



# Cibinqo (abrocitinib) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

## POLICY REVIEW CYCLE

**Effective Date**  
04-01-2024

**Date of Origin**  
09-01-2022

## FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Cibinqo™ (abrocitinib) Tablet	<p>Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.</p> <ul style="list-style-type: none"> <li>Limitation of use: Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants</li> </ul>		1

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

## CLINICAL RATIONALE

Atopic Dermatitis	<p>Atopic dermatitis (AD), also known as atopic eczema, is a chronic, pruritic inflammatory dermatosis affecting up to 25% of children and 1-5% of adults. AD follows a relapsing course and is associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and/or asthma. Onset is most common between 3 and 6 months of age, with approximately 60% of patients developing the eruption in the first year of life and 90% by age 5. While the majority of affected individuals have resolution of disease by adulthood, 10 to 30% do not, and a smaller percentage first develop symptoms as adults. AD has a complex pathogenesis involving genetic, immunologic, and environmental factors, which lead to a dysfunctional skin barrier and dysregulation of the immune system. Clinical findings include erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and lichenification. These clinical findings vary by patient age and chronicity of lesions. Pruritus is a hallmark of the condition that is responsible for much of the disease burden borne by patients and their families. Typical patterns include facial, neck and extensor involvement in infants and children; flexure involvement in any age group, with sparing of groin and axillary regions.(2)</p> <p>Goals of treatment are to reduce symptoms (pruritus and dermatitis), prevent exacerbations, and minimize therapeutics risks.(6) Despite its relapsing and remitting nature, the majority of patients with AD can achieve clinical improvement and disease control with nonpharmacological interventions (e.g., emollient use), conventional topical therapies (including corticosteroids and calcineurin inhibitors) and environmental and occupational modifications, when necessary.(4,5,6) The American Academy of Dermatology (AAD) guidelines suggest application of moisturizers should be an integral part of the treatment of patients with AD as there is strong evidence that their use reduces disease severity and need for pharmacologic intervention. They are an important component of maintenance treatment and prevention of flares.(4) The AAD recommends topical corticosteroids (TCS) for patients who fail to</p>
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respond to good skin care practices and regular use of emollients alone. Proactive, intermittent use of topical corticosteroids as maintenance therapy (1-2 times weekly) on areas that commonly flare is recommended to help prevent relapses and is more effective than use of emollients alone. Monitoring by physical exam for cutaneous side effects during long-term, potent steroid use is suggested. Proactive, once to twice weekly application of mid-potency TCS for up to 40 weeks has not demonstrated adverse events (e.g., purpura, telangiectasia, striae, focal hypertrichosis, acneiform/rosacea-like eruptions, skin atrophy) in clinical trials.(4) It is recommended that patients with acute flares use super high or high potency topical corticosteroids for one to two weeks, and then replace these with lower potency preparations until the lesions resolve.(7) AAD notes that mid- to higher potency topical corticosteroids are appropriate for short courses to gain rapid control of symptoms, but long-term management should use the least-potent corticosteroid that is effective.(4) In general, if AD is not responding after 2 weeks of treatment, evaluation to determine other treatment plans is indicated.(3,7)

Topical calcineurin inhibitors (TCIs) (e.g., pimecrolimus, tacrolimus) are recommended by the AAD as second-line therapy and are effective for acute and chronic treatment. They are particularly useful in selected clinical situations such as recalcitrance to steroids; for sensitive areas (face, anogenital, skin folds); for steroid-induced atrophy; and when there is long-term uninterrupted topical steroid use. TCIs are recommended for use on actively affected areas as a steroid-sparing agent. Proactive, intermittent use of TCIs as maintenance therapy (2-3 times per week) on areas that commonly flare is recommended to help prevent relapses while reducing need for topical corticosteroids and is more effective than use of emollients alone.(4) Prescribing information for Elidel® (pimecrolimus) cream and Protopic® (tacrolimus) ointment indicate evaluation after 6 weeks if symptoms of AD do not improve for adults and pediatrics.(8,9)

