



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/19/2022  
LAST REVIEW DATE:  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

---

## CIBINQO™ (abrocitinib)

---

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "**Description**" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "**Criteria**" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

**BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.**

---

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to [Pharmacyprecert@azblue.com](mailto:Pharmacyprecert@azblue.com). **Incomplete forms or forms without the chart notes will be returned.**

---

## CIBINQO™ (abrocitinib)

---

### Criteria:

- **Criteria for initial therapy:** Cibinqo (abrocitinib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of refractory, moderate-to-severe atopic dermatitis in a patient whose disease is not adequately controlled with systemic drug products, including biologics, or when those therapies are not advisable
  4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    - a. Lesions involve at least 10% of body surface area or involve sensitive areas of the face, head, neck, hands, feet, groin, or intertriginous areas
    - b. Disease severity defined by an Investigator's Global Assessment (IGA) score of at least 3 in the overall assessment of lesions ([See Definitions Section](#))
    - c. Eczema Area and Severity Index (EASI) score of greater than 16 ([See Definitions Section](#))
    - d. Weekly averaged Worst Daily Peak Pruritus Numeric Rating Scale (NRS) of at least 4 ([See Definitions Section](#))
    - e. Complete blood count (CBC)
    - f. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months
    - g. Screening for latent tuberculosis infection with a tuberculin skin test or blood test; if positive, treat tuberculosis with standard medical therapy before use of Cibinqo
  5. Individual has documented failure (used for > 2 consecutive months), contraindication per FDA label, intolerance, or not a candidate to **ONE** agent from **EACH** of the following categories:
    - a. Topical medium to very high potency corticosteroid
    - b. Calcineurin inhibitor (Protopic (tacrolimus) or Elidel (pimecrolimus))
    - c. Phosphodiesterase 4 inhibitor (Eucrisa (crisaborole))
  6. Individual has documented failure (used for  $\geq$  3 consecutive months), contraindication per FDA label, intolerance, or not a candidate to **BOTH** of the following medications:
    - a. Dupixent
    - b. Adbry
  7. Individual has documented failure (used for  $\geq$  3 consecutive months), contraindication per FDA label, intolerance, or not a candidate to the following medication:
    - a. Rinvoq
  8. Individual does **NOT** have **ANY** of the following:
    - a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C

---

## CIBINQO™ (abrocitinib)

---

- b. Platelet count less than 150,000/mm<sup>3</sup>
  - c. Absolute neutrophil count less than 1,000/mm<sup>3</sup>
  - d. Absolute lymphocyte count less than 500/mm<sup>3</sup>
  - e. Hemoglobin less than 8 g/dl
  - f. Severe renal impairment (eGFR less than 30 ml/minute)
  - g. Severe hepatic impairment
  - h. Concurrent use of live vaccines
9. There are no significant interacting drugs, such as:
- a. Moderate to strong inhibitors of both CYP2C19 and CYP2C9 (e.g., fluconazole)
  - b. Strong inducers of CYP2C19 or CYP2C9 (e.g., rifampin)
10. There is no concurrent use with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (e.g., Adbry, Dupixent, rituximab, infliximab, Enbrel, methotrexate, Rinvoq, Otezla, Xeljanz, Xolair, etc.)
11. There are **NO** FDA-label contraindications, such as:
- a. Concomitant antiplatelet therapies, except for low-dose aspirin (81mg/day or less), during the first 3 months of treatment

**Initial approval duration:** 6 months

➤ **Criteria for continuation of coverage (renewal request):** Cibinqo (abrocitinib) is considered **medically necessary** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist
2. Individual's condition has responded while on therapy, defined as:
  - a. No evidence of disease progression
  - b. Documented evidence of efficacy, disease stability and/or improvement
  - c. Achieved and maintains an IGA of 0 or 1 (clear or almost clear) **or** EASI-50 (improvement of at least 50% in score from baseline)
3. Individual has been adherent with the medication
4. Individual does **NOT** have **ANY** of the following:
  - a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
  - b. Severe renal impairment (eGFR less than 30 ml/minute)
  - c. Severe hepatic impairment
  - d. Concurrent use of live vaccines
5. There are no significant interacting drugs, such as:
  - a. Moderate to strong inhibitors of both CYP2C19 and CYP2C9 (e.g., fluconazole)



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/19/2022  
LAST REVIEW DATE:  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

