



Louisiana

abrocitinib (CibinqoTM)

Policy # 00795

Original Effective Date: 07/11/2022

Current Effective Date: 07/10/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of abrocitinib (CibinqoTM)[‡] for the treatment of atopic dermatitis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for abrocitinib (Cibinqo) will be considered when the following criteria are met:

Initial:

- Patient has a diagnosis of moderate to severe atopic dermatitis; AND
- Patient is 12 years of age or older; AND
- Patient has had chronic atopic dermatitis for at least 6 months; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has atopic dermatitis involvement estimated to be $\geq 10\%$ of the body surface area (BSA) according to the prescribing physician; AND
*(Note: This specific patient selection criterion is an additional Company requirement, based on clinical trials, for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE prescription GENERIC topical corticosteroid, unless there is clinical evidence or patient history that suggests the use of ONE prescription GENERIC topical corticosteroid will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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- Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC tacrolimus ointment OR GENERIC pimecrolimus cream, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) a traditional systemic therapy after at least 3 months of use unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient. Systemic therapies include: methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following after at least 3 months of therapy with EACH product: dupilumab (Dupixent®)†, tralokinumab-ldrm (Adbry™)‡, or upadacitinib (Rinvoq®)‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Requested drug is NOT being used in combination with other JAK (janus kinase) inhibitors (e.g., tofacitinib [Xeljanz/XR®]‡, ruxolitinib [Opzelura™]‡, upadacitinib [Rinvoq]), monoclonal antibodies (e.g., tralokinumab-ldrm [Adbry], dupilumab [Dupixent]), or other systemic immunosuppressants (such as methotrexate or cyclosporine); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

Continuation:

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
- Patient has been adherent to the requested drug and other medications for the condition being treated; AND

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*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Patient has had a clinically meaningful beneficial response to abrocitinib (Cibinqo) therapy as compared to their baseline status (before abrocitinib [Cibinqo] therapy) as evidenced by TWO or more of the following:
 - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
 - Reduction in the frequency or intensity of pruritus
 - Reduction in the frequency of disease exacerbations/flare
 - Reduction in the BSA with atopic dermatitis involvement (a 20% reduction in percent BSA involved over baseline)
 - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.); AND

*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Requested drug is NOT being used in combination with other JAK (janus kinase) inhibitors (e.g., tofacitinib [Xeljanz/XR], ruxolitinib [Opzelura], upadacitinib [Rinvoq]), monoclonal antibodies (e.g., tralokinumab-ldrm [Adbry], dupilumab [Dupixent]), or other systemic immunosuppressants (such as methotrexate or cyclosporine).

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of abrocitinib (Cibinqo) when any of the following criteria are NOT met to be **not medically necessary****:

- Patient has had chronic atopic dermatitis for at least 6 months
- Patient has atopic dermatitis involvement estimated to be $\geq 10\%$ of the body surface area (BSA) according to the prescribing physician
- Patient has tried and failed (e.g., intolerance or inadequate response) at least ONE prescription GENERIC topical corticosteroid
- Patient has tried and failed (e.g., intolerance or inadequate response) GENERIC tacrolimus ointment OR GENERIC pimecrolimus cream
- Patient has tried and failed a traditional systemic therapy after at least 3 months of use

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- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following after at least 3 months of therapy with EACH product: dupilumab (Dupixent), tralokinumab (Adbry), or upadacitinib (Rinvoq)
- For continuation requests: Patient has received at least 6 months of therapy with the requested drug
- For continuation requests: Patient has been adherent to the requested drug and other medications for the condition being treated
- For continuation requests: Patient has had a clinically meaningful beneficial response to abrocitinib (Cibinqo) therapy as compared to their baseline status (before abrocitinib [Cibinqo] therapy) as evidenced by TWO or more of the following:
 - Reduction in disease severity (e.g., erythema, dryness, edema/papulation, excoriations, lichenification, oozing/crusting)
 - Reduction in the frequency or intensity of pruritus
 - Reduction in the frequency of disease exacerbations/flare
 - Reduction in the BSA with atopic dermatitis involvement (a 20% reduction in percent BSA involved over baseline)
 - Improvement in overall patient quality of life (e.g., improved sleep, less depression or anxiety, etc.)

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of abrocitinib (Cibinqo) when the patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary****).

Background/Overview

Cibinqo is a janus kinase (JAK) inhibitor indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Cibinqo is available in 50 mg, 100 mg, and 200 mg tablets. The

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recommended dosage is 100 mg orally once daily. The dosage can be increased to 200 mg orally once daily in those that are not responding to 100 mg orally once daily.