Phototherapy is recommended as a treatment for both acute and chronic AD in children and adults, after failure of the mentioned above. Systemic immunomodulator agents are indicated and recommended for the subset of adult and pediatric patients in whom optimized topical regimens using emollients, topical anti-inflammatory therapies, adjunctive methods, and/or phototherapy do not adequately control the signs and symptoms of disease. Phototherapy and systemic immunomodulating agents may also be used in patients whose medical, physical, and/or psychological states are greatly affected by their skin disease. Oral cyclosporine, azathioprine, methotrexate, and mycophenolate mofetil are the most commonly used systemic immunomodulators and most efficacious for treating AD. The AAD recommends that systemic corticosteroids should be avoided if possible and should exclusively be reserved for acute, severe exacerbations and as a short-term bridge to other systemic, steroid sparing therapies.(5,10)

There is no clear consensus on how to operationalize a definition of the FDA indication for treatment of patients with "moderate to severe" AD. The severity of AD can vary substantially over time and, from a patient's perspective, can include a complex combination of intensity of itch, location, body surface area (BSA) involvement, and degree of skin impairment. Given the variability of patient phenotype and lack of familiarity among clinicians with scoring systems used in clinical trials, it is advisable to create a broad clinically relevant definition inclusive of multiple specific measures of disease intensity for example:(11)

- One of the following:
  - Affected BSA greater than or equal to 10%
  - Investigator Global Assessment (IGA) greater than or equal to 3
  - Eczema Area and Severity Index (EASI) greater than or equal to 16

OR

- One of the following:
  - Affected BSA greater than or equal to 10%

	<ul style="list-style-type: none"> <li>○ 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)</li> <li>○ Severe itch that has been unresponsive to topical therapies</li> </ul>
Efficacy	<p>The efficacy of Cibinqo as monotherapy and in combination with background topical corticosteroids was evaluated in 3 randomized, double-blind, placebo-controlled trials [Trial-AD-1 (NCT03349060), Trial-AD-2 (NCT03575871), and Trial-AD-3 (NCT03720470)] in 1615 subjects 12 years of age and older (Cibinqo is not approved for use in pediatric patients) with moderate-to-severe atopic dermatitis as defined by Investigator’s Global Assessment (IGA) score greater than or equal to 3, Eczema Area and Severity Index (EASI) score greater than or equal to 16, body surface area (BSA) involvement greater than or equal to 10%, and Peak Pruritus Numerical Rating Scale (PP-NRS) greater than or equal to 4 at the baseline visit prior to randomization.(1)</p> <p>Overall, 53% of subjects were male, 69% of subjects were white, 64% of subjects had a baseline IGA score of 3 (moderate AD), and 36% of subjects had a baseline IGA score of 4 (severe AD). The baseline mean EASI score was 30. The baseline mean age was 36 years old with 8% of subjects 12 to less than 18 years old and 92% of subjects 18 years of age or older. Subjects in these trials were those who had inadequate response to previous topical therapy or were subjects for whom topical treatments were medically inadvisable, or who had received systemic therapies including dupilumab. In each of the trials, over 40% of subjects had prior exposure to systemic therapy. In Trial-AD-1 and Trial-AD-2, 6% of the subjects had received dupilumab, whereas prior use of dupilumab was not allowed in Trial-AD-3.(1)</p> <p>The proportion of subjects achieving PP-NRS4 at week 2 (defined as an improvement of greater than or equal to 4 points from baseline in PP-NRS) was higher in subjects treated with Cibinqo monotherapy 200 mg once daily (28% in Trial-AD-1 and 24% in Trial-AD-2) and 100 mg once daily (11% in both trials) compared to placebo (2% in both trials). A higher proportion of subjects in the Cibinqo monotherapy 100 mg or 200 mg once daily arm compared to placebo achieved improvement in itching at week 12.(1)</p> <p>The proportions of subjects achieving PP-NRS4 at week 2 was higher in subjects treated with Cibinqo 200 mg once daily (30%) and 100 mg once daily (14%) in combination with background medicated topical therapies compared to placebo (8%). Examination of age, gender, race, weight, and previous systemic AD therapy treatment did not identify differences in response to Cibinqo 100 mg or 200 mg once daily among these subgroups in Trial-AD-1, Trial- AD-2, and Trial-AD-3.(1)</p>
Safety	<p>Abrocitinib carries the following boxed warnings:(1)</p> <ul style="list-style-type: none"> <li>• Increased risk of serious bacterial, fungal, viral, and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Discontinue treatment with Cibinqo if serious or opportunistic infection occurs. Test for latent TB before and during therapy, and if positive, start treatment for TB prior to use. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.</li> <li>• Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus Kinase (JAK) inhibitor vs tumor necrosis factor (TNF) blockers in RA patients</li> <li>• Malignancies have occurred in patients treated with Cibinqo. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs TNF blockers in RA patients</li> <li>• MACE (defined as cardiovascular death, myocardial infarction, and stroke) has occurred with Cibinqo. Higher rate of MACE with another JAK inhibitor vs TNF blockers in RA patients</li> </ul>