---

## CIBINQO™ (abrocitinib)

---

- b. Strong inducers of CYP2C19 or CYP2C9 (e.g., rifampin)
- 6. There is no concurrent use with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants (e.g., Adbry, Dupixent, rituximab, infliximab, Enbrel, methotrexate, Rinvoq, Otezla, Xeljanz, Xolair, etc.)
- 7. Individual has not developed any contraindications or other significant adverse drug effects that may exclude continued use, such as:
  - a. Myocardial Infarction
  - b. Stroke
  - c. Thrombosis
  - d. Significant hematologic abnormalities ([see Definitions Section](#))

**Renewal duration** 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
  - 1. **Off-Label Use of Non-cancer Medications**
  - 2. **Off-Label Use of Cancer Medications**

---

### **Description:**

Cibinqo (abrocitinib) is a Janus kinase (JAK) inhibitor that reversibly inhibits JAK1 by blocking the adenosine triphosphate (ATP) binding site. The relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known. Cibinqo is indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis whose dermatitis is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable. Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants

Treatment of atopic dermatitis initially involves use of topical prescription therapies such as corticosteroids, calcineurin inhibitors (tacrolimus ointment, pimecrolimus cream) and topical phosphodiesterase 4 (PDE-4) inhibitors (crisaborole ointment). Topical corticosteroids are considered the standard of care with choice of strength and formulation of the preparation selected based on severity, duration of treatment, location of exacerbation, and age of individual. Topical calcineurin and topical PDE-4 inhibitors should be reserved for problem areas, such as the face, neck, intertriginous and genital areas.

---

### **Definitions:**

#### **Atopic Dermatitis Therapies:**

Topical corticosteroids (TCS):

## CIBINQO™ (abrocitinib)

- Low-potency corticosteroids are recommended for maintenance therapy
- Intermediate and high-potency corticosteroids should be used for the treatment of clinical exacerbation over short periods of time
- Ultra-high-potency corticosteroids should be used only for very short periods (1-2 weeks) and in non-facial non-skinfold areas.
- Do not use potent fluorinated corticosteroids on the face, eyelids, genitalia, and intertriginous areas or in young infants.

Topical calcineurin inhibitors (TCI):

- Tacrolimus ointment (Protopic and generics) is indicated as second-line therapy for moderate to severe atopic dermatitis
- Pimecrolimus cream (Elidel and generics) is indicated as second line therapy for mild to moderate atopic dermatitis

Topical phosphodiesterase 4 (PDE-4) inhibitor:

- Eucrisa (crisaborole) ointment is indicated for treatment of mild to moderate atopic dermatitis

**Relative Potency of Selected Topical Corticosteroid Products:**

Product	Dosage form	Strength
<b>Category I – Very high potency</b>		
Augmented betamethasone dipropionate	Gel, ointment	0.05
Clobetasol propionate	Ointment, gel, cream	0.05
Fluocinonide	Cream	0.1
Diflorasone diacetate	Ointment	0.05
Halobetasol propionate	Ointment, cream	0.05
<b>Category II – High potency</b>		
Amcinonide	Ointment, cream, lotion	0.1
Augmented betamethasone dipropionate	Cream, lotion	0.05
Betamethasone dipropionate	Ointment, cream	0.05
Betamethasone valerate	Ointment	0.1
Desoximetasone	Ointment, cream	0.25
Desoximetasone	Gel	0.05
Diflorasone diacetate	Ointment (emollient base), cream	0.05
Fluocinonide	Ointment, gel, cream	0.05
Halcinonide	Ointment, cream	0.1

**Investigator Global Assessment Scale (IGA):**

[Validated-Investigator-Global-Assessment-Scale vIGA-AD 2017.pdf \(eczemacouncil.org\)](#) [Accessed May 11, 2022]

The IGA score is selected using the morphologic descriptors that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

## CIBINQO™ (abrocitinib)

Score	Morphological Description
0 – Clear	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3 – Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.
<p>Notes:</p> <p>1. In indeterminate cases, use <u>extent</u> to differentiate between scores.            For example: • Patient with marked erythema (deep or bright red), marked papulation and/or marked lichenification that is limited in extent (instead of widespread), would be considered “3 – Moderate”.</p> <p>2. Excoriations should not be considered when assessing disease severity</p>	

### **Eczema Area and Severity Index (EASI) score (A-E):**

An EASI score is a tool used to measure the extent (area) and severity of atopic eczema. EASI score does not include a grade for dryness or scaling. Include only inflamed areas.

