# Tezspire (tezepelumab-ekko) Medical Drug Criteria Program Summary

## POLICY REVIEW CYCLE

**Effective Date** 06-16-2025

**Date of Origin**

## FDA LABELED INDICATIONS AND DOSAGE

| Agent(s) | FDA Indication(s) | Notes | Ref# |
|---|---|---|---|
| Tezspire®<br><br>(tezepelumab-ekko)<br><br>Subcutaneous injection | Add-on maintenance treatment of adult and pediatric patients 12 years and older with severe asthma<br><br>Limitation of use:<br><br>• Not indicated for the relief of acute bronchospasm or status asthmaticus | | 1 |

*See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm*

## CLINICAL RATIONALE

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| Asthma | Asthma is a chronic inflammatory disorder of the airways. It is characterized by a history of respiratory symptoms along with variable expiratory airflow limitation, and is typically associated with bronchial hyperresponsiveness and underlying inflammation. Symptoms are variable and recurrent and include wheezing, coughing, shortness of breath, and chest tightness. Exercise, exposure to allergens and irritants, infections, and changes in the weather can be contributing factors to the variability in symptoms and airflow limitation.(3) Guidelines recommend evaluating respiratory symptoms, medical history, physical examination, and spirometry to determine a diagnosis of asthma.(2,3) Long-term goals for asthma management are to achieve control of symptoms, maintain normal activity level, and to minimize the future risk of exacerbations, decline in lung function, and medication side effects.(3)<br><br>Different types of asthma and levels of severity exist. Moderate asthma is asthma that requires a low- or medium-dose inhaled corticosteroid (ICS) used in combination with a long-acting beta agonist (LABA) to be well controlled. Severe asthma is asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA, or that requires high-dose ICS-LABA or biologic therapy to prevent it from becoming uncontrolled (e.g., asthma worsens when high-dose treatment is decreased). Severe asthma needs to be distinguished from difficult-to-treat asthma that remains symptomatic due to poor adherence, poor inhaler technique, comorbidities, and/or continued exposure to environmental agents since treatment and management differs between the two.(3) The European Respiratory Society (ERS)/American Thoracic Society (ATS) guidelines (2014; updated 2020) define uncontrolled asthma for adults and pediatric patients 6 years of age and older as a patient having at least one of the following:(4)<br><br>• Frequent severe exacerbations (i.e., two or more bursts of systemic corticosteroids within the past 12 months)<br>• Serious exacerbations (i.e., at least one hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months) |


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| | • Airflow limitation (i.e., FEV1 less than 80% predicted)<br>• Asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids (or additional biologics)<br><br>The Type 2 inflammatory asthma phenotype is found in the majority of people with severe asthma. Type 2 inflammation involves a systemic allergic response and elevated levels of Type 2 inflammatory cytokines such as interleukin (IL)-4, IL-5, and IL-13. Elevated eosinophils or an increased fractional exhaled nitric oxide (FeNO) are characteristics of the eosinophilic subtype of Type 2 inflammatory asthma, while the allergic asthma subtype is additionally characterized by elevated immunoglobulin E (IgE) levels and positive skin prick testing with common environmental allergens. Type 2 inflammation typically responds well to ICS treatment and rapidly improves, however, in severe asthma Type 2 inflammation may be relatively refractory to high-dose ICS. Maintenance oral corticosteroids (OCS) may elicit a response, but the risk of serious adverse effects with daily OCS use deters their usefulness and an alternative treatment should be sought.(3) Type 2 inflammation is considered refractory if any of the following are found while the patient is taking high dose ICS or daily OCS:(3)<br><br>• Blood eosinophils greater than or equal to 150 cells/microliter<br>• FeNO greater than or equal to 20 ppb<br>• Sputum eosinophils greater than or equal to 2%<br>• Asthma is clinically allergen-driven<br><br>The Global Initiative for Asthma (GINA) guidelines recommend a stepwise approach for managing asthma. The 2024 GINA guidelines recommend all patients 6 years of age and older with asthma should receive ICS-containing controller medication to reduce the risk of serious exacerbation, even in patients with infrequent symptoms. It is recommended that patients with asthma symptoms most days should be started on low dose maintenance ICS-formoterol or an alternative ICS-LABA product. Patients' response to treatment should be reviewed after 2 to 3 months. If symptoms remain uncontrolled despite good adherence and correct inhaler technique, the next step up (Step 4) involves increasing controller therapy to medium or high dose ICS-formoterol (ICS-LABA). Other controller options that may be added on to ICS treatment at Step 4 include a long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline. Both LTRA and theophylline are considered less efficacious than adding on a LABA or LAMA, and also come with safety concerns. Patients with uncontrolled symptoms and/or exacerbations despite being on Step 4 treatment for 3 to 6 months should be assessed for contributory factors, have their treatment optimized, and be referred for expert assessment, phenotyping, and potential add on biologic therapy. Maintenance oral corticosteroids (OCS) should be used only as last resort because short-term and long-term systemic side-effects are common and serious.(3)<br><br>Biologic agents should be considered as add-on therapy for patients with refractory Type 2 inflammation with exacerbations and/or poor symptom control despite taking at least high dose ICS-LABA, and who have allergic or eosinophilic biomarkers or need maintenance OCS, and only after treatment has been optimized.(3) Tezepelumab is considered a broad-acting biologic and may be considered in patients without a Type 2 inflammatory phenotype due to it binding to circulating thymic stromal lymphopoietin (TSLP), which is upstream on the inflammatory cascade.(3,5) Based on efficacy results from clinical trials, the indication of use for tezepelumab is not restricted to a biomarker-defined phenotype.(5) 2024 GINA guidelines recommend the use of biologics based on the following patient eligibility factors:(3)<br><br>• Anti-IgE (omalizumab) for moderate to severe allergic asthma<br>  ○ Sensitization to inhaled allergen(s) on skin prick testing for specific IgE<br>  ○ Total serum IgE and body weight within dosing range<br>  ○ Exacerbations within the last year<br>• Anti-IL5 (mepolizumab, reslizumab) /Anti-IL5Ra (benralizumab) for severe eosinophilic asthma |


