



IL-4 Inhibitors Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
04-01-2026

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
Dupixent	dupilumab subcutaneous soln auto-injector ; dupilumab subcutaneous soln prefilled syringe	200 MG/1.14ML ; 300 MG/2ML	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
Dupixent	Dupilumab Subcutaneous Soln Pen-injector 200 MG/1.14ML	200 MG/1.14 ML	2	Pens	28	DAYS	2 pens=2.28 mLs		
Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	2	Pens	28	DAYS			
Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14 ML	2	Syringes	28	DAYS	2 syringes = 2.28 mL		
Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	2	Syringes	28	DAYS			

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027302000D515	Dupixent	Dupilumab Subcutaneous Soln Pen-injector 200 MG/1.14ML	200 MG/1.14 ML	2 pens=2.28 mLs		09-23-2024	

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
9027302000E515	Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14 ML	2 syringes = 2.28 mL			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Dupixent	dupilumab subcutaneous soln auto-injector ; dupilumab subcutaneous soln prefilled syringe	200 MG/1.14ML ; 300 MG/2ML	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
Dupixent	Dupilumab Subcutaneous Soln Pen-injector 200 MG/1.14ML	200 MG/1.14ML	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
Dupixent	Dupilumab Subcutaneous Soln Pen-injector 300 MG/2ML	300 MG/2ML	Balanced ; Balanced Biosimilar ; Basic ; Enhanced ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; 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

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Select Biosimilar ; Topaz ; Whole Foods
Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 200 MG/1.14ML	200 MG/1.14ML	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
Dupixent	Dupilumab Subcutaneous Soln Prefilled Syringe 300 MG/2ML	300 MG/2ML	Balanced ; Balanced Biosimilar ; Basic ; Enhanced ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM Performance Full ; OK Performance Full ; Performance ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

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	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is eligible for continuation of therapy AND the following: <div style="border: 1px solid black; padding: 5px; margin: 10px auto; width: fit-content;"> <p style="text-align: center;">Agents Eligible for Continuation of Therapy</p> <p style="text-align: center;">All target agents are eligible for continuation of therapy</p> </div> 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 OR B. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has at least 10% body surface area involvement OR

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	<ul style="list-style-type: none"> B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) OR C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 OR D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 AND <p>2. ONE of the following:</p> <ul style="list-style-type: none"> A. BOTH of the following: <ul style="list-style-type: none"> 1. The patient has ONE of the following: <ul style="list-style-type: none"> A. Tried and had an inadequate response to ONE at least medium-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy OR B. An intolerance or hypersensitivity to ONE at least medium-potency topical corticosteroid used in the treatment of AD OR C. An FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD AND 2. The patient has ONE of the following: <ul style="list-style-type: none"> A. Tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy OR B. An intolerance or hypersensitivity to ONE topical calcineurin inhibitor used in the treatment of AD OR C. An FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD OR B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of AD OR <p>B. The patient has a diagnosis of moderate-to-severe asthma AND BOTH of the following:</p> <ul style="list-style-type: none"> 1. ONE of the following: <ul style="list-style-type: none"> A. The patient has eosinophilic type asthma AND the diagnosis has been confirmed by ONE of the following: <ul style="list-style-type: none"> 1. 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 OR 2. The patient has a fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled

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	<p style="text-align: right;">corticosteroids or daily oral corticosteroids OR</p> <p>3. The patient has sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids OR</p> <p>B. The patient has oral corticosteroid dependent type asthma AND</p> <p>2. ONE of the following:</p> <p>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:</p> <ol style="list-style-type: none"> 1. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months OR 2. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months OR 3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered OR 4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted OR <p>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 OR</p> <p>C. The patient has a diagnosis of bullous pemphigoid (BP) AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient has clinical features of BP (e.g., urticarial or eczematous or erythematous plaques, bullae, pruritus) AND 2. The patient's diagnosis was confirmed after evaluating findings from histopathologic, immunopathologic, and serologic assessment AND 3. The patient has a baseline (prior to therapy with the requested agent) Bullous Pemphigoid Disease Area Index (BPDAI) activity score of greater than or equal to 24 AND 4. The patient has ONE of the following: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE super-potent topical corticosteroid (e.g., clobetasol propionate) used in the treatment of BP after at least a 4-week duration of therapy OR B. Tried and had an inadequate response to ONE oral corticosteroid started at a dose of at least 0.5 mg prednisone/kg/day (or an equivalent) used in the treatment of BP after at least a 3-week duration of therapy (NOTE: tapering of the dose within the 3-week duration is approvable) OR C. An intolerance or hypersensitivity to ONE super-potent topical corticosteroid or oral corticosteroid used in the treatment of BP OR D. An FDA labeled contraindication to ALL super-potent topical corticosteroids AND oral corticosteroids used in the treatment of BP OR