	<ul style="list-style-type: none"> <li>Thrombosis has occurred in patients treated with Cibinqo. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs TNF blockers.</li> </ul> <p>Abrocitinib is contraindicated in patients taking antiplatelet therapies, except for low dose aspirin (less than or equal to 81 mg daily), during the first 3 months of treatment.(1)</p>
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## REFERENCES

Number	Reference
1	Cibinqo prescribing information. Pfizer Labs. February 2023.
2	Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. <i>J Am Acad Dermatol</i> . 2014 Feb;70(2):338-51.
3	Weston, William L., MD., et al. Treatment of Atopic Dermatitis (eczema). UpToDate. Last updated February 2023. Literature review current through February 2023.
4	Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis. Section 2. Management and treatment of atopic dermatitis with topical therapies. <i>J Am Acad Dermatol</i> 2014;71(1):116-32.
5	Sidbury, Robert, MD., et al. Guidelines of Care for the Management of Atopic Dermatitis. Section 3. Management and Treatment with Phototherapy and Systemic Agents. <i>J Am Acad Dermatol</i> 2014; 71 (2): 327-349.
6	Sidbury R, Tom WL, Bergman JN, Cooper KD, Silverman RA, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. <i>J Am Acad Dermatol</i> . 2014 Dec;71(6):1218-33.
7	Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. <i>J Allergy Clin Immunol</i> 2013; 131:295.
8	Elidel prescribing information. Valeant Pharmaceuticals. September 2020.
9	Protopic prescribing information. Astellas Pharma US Inc. February 2019.
10	European Task Force on Atopic Dermatitis (ETFAD) / European Academy of Dermatology and Venereology (EADV) Eczema Task Force Position Paper on Diagnosis and Treatment of Atopic Dermatitis in Adults and Children. <i>J Eur Acad Dermatol Venereol</i> . 2020;34(12):2717-2744.
11	Institute For Clinical and Economic Review (CER). JAK Inhibitors and Monoclonal Antibodies for the Treatment of Atopic Dermatitis: Effectiveness and Value. Final Evidence Report. August 2021. Updated February 2023.

## POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Cibinqo	abrocitinib tab	100 MG ; 200 MG ; 50 MG	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
Cibinqo	Abrocitinib Tab	50 MG	30	Tablets	30	DAYS			
Cibinqo	Abrocitinib Tab	100 MG	30	Tablets	30	DAYS			
Cibinqo	Abrocitinib Tab	200 MG	30	Tablets	30	DAYS			

### CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Cibinqo	abrocitinib tab	100 MG ; 200 MG ; 50 MG	Medicaid

### CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Cibinqo	Abrocitinib Tab	50 MG	Medicaid
Cibinqo	Abrocitinib Tab	200 MG	Medicaid
Cibinqo	Abrocitinib Tab	100 MG	Medicaid