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| | ○ Blood eosinophils greater than or equal to 150 cells/microliter or greater than or equal to 300 cells/microliter<br>○ Severe exacerbations within the last year<br>• Anti-IL4Ra (dupilumab) for severe eosinophilic/Type 2 asthma or patients requiring maintenance OCS<br>○ Blood eosinophil greater than or equal to 150 cells/microliter but less than or equal to 1500 cells/microliter, or FeNO greater than or equal to 25 ppb, or taking maintenance OCS<br>○ Severe exacerbations within the last year<br>• Anti-TSLP (tezepelumab) for severe asthma<br>○ Severe exacerbations within the last year<br><br>Patient response to biologic therapy should be evaluated 4 months after initiating therapy, and the patient should be re-evaluated every 3 to 6 months. If response is unclear after 4 months, the trial should be extended to 6-12 months.(3)<br><br>2024 GINA guidelines recommend the following step-down therapy process in patients responding well to targeted biologic therapy:(3)<br><br>• Re-evaluate the need for each asthma medication every 3 to 6 months, but inhaled therapy (e.g., ICS-containing therapy) should not be completely stopped<br>• The order of reduction of treatments should be based on observed benefit, potential side-effects, cost, and patient preference. However, minimizing the use of OCS is a very high priority.<br>• First, consider decreasing/stopping OCS due to their significant adverse effects. Then consider stopping other add-on asthma medications.<br>• Then, if asthma is well controlled for 3-6 months, consider reducing maintenance ICS dose, but do not stop maintenance ICS-containing therapy (e.g., ICS-LABA)<br>• Re-evaluate the need for ongoing biologic therapy, but a trial of withdrawal of the biologic should not be considered until after at least 12 months of treatment and only if asthma remains well controlled on medium-dose ICS-containing therapy<br>○ For allergic asthma, also confirm there is no further exposure to an allergic trigger |
| Efficacy | The efficacy of Tezspire was evaluated in two randomized, double-blind, parallel group, placebo-controlled clinical trials (PATHWAY [NCT02054130] and NAVIGATOR [NCT03347279]) of 52 weeks duration. The two trials enrolled a total of 1609 patients 12 years of age and older with severe asthma.(1)<br><br>PATHWAY was a 52-week dose-ranging exacerbation trial that enrolled 550 adult patients with severe asthma who received treatment with tezepelumab-ekko 70 mg subcutaneously every 4 weeks, Tezspire 210 mg subcutaneously every 4 weeks, tezepelumab-ekko 280 mg subcutaneously every 2 weeks, or placebo subcutaneously. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or 1 asthma exacerbation resulting in hospitalization in the past 12 months.(1)<br><br>NAVIGATOR was a 52-week exacerbation trial that enrolled 1061 patients (adult and pediatric patients 12 years of age and older) with severe asthma who received treatment with Tezspire 210 mg subcutaneously every 4 weeks or placebo subcutaneously every 4 weeks. Patients were required to have a history of 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment or resulting in hospitalization in the past 12 months.(1)<br><br>In both PATHWAY and NAVIGATOR, patients were required to have an Asthma Control Questionnaire 6 (ACQ-6) score of 1.5 or more at screening and reduced lung function at baseline [pre-bronchodilator forced expiratory volume in 1 second (FEV1) below |


