) in combination with the requested agent <b>AND</b></li> </ol> </li> <li>4. If the patient has a diagnosis of hypereosinophilic syndrome (HES), then the patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-a, immunosuppressant) in combination with the requested agent <b>AND</b></li> <li>5. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), BOTH of the following: <ol style="list-style-type: none"> <li>A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) <b>AND</b></li> <li>B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent <b>AND</b></li> </ol> </li> <li>6. The prescriber is a specialist in the area of the patient's diagnosis (e.g., asthma or COPD: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; EGPA or HES: allergist, immunologist, pulmonologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>7. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>8. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Compendia Allowed:</b> AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p>

Module	Clinical Criteria for Approval
	<p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p><b>The requested agent will also be approved when ONE of the following is met:</b></p> <ol style="list-style-type: none"> <li>1. The request is for a BCBS MT Fully Insured or MT HIM member <b>AND</b> <ol style="list-style-type: none"> <li>A. The patient is under the age of 18 years old <b>AND</b></li> <li>B. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>AND</b></li> <li>D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <b>OR</b></li> </ol> </li> <li>2. ALL of the following: <ol style="list-style-type: none"> <li>A. The member resides in Ohio <b>AND</b></li> <li>B. The plan is Fully Insured or HIM Shop (SG) <b>AND</b></li> <li>C. The patient does NOT have any FDA labeled contraindications to the requested agent <b>AND</b></li> <li>D. ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has another FDA labeled indication for the requested agent and route of administration <b>OR</b></li> <li>2. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>OR</b></li> <li>3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</li> </ol> </li> </ol> </li> </ol> <p><b>Non-oncology compendia allowed:</b> DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p><b>Oncology compendia allowed:</b> NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p><b>Length of Approval:</b></p> <p>BCBSOK: 36 months</p>

Module	Clinical Criteria for Approval
	<p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p><b>Renewal Evaluation</b></p> <p><b>Target Agent(s)</b> will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> <li>1. The patient has been previously approved for the requested agent through the plan’s Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) <b>AND</b></li> <li>2. The patient has had clinical benefit with the requested agent <b>AND</b></li> <li>3. If the patient has a diagnosis of severe eosinophilic asthma, then the patient is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) [chart notes required] <b>AND</b></li> <li>4. If the patient has a diagnosis of chronic obstructive pulmonary disease (COPD), then the patient is currently treated within the past 90 days and is compliant with COPD inhaled maintenance therapy (i.e., inhaled corticosteroid [ICS]/long-acting muscarinic antagonist [LAMA]/long-acting beta-2 agonist [LABA] triple therapy, LAMA/LABA dual therapy) [chart notes required] <b>AND</b></li> <li>5. If the patient has a diagnosis of hypereosinophilic syndrome (HES), then the patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-a, immunosuppressant) in combination with the requested agent <b>AND</b></li> <li>6. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then the patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent <b>AND</b></li> <li>7. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., asthma or COPD: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; EGPA or HES: allergist, immunologist, pulmonologist, rheumatologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>8. ONE of the following (Please refer to “Agents NOT to be used Concomitantly” table): <ol style="list-style-type: none"> <li>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) <b>OR</b></li> <li>B. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND BOTH</b> of the following: <ol style="list-style-type: none"> <li>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent <b>AND</b></li> <li>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>9. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Length of Approval:</b></p> <p>BSBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

**QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL**

Module	Clinical Criteria for Approval
	<p><b>Quantity Limit for the Target Agent(s)</b> will be approved when ONE of the following is met:</p>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> <li>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:               <ol style="list-style-type: none"> <li>A. BOTH of the following:                   <ol style="list-style-type: none"> <li>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for therapy with a higher dose for the requested indication <b>OR</b></li> </ol> </li> <li>B. BOTH of the following:                   <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit</li> </ol> </li> </ol> </li> </ol> <p><b>Length of Approval:</b> 12 months</p>

## CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p><b>Agents NOT to be used Concomitantly</b></p> <p>Abrilada (adalimumab-afzb)            Actemra (tocilizumab)            Adalimumab            Adbry (tralokinumab-ldrm)            Amjevita (adalimumab-atto)            Arcalyst (rilonacept)            Avsola (infliximab-axxq)            Avtozma (tocilizumab-anoh)            Benlysta (belimumab)            Bimzelx (bimekizumab-bkzx)            Cibirgo (abrocitinib)            Cimzia (certolizumab)            Cinqair (reslizumab)            Cosentyx (secukinumab)            Cyltezo (adalimumab-adbm)            Dupixent (dupilumab)            Ebglyss (lebrikizumab-lbkz)            Enbrel (etanercept)            Entyvio (vedolizumab)            Fasentra (benralizumab)            Hadlima (adalimumab-bwwd)            Hulio (adalimumab-fkjp)            Humira (adalimumab)            Hyrimoz (adalimumab-adaz)            Idacio (adalimumab-aacf)            Ilaris (canakinumab)            Ilumya (tildrakizumab-asmn)            Imuldosa (ustekinumab-srlf)            Inflectra (infliximab-dyyb)            Infliximab            Kevzara (sarilumab)            Kineret (anakinra)            Leqselvi (deuruxolitinib)            Litfulo (ritlectinib)            Nemluvio (nemolizumab-ilto)            Nucala (mepolizumab)            Olumiant (baricitinib)</p>

**Contraindicated as Concomitant Therapy**

Omlyclo (omalizumab-igec)  
Omvoh (mirikizumab-mrkz)  
Opzelura (ruxolitinib)  
Orencia (abatacept)  
Otezla (apremilast)  
Otezla XR (apremilast extended-release)  
Otulfi (ustekinumab-aauz)  
Pyzchiva (ustekinumab-ttwe)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Rhapsido (remibrutinib)  
Riabni (rituximab-arrx)  
Rinvoq (upadacitinib)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Saphnelo (anifrolumab-fnia)  
Selarsdi (ustekinumab-aekn)  
Siliq (brodalumab)  
Simlandi (adalimumab-ryvk)  
Simponi (golimumab)  
Simponi ARIA (golimumab)  
Skyrizi (risankizumab-rzaa)  
Sotyktu (deucravacitinib)  
Spevigo (spesolimab-sbzo) subcutaneous injection  
Starjemza (ustekinumab-hmny)  
Stelara (ustekinumab)  
Steqeyma (ustekinumab-stba)  
Taltz (ixekizumab)  
Tezspire (tezepelumab-ekko)  
Tofidence (tocilizumab-bavi)  
Tremfya (guselkumab)  
Truxima (rituximab-abbs)  
Tyenne (tocilizumab-aazg)  
Tyruko (natalizumab-sztn)  
Tysabri (natalizumab)  
Ustekinumab  
Velsipity (etrasimod)  
Wezlana (ustekinumab-auub)  
Xeljanz (tofacitinib)  
Xeljanz XR (tofacitinib extended release)  
Xolair (omalizumab)  
Yesintek (ustekinumab-kfce)  
Yuflyma (adalimumab-aaty)  
Yusimry (adalimumab-aqvh)  
Zeposia (ozanimod)  
Zymfentra (infliximab-dyyb)