### 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. Information has been provided that indicates the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days <b>OR</b></li> <li>B. 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>C. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND ALL 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 at least 10% body surface area involvement <b>OR</b></li> <li>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) <b>OR</b></li> <li>C. The patient has an Eczema Area and Severity Index (EASI) score of greater than or equal to 16 <b>OR</b></li> <li>D. The patient has an investigator Global Assessment (IGA) score of greater than or equal to 3 <b>AND</b></li> </ol> </li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient's medication history includes at least a mid- potency topical steroid used in the treatment of AD AND ONE of the following: <ol style="list-style-type: none"> <li>1. The patient has had an inadequate response to mid-potency topical steroids used in the treatment of AD <b>OR</b></li> </ol> </li> </ol> </li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over mid- potency topical steroids used in the treatment of AD <b>OR</b></p> <p>B. The patient has an intolerance or hypersensitivity to at least a mid- potency topical steroid used in the treatment of AD <b>OR</b></p> <p>C. The patient has an FDA labeled contraindication to ALL mid-, high-, and super-potency topical steroids used in the treatment of AD <b>OR</b></p> <p>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:</p> <ol style="list-style-type: none"> <li>1. A statement by the prescriber that the patient is currently taking the requested agent <b>AND</b></li> <li>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent <b>AND</b></li> <li>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm <b>OR</b></li> </ol> <p>E. The prescriber has provided documentation that ALL mid-, high-, and super-potency topical steroids used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm <b>AND</b></p> <p>3. ONE of the following:</p> <p>A. The patient's medication history includes a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD AND ONE of the following:</p> <ol style="list-style-type: none"> <li>1. The patient has had an inadequate response to a topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD <b>OR</b></li> <li>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over topical calcineurin inhibitors (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD <b>OR</b></li> </ol> <p>B. The patient has an intolerance or hypersensitivity to a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD <b>OR</b></p> <p>C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD <b>OR</b></p> <p>D. The patient is currently being treated with the requested agent as indicated by ALL of the following:</p> <ol style="list-style-type: none"> <li>1. A statement by the prescriber that the patient is currently taking the requested agent <b>AND</b></li> <li>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent <b>AND</b></li> <li>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm <b>OR</b></li> </ol> <p>E. The prescriber has provided documentation that ALL topical calcineurin inhibitors used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm <b>AND</b></p> <p>4. ONE of the following:</p> <p>A. The patient's medication history includes a systemic immunosuppressant, including a biologic AND ONE of the following:</p>

Module	Clinical Criteria for Approval
	<ol style="list-style-type: none"> <li>1. The patient has had an inadequate response to a systemic immunosuppressant, including a biologic <b>OR</b></li> <li>2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over systemic immunosuppressant, including a biologic <b>OR</b></li> <li>B. The patient has an intolerance or hypersensitivity to therapy with systemic immunosuppressants, including a biologic, used in the treatment of AD <b>OR</b></li> <li>C. The patient has an FDA labeled contraindication to ALL systemic immunosuppressants, including biologics, used in the treatment of AD <b>OR</b></li> <li>D. The patient is currently being treated with the requested agent as indicated by ALL of the following: <ol style="list-style-type: none"> <li>1. A statement by the prescriber that the patient is currently taking the requested agent <b>AND</b></li> <li>2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent <b>AND</b></li> <li>3. The prescriber states that a change in therapy is expected to be ineffective or cause harm <b>OR</b></li> </ol> </li> <li>E. The prescriber has provided documentation that ALL systemic immunosuppressants, including biologics, used in the treatment of AD cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm <b>AND</b></li> <li>5. The prescriber has documented the patient's baseline (prior to therapy with the requested agent) pruritus and other symptom severity (e.g., erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification) <b>AND</b></li> <li>6. BOTH of the following: <ol style="list-style-type: none"> <li>1. The patient is currently treated with topical emollients and practicing good skin care <b>AND</b></li> <li>2. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent <b>OR</b></li> </ol> </li> <li>D. The patient has another FDA approved indication for the requested agent and route of administration <b>OR</b></li> <li>E. The patient has another indication that is supported in compendia for the requested agent and route of administration <b>AND</b></li> <li>2. If the patient has an FDA approved indication, ONE of the following: <ol style="list-style-type: none"> <li>1. The patient's age is within FDA labeling for the requested indication for the requested agent <b>OR</b></li> <li>2. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication <b>AND</b></li> </ol> </li> <li>3. The patient has been tested for latent tuberculosis (TB) <b>AND</b> if positive the patient has begun therapy for latent TB <b>AND</b></li> <li>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis <b>AND</b></li> <li>5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): <ol style="list-style-type: none"> <li>1. 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>2. The patient will be using the requested agent in combination with another immunomodulatory agent <b>AND</b> 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> </ol>