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	<p>D. The patient has a diagnosis of chronic obstructive pulmonary disease (COPD) AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient's diagnosis was confirmed by spirometry with a post-bronchodilator FEV1/FVC ratio less than 0.7 AND 2. 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 AND 3. ONE of the following: <ol style="list-style-type: none"> 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"> 1. Frequent COPD exacerbations (i.e., 2 or more moderate exacerbations) requiring one or more courses of systemic corticosteroids within the past 12 months OR 2. A severe COPD exacerbation requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months OR 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 OR <p>E. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): <ol style="list-style-type: none"> A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain AND 2. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks AND 3. The patient's diagnosis was confirmed by ONE of the following: <ol style="list-style-type: none"> A. Anterior rhinoscopy OR B. Nasal endoscopy OR C. Computed tomography (CT) of the sinuses AND 4. The patient has ONE of the following: <ol style="list-style-type: none"> 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 OR B. An intolerance or hypersensitivity to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) OR C. An FDA labeled contraindication to ALL intranasal corticosteroids OR <p>F. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following:</p> <ol style="list-style-type: none"> 1. The patient has had hives and itching for more than 6 weeks AND 2. The prescriber has evaluated the patient to determine if the patient is currently treated with medication known to cause or worsen urticaria (e.g., NSAIDs) in order to reduce urticaria risk AND

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	<p>3. The patient has ONE of the following:</p> <ul style="list-style-type: none"> A. Tried and had an inadequate response to the FDA labeled maximum dose of ONE second-generation H1-antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has tried and had an inadequate response to a maximally tolerated dose of ONE second-generation H1-antihistamine titrated up to 4 times above the FDA labeled maximum dose after at least a 2-week duration of therapy OR 2. There is support that the patient cannot be treated with a second-generation H1-antihistamine at a dose above the FDA labeled maximum dose OR B. An intolerance or hypersensitivity to ONE second-generation H1-antihistamine OR C. An FDA labeled contraindication to ALL second-generation H1-antihistamines OR <p>G. The patient has a diagnosis of eosinophilic esophagitis (EoE) AND BOTH of the following:</p> <ul style="list-style-type: none"> 1. The patient's diagnosis has been confirmed by ALL of the following: <ul style="list-style-type: none"> A. Chronic symptoms of esophageal dysfunction AND B. Greater than or equal to 15 eosinophils per high-power field on esophageal biopsy AND C. Other causes that may be responsible for or contributing to symptoms and esophageal eosinophilia have been ruled out AND 2. The patient has ONE of the following: <ul style="list-style-type: none"> A. Tried and had an inadequate response to ONE standard corticosteroid therapy (i.e., budesonide oral suspension, swallowed budesonide nebulizer suspension, swallowed fluticasone from a metered dose inhaler [MDI]) used in the treatment of EoE after at least an 8-week duration of therapy OR B. An intolerance or hypersensitivity to ONE standard corticosteroid therapy used in the treatment of EoE OR C. An FDA labeled contraindication to ALL standard corticosteroid therapies used in the treatment of EoE OR D. Tried and had an inadequate response to ONE proton pump inhibitor (PPI) used in the treatment of EoE after at least an 8-week duration of therapy OR E. An intolerance or hypersensitivity to ONE PPI used in the treatment of EoE OR F. An FDA labeled contraindication to ALL PPIs used in the treatment of EoE OR <p>H. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following:</p> <ul style="list-style-type: none"> 1. The patient has ALL of the following features associated with PN: <ul style="list-style-type: none"> A. Presence of greater than or equal to 20 firm, nodular lesions AND B. Pruritus that has lasted for at least 6 weeks AND C. History and/or signs of repeated scratching, picking, or rubbing AND

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	<p>2. ONE of the following:</p> <p>A. BOTH of the following:</p> <p>1. ONE of the following:</p> <p>A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR</p> <p>B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND</p> <p>2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR</p> <p>B. The patient has ONE of the following:</p> <p>1. Tried and had an inadequate response to ONE at least medium-potency topical corticosteroid used in the treatment of PN after at least a 2-week duration of therapy OR</p> <p>2. An intolerance or hypersensitivity to ONE at least medium-potency topical corticosteroid used in the treatment of PN OR</p> <p>3. An FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of PN OR</p> <p>C. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of PN OR</p> <p>I. The patient has another FDA labeled indication for the requested agent and route of administration AND</p> <p>2. If the patient has an FDA labeled indication, then ONE of the following:</p> <p>A. The patient's age is within FDA labeling for the requested indication for the requested agent OR</p> <p>B. There is support for using the requested agent for the patient's age for the requested indication OR</p> <p>C. The patient has another indication that is supported in compendia for the requested agent and route of administration AND</p> <p>2. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then BOTH of the following:</p> <p>A. The patient is currently treated with topical emollients and practicing good skin care AND</p> <p>B. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent AND</p> <p>3. If the patient has a diagnosis of bullous pemphigoid (BP), then ONE of the following:</p>

