

## **Clinical Policy: Abrocitinib (Cibinqo)**

Reference Number: CP.PHAR.578

Effective Date: 06.01.22

Last Review Date: 08.22

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Abrocitinib (Cibinqo<sup>™</sup>) is a Janus kinase (JAK) inhibitor.

### **FDA Approved Indication(s)**

Cibinqo is indicated for the treatment of adults 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.

Limitation(s) of use: Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Cibinqo is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Atopic Dermatitis** (must meet all):

1. Diagnosis of atopic dermatitis affecting one of the following (a or b):
  - a. At least 10% of the member's body surface area (BSA);
  - b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age  $\geq$  18 years;
4. Failure of all of the following (a, b, and c), unless contraindicated or clinically significant adverse effects are experienced:
  - a. Two formulary medium to very high potency topical corticosteroids, each used for  $\geq$  2 weeks;
  - b. One non-steroidal topical therapy\* used for  $\geq$  4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa<sup>®</sup>;  
*\*These agents may require prior authorization*
  - c. One systemic agent used for  $\geq$  3 months: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
5. Cibinqo is not prescribed concurrently with another biologic immunomodulators (e.g. Adbry<sup>™</sup>, Dupixent<sup>®</sup>) or a JAK inhibitor (Olumiant<sup>®</sup>, Rinvoq<sup>®</sup>, Cibinqo<sup>®</sup>, Opzelura<sup>™</sup>);

6. Dose does not exceed one of the following (a or b):
  - a. 100 mg (one tablet) per day;
  - b. 200 mg (one tablet) per day and medical justification supports inadequate response to 100 mg daily after 12 weeks.

**Approval duration: 6 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**II. Continued Therapy**

**A. Atopic Dermatitis (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
3. Cibinqo is not prescribed concurrently with another biologic immunomodulator (e.g. Adbry, Dupixent) or a JAK inhibitor (Olumiant, Rinvoq, Cibinqo, Opzelura);
4. Dose does not exceed one of the following (a or b):
  - a. 100 mg (one tablet) per day;
  - b. 200 mg (one tablet) per day and medical justification supports inadequate response to 100 mg daily after 12 weeks.

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

AD: atopic dermatitis

BSA: body surface area

FDA: Food and Drug Administration

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
<b>Very High Potency Topical Corticosteroids</b>		
augmented betamethasone 0.05% (Diprolene <sup>®</sup> AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
clobetasol propionate 0.05% (Temovate <sup>®</sup> ) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor <sup>®</sup> , Psorcon E <sup>®</sup> ) cream, ointment		
halobetasol propionate 0.05% (Ultravate <sup>®</sup> ) cream, ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>High Potency Topical Corticosteroids</b>		
augmented betamethasone 0.05% (Diprolene <sup>®</sup> AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
diflorasone 0.05% (Florone <sup>®</sup> , Florone E <sup>®</sup> , Maxiflor <sup>®</sup> , Psorcon E <sup>®</sup> ) cream		
fluocinonide acetonide 0.05% (Lidex <sup>®</sup> , Lidex E <sup>®</sup> ) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment		
<b>Medium Potency Topical Corticosteroids</b>		
desoximetasone 0.05% (Topicort <sup>®</sup> ) cream, ointment, gel	Apply topically to the affected area(s) BID	Varies
fluocinolone acetonide 0.025% (Synalar <sup>®</sup> ) cream, ointment		
mometasone 0.1% (Elocon <sup>®</sup> ) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment		
<b>Low Potency Topical Corticosteroids</b>		
alclometasone 0.05% (Aclovate <sup>®</sup> ) cream, ointment	Apply topically to the affected area(s) BID	Varies
desonide 0.05% (Desowen <sup>®</sup> ) cream, ointment, lotion		
fluocinolone acetonide 0.01% (Synalar <sup>®</sup> ) solution		
hydrocortisone 2.5% (Hytone <sup>®</sup> ) cream, ointment		
<b>Other Classes of Agents</b>		
Protopic <sup>®</sup> (tacrolimus), Elidel <sup>®</sup> (pimecrolimus)	Children $\geq$ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa <sup>®</sup> (crisaborole)	Apply to the affected areas BID	Varies
cyclosporine	3-6 mg/kg/day PO BID	300 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
azathioprine	1-3 mg/kg/day PO QD	Weight-based
methotrexate	7.5-25 mg/wk PO once weekly	25 mg/week
mycophenolate mofetil	1-1.5 g PO BID	3 g/day

Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): Antiplatelet therapies except for low-dose aspirin ( $\leq 81$  mg daily), during the first 3 months of treatment.
- Boxed warning(s): serious infections, mortality, malignancy, major adverse cardiovascular events, and thrombosis

*Appendix D: General Information*

- Topically applied corticosteroids and emollients are the main stay of therapy for atopic dermatitis. Immunosuppressant calcineurin inhibitors are next used if topical steroids are not adequate.
- In severe, refractory cases, systemic options such as oral immunosuppressants or dupilumab (Dupixent<sup>®</sup>) may be used.
- Disease severity scales
  - Although there is no gold-standard measurement scale for atopic dermatitis, the most commonly used disease severity scales are SCORing Atopic Dermatitis (SCORAD) index, EASI, IGA, and Six area, Six Sign Atopic Dermatitis (SASSAD) severity score.

*Appendix E: EASI*

- The final EASI score ranges from 0-72:
  - 0 = clear
  - 0.1-1.0 = almost clear
  - 1.1-7.0 = mild
  - 7.1-21.0 = moderate
  - 21.1-50 = severe
  - 50.1 -72 = very severe

*Appendix F: IGA Scale*

- IGA scores ranges from 0-4:
  - 0 = clear
  - 1 = almost clear
  - 2 = mild disease
  - 3 = moderate disease
  - 4 = severe disease

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Moderate-to-severe atopic dermatitis	100 PO QD  200 mg orally once daily is recommended for those patients who are not responding to 100 mg once daily	200 mg/ day

**VI. Product Availability**

Tablet: 50 mg, 100 mg, and 200 mg

**VII. References**

1. Cibinqo. Prescribing Information. New York, NY: Pfizer Inc.; January 2022. Available at [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2022/213871s000lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/213871s000lbl.pdf). Accessed July 26, 2022.
2. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dermatitis. *J Am Acad Dermatol*. 2014 February; 70(2): 338–351.
3. Leshem YA, Hajar T, Hanifin JM, et al. What the Eczema Area and Severity Index score tells us about the severity of atopic dermatitis: an interpretability study. *British Journal of Dermatology* 2015; 172(5):1353-1357.
4. Clinical Review Report: Dupilumab (Dupixent): Sanofi-Aventis Canada Inc. Indication: Moderate-to-severe atopic dermatitis (AD) Ottawa (ON): Canadian Agency for Drugs and Technologies in Health; 2018 Jul. Appendix 5, Validity of Outcomes Measures. Available from <https://www.ncbi.nlm.nih.gov/books/NBK539234/>.
5. Drucker AM, Ellis AG, Bohdanowicz M, et al. Systemic Immunomodulatory Treatments for Patients with Atopic Dermatitis: A Systematic Review and Network Meta-analysis. *JAMA Dermatol*. 2020;156(6):659-667. doi:10.1001/jamadermatol.2020.0796.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	02.02.22	05.22
3Q 2022 annual review: no significant changes; added length requirement “after 12 weeks” to initial criteria 6b and continuation of therapy criteria 4b to clarify when 200 mg maximum dose is appropriate; references reviewed and updated.	07.26.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.19.22	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in

developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

©2022 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international

copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene<sup>®</sup> and Centene Corporation<sup>®</sup> are registered trademarks exclusively owned by Centene Corporation.