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| | 80% predicted in adults, and below 90% predicted in adolescents]. Patients were required to have been on regular treatment with medium or high-dose inhaled corticosteroids (ICS) and at least one additional asthma controller, with or without oral corticosteroids (OCS). Patients continued background asthma therapy throughout the duration of the trials. In both trials, patients were enrolled without requiring a minimum baseline level of blood eosinophils or FeNO.(1)<br><br>The primary endpoint for PATHWAY and NAVIGATOR was the rate of clinically significant asthma exacerbations measured over 52 weeks. Clinically significant asthma exacerbations were defined as worsening of asthma requiring the use of or increase in oral or injectable corticosteroids for at least 3 days, or a single depo-injection of corticosteroids, and/or emergency department visits requiring use of oral or injectable corticosteroids and/or hospitalization. In both PATHWAY and NAVIGATOR, patients receiving Tezspire had significant reductions in the annualized rate of asthma exacerbations compared to placebo. There were also fewer exacerbations requiring emergency room visits and/or hospitalization in patients treated with Tezspire compared with placebo. In NAVIGATOR, patients receiving Tezspire experienced fewer exacerbations than those receiving placebo regardless of baseline levels of blood eosinophils or FeNO and similar results were seen in PATHWAY. The time to first exacerbation was longer for the patients receiving Tezspire compared with placebo in NAVIGATOR and similar findings were seen in PATHWAY. Change from baseline in FEV1 was assessed as a secondary endpoint in PATHWAY and NAVIGATOR. Compared with placebo, Tezspire provided clinically meaningful improvements in the mean change from baseline in FEV1 in both trials. In NAVIGATOR, improvement in FEV1 was seen as early as 2 weeks after initiation of treatment and was sustained through week 52.(1)<br><br>Changes from baseline in Asthma Control Questionnaire 6 (ACQ-6) and Standardized Asthma Quality of Life Questionnaire for ages 12 and older [AQLQ(S)+12] were also assessed as secondary endpoints in PATHWAY and NAVIGATOR. In both trials, more patients treated with Tezspire compared to placebo had a clinically meaningful improvement in ACQ-6 and AQLQ(S)+12. Clinically meaningful improvement (responder rate) for both measures was defined as improvement in score of 0.5 or more at end of trial. In NAVIGATOR, the ACQ-6 responder rate for Tezspire was 86% compared with 77% for placebo (OR=1.99; 95% CI 1.43, 2.76) and the AQLQ(S)+12 responder rate for Tezspire was 78% compared with 72% for placebo (OR=1.36; 95% CI 1.02, 1.82). Similar findings were seen in PATHWAY.(1)<br><br>In an additional randomized, double-blind, parallel group, placebo-controlled clinical trial, the effect of Tezspire (210 mg subcutaneously every 4 weeks) on reducing the use of maintenance OCS was evaluated. The trial enrolled 150 adult patients with severe asthma who required treatment with daily OCS (7.5 mg to 30 mg per day) in addition to regular use of high-dose ICS and a long-acting beta-agonist with or without additional controller(s). The primary endpoint was categorized percent reduction from baseline of the final OCS dose at Week 48 (greater than or equal to 90% reduction, greater than or equal to 75% to less than 90% reduction, greater than or equal to 50% to less than 75% reduction, greater than 0% to less than 50% reduction, and no change or no decrease in OCS), while maintaining asthma control. Tezspire did not demonstrate a statistically significant reduction in maintenance OCS dose compared with placebo (cumulative OR=1.28; 95% CI 0.69, 2.35).(1) |
| Safety | Tezepelumab-ekko is contraindicated in patients who have a known hypersensitivity to tezepelumab-ekko or any of its excipients.(1) |

## REFERENCES


| Number | Reference |
|---|---|
| 1 | Tezspire prescribing information. Amgen Inc. May 2023. |
| 2 | Louis R, Satia I, Ojanguren I, et al. European Respiratory Society guidelines for the diagnosis of asthma in adults. *European Respiratory Journal*. 2022;60(3):2101585. doi:10.1183/13993003.01585-2021 |



