



## PRIOR AUTHORIZATION POLICY

**POLICY:** Inflammatory Conditions – Cibinqo Prior Authorization Policy

- Cibinqo® (abrocitinib tablets – Pfizer)

**REVIEW DATE:** 02/26/2025; selected revision 04/23/2025

### 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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 NATIONAL FORMULARY COVERAGE:

### OVERVIEW

Cibinqo, a Janus kinase inhibitor (JAKi), is indicated for treatment of refractory, moderate to severe **atopic dermatitis** in patients  $\geq 12$  years of age whose disease is not adequately controlled with other systemic drug products (including biologics) or when those therapies are not advisable.<sup>1</sup>

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.<sup>2,3</sup> 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 systemic therapy, including biologics.

## **POLICY STATEMENT**

Prior Authorization is recommended for prescription 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® (abrocitinib tablets – Pfizer)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

## **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 ALL of the following (i, ii, and iii):

**i.** Patient is ≥ 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), Ebglyss (lebrikizumab-lbkz subcutaneous injection), Nemluvio (nemolizumab-ilto 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; OR

**B) Patient is Currently Receiving Cibinqo.** Approve for 1 year if the patient meets ALL of 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.

## CONDITIONS NOT COVERED

- **Cibinqo® (abrocitinib tablets – Pfizer)**

**is(are) considered not medically necessary for ANY other use(s) 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.<sup>1</sup>  
Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Ebglyss (lebrikizumab-lbkz subcutaneous injection), Nemluvio (nemolizumab-ildo 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).<sup>1</sup>
- 4. Concurrent Use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).<sup>1</sup> Coadministration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.

## 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.

## HISTORY

| Type of Revision  | Summary of Changes   | Review Date |
|-------------------|--|-------------|
| Annual Revision   | <b>Atopic Dermatitis:</b> To align with the updated labeling, a requirement that the patient is $\geq 12$ years of age was added for initial therapy (previously was $\geq 18$ years of age).<br><b>Conditions Not Covered:</b> Concurrent Use with a Biologic Immunomodulator was added as a Condition Not Recommended for Approval. Concurrent Use with Xolair (omalizumab subcutaneous injection) and Concurrent Use with an Anti-Interleukin Monoclonal Antibody were removed (not needed).  | 02/15/2023  |
| Annual Revision   | <b>Atopic Dermatitis:</b> The requirement that the patient has tried one traditional systemic agent (i.e., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil) was changed to require a trial of one "systemic" agent. The Note of examples of "systemic" agents was changed to include Dupixent (dupilumab subcutaneous injection) and Adbry (tralokinumab-ldrm subcutaneous injection). A notation was added that a trial of a traditional systemic agent would count towards the trial of one systemic therapy. The duration of such trial of a systemic agent was changed from 3 months to 4 months. There were no other changes to the criteria. | 02/07/2024  |
| Selected Revision | <b>Conditions Not Covered:</b> Concurrent use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug was changed to as listed (previously oral small molecule drug was listed as Disease-Modifying Antirheumatic Drug).   | 09/11/2024  |
| Annual Revision   | <b>Atopic Dermatitis:</b> Ebglyss (lebrikizumab-lbkz subcutaneous injection) and Nemluvio (nemolizumab-ilto subcutaneous injection) were added to the note listing examples of systemic therapies.<br><b>Conditions Not Covered:</b> Ebglyss and Nemluvio were also added as examples of biologic immunomodulators which are not allowed concurrently with Cibinqo.  | 02/26/2025  |
| Selected Revision | Removed the following from the Policy Statement: "All reviews for use of Cibinqo for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director."<br><b>Conditions Not Covered:</b> Removed COVID-19.  | 04/23/2025  |

## APPENDIX

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

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

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