#### **A. Body regions:**

There are four body regions:

- Head and neck
  - Face occupies 33% (17% each side), neck 33% (17% front and back) and scalp 33% of the head and neck region
- Trunk (including genital area)
  - Front occupies 55% and back 45% of the trunk
- Upper limbs
  - Each arm occupies 50% of the upper limbs region (front or back of one arm is 25%)
- Lower limbs (including buttocks)
  - Each leg occupies 45% (front or back of one leg is 22.5%) and buttocks 10% of the lower limbs region

#### **B. Area score:**

Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1-9
2	10-29



An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINES**  
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 5/19/2022**  
**LAST REVIEW DATE:**  
**LAST CRITERIA REVISION DATE:**  
**ARCHIVE DATE:**

## CIBINQO™ (abrocitinib)

3	30-49
4	50-69
5	70-89
6	90-100: the entire region is affected by eczema

### C. Severity score:

Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3). Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level.

Score	Intensity of redness, thickness/swelling, scratching, lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)
3	Severe

### D. Calculations:

For each region, record the intensity for each of four signs and calculate the severity score.

- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiply the severity score by the area score and by a multiplier. The multiplier is different for each body site.

- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72.

### E. Interpretation:

The suggested severity levels for the EASI are as follows:

0	Clear
0.1-1.0	Almost clear
1.1-7.0	Mild
7.1-21.0	Moderate
21.1-50.0	Severe
50.1-72.0	Very severe



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES  
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/19/2022  
LAST REVIEW DATE:  
LAST CRITERIA REVISION DATE:  
ARCHIVE DATE:

## CIBINQO™ (abrocitinib)

### **Pruritus Numerical Rating Scale (NRS):**

[Numerical Rating Scale - Pruritus Resources \(pruritussymposium.de\)](http://pruritussymposium.de) [Accessed October 09, 2021]

The NRS is comprised of one item and is represented by numbers 0 (“no itch”) to 10 (“worst imaginable itch”). Patients are asked to rate the intensity of their itch using this scale. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format. Time needed for completion: 1 minute. It has been validated in several languages.

- It can be interpreted as follows:
  - NRS 0 - no pruritus
  - NRS < 3 - mild pruritus
  - NRS ≥ 3 < 7 - moderate pruritus
  - NRS ≥ 7 < 9 - severe pruritus
  - NRS ≥ 9 - very severe pruritus

On a scale from 0 (no itch) to 10 (worst imaginable itch), how would you rate your itch overall (on average) during the past 24-hour? (Select number)

0	1	2	3	4	5	6	7	8	9	10
---	---	---	---	---	---	---	---	---	---	----

### **Recommendations for Discontinuation for Cibinqo Discontinuation for Hematologic Abnormalities**

Laboratory Measure	Recommendation
Platelet Count < 50,000/mm <sup>3</sup>	Discontinue and follow with CBC until > 100,000/mm <sup>3</sup>
Absolute lymphocyte count (ALC) < 500/mm <sup>3</sup>	Temporarily discontinue if ALC is < 500 cell/mm <sup>3</sup> and may restart once ALC above this value
Absolute neutrophil count (ANC) < 1,000/mm <sup>3</sup>	Temporarily discontinue if ANC is < 1000 cell/mm <sup>3</sup> and may restart once ANC above this value
Hemoglobin (Hb) < 8g/dl	Temporarily discontinue if Hb < 8g/dl and may restart once Hb above this value

### **Resources:**

Cibinqo (abrocitinib) prescribing information, revised by Pfizer Laboratories Div Pfizer Inc. 01-2022. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed May 11, 2022.

Howe W. Treatment of atopic dermatitis (eczema). In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated March 11, 2021. Accessed May 11, 2022.

Berger TG. Evaluation and management of severe refractory atopic dermatitis (eczema) in adults. In: UpToDate, Fowler J, Levy ML, Dellavalle RP, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated March 18, 2021. Accessed May 11, 2022.





An Independent Licensee of the Blue Cross Blue Shield Association

**PHARMACY COVERAGE GUIDELINES**  
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE:** 5/19/2022  
**LAST REVIEW DATE:**  
**LAST CRITERIA REVISION DATE:**  
**ARCHIVE DATE:**

---

## **CIBINQO™ (abrocitinib)**

---

Weston WL, Howe W. Atopic dermatitis (eczema): Pathogenesis, clinical manifestations, and diagnosis. In: UpToDate, Dellavalle RP, Levy ML, Fowler J, Corona R (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at <http://uptodate.com>. Topic last updated March 21, 2021. Accessed May 11, 2022.