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| Number | Reference |
|---|---|
| 3 | Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2024. Updated May 2024. Available from: www.ginasthma.org |
| 4 | Chung KF, Wenzel SE, Brożek J, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *The European Respiratory Journal*. 2014;43(2):343-373. doi:10.1183/09031936.00202013 |
| 5 | Bourdin A, Brusselle G, Couillard S, et al. Phenotyping of severe asthma in the era of broad-acting anti-asthma biologics. *The Journal of Allergy and Clinical Immunology in Practice*. 2024;12(4):809-823. doi:10.1016/j.jaip.2024.01.023 |


## POLICY AGENT SUMMARY – MEDICAL PRIOR AUTHORIZATION

| HCPC Codes | Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Targeted MSC | Available MSC | Final Age Limit | Preferred Status |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| J2356 | Tezspire | tezepelumab-ekko subcutaneous soln auto-inj ; tezepelumab-ekko subcutaneous soln pref syr | 210 MG/1.91ML | 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 |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | |
| Tezspire | tezepelumab-ekko subcutaneous soln auto-inj | 210 MG/1.91 ML | 1 | Pen | 28 | DAYS | | | |
| Tezspire | tezepelumab-ekko subcutaneous soln pref syr | 210 MG/1.91 ML | 1 | Syringe | 28 | DAYS | | | |

## CLIENT SUMMARY – PRIOR AUTHORIZATION

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Tezspire | tezepelumab-ekko subcutaneous soln auto-inj ; tezepelumab-ekko subcutaneous soln pref syr | 210 MG/1.91ML | Commercial ; HIM ; ResultsRx |

## CLIENT SUMMARY – QUANTITY LIMITS

| Target Brand Agent Name(s) | Target Generic Agent Name(s) | Strength | Client Formulary |
|---|---|---|---|
| Tezspire | tezepelumab-ekko subcutaneous soln auto-inj | 210 MG/1.91ML | Commercial ; HIM ; ResultsRx |
| Tezspire | tezepelumab-ekko subcutaneous soln pref syr | 210 MG/1.91ML | Commercial ; HIM ; ResultsRx |

## PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL


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| Module | Clinical Criteria for Approval |
|---|---|
| PA | **Initial Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br><br>1. ONE of the following:<br>A. The requested agent is eligible for continuation of therapy AND ONE of the following:<br><br>**Agents Eligible for Continuation of Therapy**<br>All target agents are eligible for continuation of therapy<br><br>1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**<br>2. 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**<br>B. BOTH of the following:<br>1. ONE of the following:<br>A. BOTH of the following<br>1. The patient has a diagnosis of severe asthma **AND**<br>2. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following:<br>A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR**<br>B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR**<br>C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR**<br>D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR**<br>B. The patient has another FDA labeled indication for the requested agent and route of administration **AND**<br>2. If the patient has an FDA labeled indication, then ONE of the following:<br>A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR**<br>B. There is support for using the requested agent for the patient's age for the requested indication **OR**<br>C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND**<br>2. If the patient has a diagnosis of severe asthma, then ALL of the following:<br>A. ONE of the following:<br>1. The patient is NOT currently treated with 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 **OR**<br>2. The patient is currently treated with the requested agent AND ONE of the following:<br>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**<br>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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| Module | Clinical Criteria for Approval |
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| | 3. The patient has an intolerance or hypersensitivity to therapy with an inhaled corticosteroid **OR**<br>4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND**<br>B. ONE of the following:<br>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:<br>A. A long-acting beta-2 agonist (LABA) **OR**<br>B. A long-acting muscarinic antagonist (LAMA) **OR**<br>C. A leukotriene receptor antagonist (LTRA) **OR**<br>D. Theophylline **OR**<br>2. The patient has an intolerance or hypersensitivity to therapy with a long-acting beta-2 agonist (LABA), a long-acting muscarinic antagonist (LAMA), a leukotriene receptor antagonist (LTRA), or theophylline **OR**<br>3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND**<br>C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):<br>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**<br>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<br>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**<br>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**<br>5. The patient does NOT have any FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**Length of Approval:** 6 months<br><br>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria.<br><br>**Renewal Evaluation**<br><br>**Target Agent(s)** will be approved when ALL of the following are met:<br><br>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**<br>2. ONE of the following:<br>A. The patient has a diagnosis of severe asthma AND BOTH of the following:<br>1. The patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:<br>A. The patient has had an increase in percent predicted Forced Expiratory Volume (FEV1) **OR**<br>B. The patient has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma **OR**<br>C. The patient has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** |