Module	Clinical Criteria for Approval
	<p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p><b>Compendia Allowed:</b> CMS Approved Compendia</p> <p><b>Length of Approval:</b> 6 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 <b>AND</b></li> <li>2. ONE of the following: <ol style="list-style-type: none"> <li>A. The patient has a diagnosis of moderate-to-severe atopic dermatitis <b>AND BOTH</b> of the following: <ol style="list-style-type: none"> <li>1. The patient has had a reduction or stabilization from baseline (prior to therapy with the requested agent) of ONE of the following: <ol style="list-style-type: none"> <li>A. Affected body surface area <b>OR</b></li> <li>B. Flares <b>OR</b></li> <li>C. Pruritus, erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and/or lichenification <b>OR</b></li> <li>D. A decrease in Eczema Area and Severity Index (EASI) score <b>OR</b></li> <li>E. A decrease in the Investigator Global Assessment (IGA) score <b>AND</b></li> </ol> </li> <li>2. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent <b>OR</b></li> </ol> </li> <li>B. The patient has a diagnosis other than moderat-to-severe atopic dermatitis <b>AND</b> has had clinical benefit with the requested agent <b>AND</b></li> </ol> </li> <li>3. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., dermatologist, allergist, immunologist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis <b>AND</b></li> <li>4. ONE of the following (Please refer to “Agents NOT to be used Concomitantly” table): <ol style="list-style-type: none"> <li>1. 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>2. 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) <b>AND</b></li> </ol> </li> </ol> </li> <li>5. The patient does NOT have any FDA labeled contraindications to the requested agent</li> </ol> <p><b>Compendia Allowed:</b> CMS Approved Compendia</p> <p><b>Length of Approval:</b> 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> <ol style="list-style-type: none"> <li>1. The requested quantity (dose) does NOT exceed the program quantity limit <b>OR</b></li> </ol>



Module	Clinical Criteria for Approval
	<p>2. ALL of the following:</p> <ul style="list-style-type: none"> <li>A. The requested quantity (dose) exceeds the program quantity limit <b>AND</b></li> <li>B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication <b>AND</b></li> <li>C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit</li> </ul> <p><b>Length of Approval:</b>  Initial - 6 months  Renewal - 12 months</p>

## CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p><b>Agents NOT to be used Concomitantly</b></p> <p>Abrilada (adalimumab-afzb)</p> <p>Actemra (tocilizumab)</p> <p>Adalimumab</p> <p>Adbry (tralokinumab-ldrm)</p> <p>Amjevita (adalimumab-atto)</p> <p>Arcalyst (rilonacept)</p> <p>Avsola (infliximab-axxq)</p> <p>Benlysta (belimumab)</p> <p>Bimzelx (bimekizumab-bkzx)</p> <p>Cibinqo (abrocitinib)</p> <p>Cimzia (certolizumab)</p> <p>Cinqair (reslizumab)</p> <p>Cosentyx (secukinumab)</p> <p>Cyltezo (adalimumab-adbm)</p> <p>Dupixent (dupilumab)</p> <p>Enbrel (etanercept)</p> <p>Entyvio (vedolizumab)</p> <p>Fasenra (benralizumab)</p> <p>Hadlima (adalimumab-bwwd)</p>

**Contraindicated as Concomitant Therapy**

Hulio (adalimumab-fkjp)  
Humira (adalimumab)  
Hyrimoz (adalimumab-adaz)  
Idacio (adalimumab-aacf)  
Ilaris (canakinumab)  
Ilumya (tildrakizumab-asmn)  
Inflectra (infliximab-dyyb)  
Infliximab  
Kevzara (sarilumab)  
Kineret (anakinra)  
Litfulo (ritlecitinib)  
Nucala (mepolizumab)  
Olumiant (baricitinib)  
Omvoh (mirikizumab-mrkz)  
Opzelura (ruxolitinib)  
Orencia (abatacept)  
Otezla (apremilast)  
Remicade (infliximab)  
Renflexis (infliximab-abda)  
Riabni (rituximab-arrx)  
Rinvoq (upadacitinib)  
Rituxan (rituximab)  
Rituxan Hycela (rituximab/hyaluronidase human)  
Ruxience (rituximab-pvvr)  
Siliq (brodalumab)  
Simponi (golimumab)  
Simponi ARIA (golimumab)

**Contraindicated as Concomitant Therapy**

Skyrizi (risankizumab-rzaa)

Sotyktu (deucravacitinib)

Stelara (ustekinumab)

Taltz (ixekizumab)

Tezspire (tezepelumab-ekko)

Tremfya (guselkumab)

Truxima (rituximab-abbs)

Tysabri (natalizumab)

Velsipity (etrasimod)

Wezlana (ustekinumab-auub)

Xeljanz (tofacitinib)

Xeljanz XR (tofacitinib extended release)

Xolair (omalizumab)

Yuflyma (adalimumab-aaty)

Yusimry (adalimumab-aqvh)

Zeposia (ozanimod)

Zymfentra (infliximab-dyyb)