



Drug Coverage Policy

Effective Date.....11/01/2024
Coverage Policy Number.....IP0677
Policy Title.....Cibinqo Prior
Authorization Policy

Inflammatory Conditions – Cibinqo Prior Authorization Policy

- Cibinqo® (abrocitinib tablets – Pfizer)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

Overview

Cibinqo, a Janus kinase inhibitor (JAKi), is indicated for treatment of refractory, moderate to severe **atopic dermatitis** in patients ≥ 12 years of age whose disease is not adequately controlled with other systemic drug products (including biologics) or when those therapies are not

advisable.¹ Cibinqo is not recommended for use in combination with other JAKis, biologic immunomodulators, or with other immunosuppressants.

Guidelines

Guidelines for the care and management of atopic dermatitis from the American Academy of Dermatology (2023) and the American Academy of Allergy, Asthma and Immunology (2023) have been updated to address Cibinqo.^{2,3} Systemic therapies are recommended in patients with moderate to severe or widespread disease, in those with impaired quality of life, and those whose atopic dermatitis is refractory to topical therapies. Biologic agents, such as Dupixent® (dupilumab subcutaneous injection) and Adbry® (tralokinumab-ldrm subcutaneous injection), are recommended as initial systemic treatment due to their favorable efficacy and safety profiles compared to traditional systemic therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil). Cibinqo may be considered in adults refractory or intolerant to Dupixent or Adbry.

Medical Necessity Criteria

Policy Statement

Prior Authorization is recommended for benefit coverage of Cibinqo. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cibinqo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cibinqo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Cibinqo is considered medically necessary when the following are met:

FDA-Approved Indication

1. Atopic Dermatitis. Approve for the duration noted if the patient meets one of the following (A or B):

A) Initial Therapy. Approve for 3 months if the patient meets the following (i, ii, and iii):

i. Patient is \geq 12 years of age; AND

ii. Patient meets one of the following (a or b):

a) Patient has had a 4-month trial of at least ONE systemic therapy; OR

b) Patient has tried at least ONE systemic therapy but was unable to tolerate a 4-month trial; AND

Note: Examples of systemic therapies include Dupixent (dupilumab subcutaneous injection) and Adbry (tralokinumab-ldrm subcutaneous injection). Methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil also count towards trial of a systemic therapy.

iii. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Cibinqo. Approve for 1 year if the patient meets the following (i, ii, and iii):

i. Patient has already received at least 90 days of therapy with Cibinqo; AND

Note: A patient who has received < 90 days of therapy or who is restarting therapy with Cibinqo should be considered under Initial Therapy.

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations,

lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis; AND

- iii. Compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such as decreased itching.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

- 1. Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drugs.** The requested medication should not be administered in combination with a biologic used for an inflammatory condition or with a targeted synthetic oral small molecule drug (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of controlled clinical trial data supporting additive efficacy.
- 2. Concurrent Use with a Biologic Immunomodulator.** Cibinqo is not recommended in combination with biologic immunomodulators.¹
Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).
- 3. Concurrent Use with Other Janus Kinase Inhibitors (JAKis).** Cibinqo is not recommended in combination with other JAKis, such as Rinvoq (upadacitinib tablets), Xeljanz/Xeljanz XR (tofacitinib tablets/ tofacitinib extended-release tablets), Olumiant (baricitinib tablets).¹
- 4. Concurrent Use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).¹ Coadministration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.
- 5. COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.
Note: This includes requests for cytokine release syndrome associated with COVID-19.

References

1. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; December 2023.
2. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2023 Nov 3 [Epub ahead of print].
3. Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE-and Institute of Medicine-

based recommendations. *Ann Allergy Asthma Immunol.* 2023 Dec 18:S1081-1206(23)01455-2.

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia ® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra ® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi ®, Simponi Aria ® (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara ® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia ® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret ® (anakinra SC injection)	Inhibition of IL-1	JIA [^] , RA
Omvo ® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC
Stelara ® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq ® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx ® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz ® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx ® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO
Ilumya ® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi ® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya ® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: PsA, PsO, UC
		IV formulation: UC
Entyvio ® (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla ® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinzo ™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant ® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
Litfulo ® (ritlecitinib capsules)	Inhibition of JAK pathways	AA

Leqselvi [®] (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq [®] (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
Rinvoq [®] LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu [®] (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz [®] (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz [®] XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia [®] (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity [®] (etrasimod tablets)	Sphingosine 1 phosphate receptor modulator	UC

* Not an all-inclusive list of indications. Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024

The policy effective date is in force until updated or retired.

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