Atopic Dermatitis

There are various treatment options for atopic dermatitis, including first line agents such as topical corticosteroids (many of which are in generic form) and topical immunomodulatory agents such as generic tacrolimus and generic pimecrolimus. For those that are refractory to topical therapies, systemic immunomodulatory agents are an option for therapy. Cibinqo has not yet been integrated into the American Academy of Dermatology guidelines at the time of this publication.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Cibinqo is indicated for the treatment of adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Cibinqo as monotherapy and in combination with background topical corticosteroids were evaluated in 3 randomized, double-blind, placebo-controlled trials (Trial-AD-1, Trial-AD-2, and Trial-AD-3) in 1,615 subjects 12 years of age and older with moderate-to-severe atopic dermatitis as defined by Investigator's Global Assessment (IGA) score ≥ 3 , Eczema Area and Severity Index (EASI) score ≥ 16 , body surface area (BSA) involvement $\geq 10\%$, and Peak Pruritus Numerical Rating Scale (PP-NRS) ≥ 4 at the baseline visit prior to randomization.

The efficacy and safety of Cibinqo in combination with background topical corticosteroids were further evaluated in adolescent subjects in a randomized, double-blind, placebo-controlled trial (Trial-AD-4). The trial included 284 subjects who were 12 to less than 18 years of age with

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moderate-to severe atopic dermatitis as defined by IGA score ≥ 3 , EASI score ≥ 16 , BSA involvement $\geq 10\%$, and PP-NRS ≥ 4 at the baseline visit prior to randomization.

Overall, 53% of subjects were male, 69% of subjects were white, 64% of subjects had a baseline IGA score of 3 (moderate atopic dermatitis), and 36% of subjects had a baseline IGA score of 4 (severe atopic dermatitis). The baseline mean EASI score was 30. Subjects in these trials were those who had inadequate response to previous topical therapy, were subjects for whom topical treatments were medically inadvisable, or who had received systemic therapies including Dupixent. 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 Dupixent, whereas prior use of Dupixent was not allowed in Trial-AD-3.

In Trial-AD-4, 49% of subjects were female, 56% of subjects were White, 33% of subjects were Asian and 6% of subjects were Black. The median age was 15 years and the proportion of subjects with severe atopic dermatitis (IGA of 4) was 38%.

Trial-AD-1, Trial-AD-2, Trial-AD-3, and Trial-AD-4 assessed the co-primary endpoints of IGA and EASI-75 responses at Week 12. In Trial-AD-1, 44% of subjects receiving Cibinqo 200 mg daily, 24% of subjects receiving Cibinqo 100 mg daily, and 8% of subjects receiving placebo achieved an IGA of 0 or 1. In that same trial, 62% of subjects receiving Cibinqo 200 mg daily, 40% of subjects receiving Cibinqo 100 mg daily, and 12% of subjects receiving placebo achieved EASI-75. In Trial-AD-2, 38% of subjects receiving Cibinqo 200 mg daily, 28% of subjects receiving Cibinqo 100 mg daily, and 9% of subjects receiving placebo achieved an IGA of 0 or 1. In that same trial, 61% of subjects receiving Cibinqo 200 mg daily, 44% of subjects receiving Cibinqo 100 mg daily, and 10% of subjects receiving placebo achieved EASI-75. In Trial-AD-3, 47% of subjects receiving Cibinqo 200 mg daily plus topical corticosteroids, 36% of subjects receiving Cibinqo 100 mg daily plus topical corticosteroids, and 14% of subjects receiving placebo plus topical corticosteroids achieved an IGA of 0 or 1. In that same trial, 68% of subjects receiving Cibinqo 200 mg daily plus topical corticosteroids, 58% of subjects receiving Cibinqo 100 mg daily plus topical corticosteroids, and 27% of subjects receiving placebo plus topical corticosteroids achieved EASI-75. In Trial-AD-4, 46% of subjects receiving Cibinqo 200 mg daily, 39% of subjects receiving Cibinqo 100 mg daily, and 24% of subjects receiving placebo achieved an IGA of 0 or 1. In the same trial, 71% of subjects receiving Cibinqo 200 mg daily, 64% of subjects receiving Cibinqo daily, and 41% of subjects receiving placebo achieved EASI-75.

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References

1. Cibinqo [package insert]. Pfizer Labs. New York, New York. February 2023.

Policy History

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06/02/2022 Medical Policy Committee review

06/08/2022 Medical Policy Implementation Committee approval. New policy.

06/01/2023 Medical Policy Committee review

06/14/2023 Medical Policy Implementation Committee approval. Updated eligibility criteria to reflect age update in FDA label.

Next Scheduled Review Date: 06/2024

***Investigational** – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

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would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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