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| Module | Clinical Criteria for Approval |
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| | D. The patient has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **AND**<br>2. 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) **OR**<br>B. The patient has a diagnosis other than severe asthma AND has had clinical benefit with the requested agent **AND**<br>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND**<br>4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table):<br>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**<br>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:<br>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND**<br>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND**<br>5. The patient does NOT have an FDA labeled contraindications to the requested agent<br><br>**Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use<br><br>**Length of Approval:** 12 months<br><br>NOTE: Quantity Limit applies, please refer to Quantity Limit Criteria. |

## QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

| Module | Clinical Criteria for Approval |
|---|---|
| Universal QL | **Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met:<br><br>1. The requested quantity (dose) does NOT exceed the program quantity limit **OR**<br>2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following:<br>A. BOTH of the following:<br>1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication **AND**<br>2. There is support for therapy with a higher dose for the requested indication **OR**<br>B. BOTH of the following:<br>1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND**<br>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 **OR**<br>C. BOTH of the following:<br>1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND**<br>2. There is support for therapy with a higher dose for the requested indication<br><br>**Length of Approval:** up to 12 months |


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## CONTRAINDICATION AGENTS

| Contraindicated as Concomitant Therapy |
| --- |
| **Agents NOT to be used Concomitantly**<br><br>Abrilada (adalimumab-afzb)<br>Actemra (tocilizumab)<br>Adalimumab<br>Adbry (tralokinumab-ldrm)<br>Amjevita (adalimumab-atto)<br>Arcalyst (rilonacept)<br>Avsola (infliximab-axxq)<br>Avtozma (tocilizumab-anoh)<br>Benlysta (belimumab)<br>Bimzelx (bimekizumab-bkzx)<br>Cibinqo (abrocitinib)<br>Cimzia (certolizumab)<br>Cinqair (reslizumab)<br>Cosentyx (secukinumab)<br>Cyltezo (adalimumab-adbm)<br>Dupixent (dupilumab)<br>Ebglyss (lebrikizumab-lbkz)<br>Enbrel (etanercept)<br>Entyvio (vedolizumab)<br>Fasenra (benralizumab)<br>Hadlima (adalimumab-bwwd)<br>Hulio (adalimumab-fkjp)<br>Humira (adalimumab)<br>Hyrimoz (adalimumab-adaz)<br>Idacio (adalimumab-aacf)<br>Ilaris (canakinumab)<br>Ilumya (tildrakizumab-asmn)<br>Imuldosa (ustekinumab-srlf)<br>Inflectra (infliximab-dyyb)<br>Infliximab<br>Kevzara (sarilumab)<br>Kineret (anakinra)<br>Leqselvi (deuruxolitinib)<br>Litfulo (ritlecitinib)<br>Nemluvio (nemolizumab-ilto)<br>Nucala (mepolizumab)<br>Olumiant (baricitinib)<br>Omlyclo (omalizumab-igec)<br>Omvoh (mirikizumab-mrkz)<br>Opzelura (ruxolitinib)<br>Orencia (abatacept)<br>Otezla (apremilast)<br>Otulfi (ustekinumab-aauz)<br>Pyzchiva (ustekinumab-ttwe)<br>Remicade (infliximab)<br>Renflexis (infliximab-abda)<br>Riabni (rituximab-arrx)<br>Rinvoq (upadacitinib)<br>Rituxan (rituximab)<br>Rituxan Hycela (rituximab/hyaluronidase human)<br>Ruxience (rituximab-pvvr)<br>Saphnelo (anifrolumab-fnia)<br>Selarsdi (ustekinumab-aekn)<br>Siliq (brodalumab)<br>Simlandi (adalimumab-ryvk)<br>Simponi (golimumab)<br>Simponi ARIA (golimumab)<br>Skyrizi (risankizumab-rzaa)<br>Sotyktu (deucravacitinib) |


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| Contraindicated as Concomitant Therapy |
| --- |
| Spevigo (spesolimab-sbzo) subcutaneous injection |
| Stelara (ustekinumab) |
| Steqeyma (ustekinumab-stba) |
| Taltz (ixekizumab) |
| Tezspire (tezepelumab-ekko) |
| Tofidence (tocilizumab-bavi) |
| Tremfya (guselkumab) |
| Truxima (rituximab-abbs) |
| Tyenne (tocilizumab-aazg) |
| 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) |


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