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	<ul style="list-style-type: none"> A. The patient will be using a tapering course of an oral corticosteroid started at a dose of at least 0.5 mg prednisone/kg/day (or an equivalent) in combination with the requested agent OR B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL oral corticosteroids used in the treatment of BP OR C. The patient is currently treated with the requested agent AND after achieving initial control of disease activity, concurrent oral corticosteroids were tapered and discontinued AND <p>4. If the patient has a diagnosis of chronic obstructive pulmonary disease (COPD), then ALL of the following:</p> <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 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] OR 2. The patient has an intolerance or hypersensitivity to ONE inhaled corticosteroid OR 3. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids AND 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] AND 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 AND <p>5. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then BOTH of the following:</p> <ul style="list-style-type: none"> 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]) AND 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 AND <p>6. If the patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]), then ONE of the following:</p> <ul style="list-style-type: none"> A. BOTH of the following: <ul style="list-style-type: none"> 1. The patient is currently treated with second-generation H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND 2. The patient will continue second-generation H1-antihistamine therapy in combination with the requested agent OR B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines AND <p>7. If the patient has a diagnosis of moderate-to-severe asthma, then ALL of the following:</p> <ul style="list-style-type: none"> A. ONE of the following: <ul style="list-style-type: none"> 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) AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days [chart notes required] OR 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) AND ONE of the following [chart notes required]: <ul style="list-style-type: none"> A. The patient is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days OR B. The patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days OR

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	<p>3. The patient has an intolerance or hypersensitivity ONE inhaled corticosteroid OR</p> <p>4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids AND</p> <p>B. ONE of the following:</p> <p>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]:</p> <p>A. A long-acting beta-2 agonist (LABA) OR</p> <p>B. A long-acting muscarinic antagonist (LAMA) OR</p> <p>C. A leukotriene receptor antagonist (LTRA) OR</p> <p>D. Theophylline OR</p> <p>2. The patient has an intolerance or hypersensitivity to ONE long-acting beta-2 agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline OR</p> <p>3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) AND</p> <p>C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent AND</p> <p>8. If the patient has a diagnosis of eosinophilic esophagitis (EoE), the patient weighs 15 kg or greater AND</p> <p>9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., AD, BP, CSU, or PN: dermatologist, allergist, immunologist; asthma or COPD: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, pulmonologist; EoE: allergist, immunologist, gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>10. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):</p> <p>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) OR</p> <p>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:</p> <p>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND</p> <p>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND</p> <p>11. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</p> <p>Length of Approval:</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>The requested agent will also be approved when ONE of the following is met:</p> <p>1. The request is for a BCBS MT Fully Insured or MT HIM member AND</p> <p>A. The patient is under the age of 18 years old AND</p> <p>B. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>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</p>

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	<p>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] AND</p> <p>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] OR</p> <p>2. ALL of the following:</p> <p>A. The member resides in Ohio AND</p> <p>B. The plan is Fully Insured or HIM Shop (SG) AND</p> <p>C. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>D. ONE of the following:</p> <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 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] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: 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>Length of Approval:</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>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 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) AND 2. The patient has had clinical benefit with the requested agent AND 3. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then the patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent AND 4. If the patient has a diagnosis of moderate-to-severe 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 [LABA], leukotriene receptor

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	<p>antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) [chart notes required] OR</p> <ol style="list-style-type: none"> 5. 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] OR 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 AND 7. If the patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]), then ONE of the following: <ol style="list-style-type: none"> A. The patient will continue second-generation H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in combination with the requested agent OR B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines AND 8. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., AD, BP, CSU, or PN: dermatologist, allergist, immunologist; asthma or COPD: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, pulmonologist; EoE: allergist, immunologist, gastroenterologist), or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND 9. ONE of the following (please refer to “Agents NOT to be used Concomitantly” table): <ol style="list-style-type: none"> 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) OR 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"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND 2. There is support for use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND 10. The patient does NOT have any FDA labeled contraindications to the requested agent <p>Length of Approval:</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>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND

Module	Clinical Criteria for Approval
	<p>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</p> <p>Length of Approval: 12 months</p> <p><u>Note:</u> If approving initial loading dose, the loading dose plus maintenance dose may be approved for 1 month per FDA labeling, followed by maintenance dosing for the remainder of the length of approval.</p>

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p>Agents NOT to be used Concomitantly</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) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (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 (ritlecitinib) Nemluvio (nemolizumab-ilto) Nucala (mepolizumab) Olumiant (baricitinib) Omlyclo (omalizumab-igec) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Otezla XR (apremilast extended-release) Otulfi (ustekinumab-aauz)</p>

Contraindicated as Concomitant Therapy

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)