

**Cibinqo® (abrocitinib)**  
Effective 11/01/2022

|                              |  |                     |   |
|------------------------------|--|---------------------|---|
| <b>Plan</b>                  | <input checked="" type="checkbox"/> MassHealth<br><input type="checkbox"/> Commercial/Exchange         | <b>Program Type</b> | <input checked="" type="checkbox"/> Prior Authorization                                     |
| <b>Benefit</b>               | <input checked="" type="checkbox"/> Pharmacy Benefit<br><input type="checkbox"/> Medical Benefit (NLX) |                     | <input checked="" type="checkbox"/> Quantity Limit<br><input type="checkbox"/> Step Therapy |
| <b>Specialty Limitations</b> | This medication has been designated specialty and must be filled at a contracted specialty pharmacy.   |                     |   |
| <b>Contact Information</b>   | <b>Specialty Medications</b>   |                     |   |
|                              | All Plans  | Phone: 866-814-5506 | Fax: 866-249-6155   |
|                              | <b>Non-Specialty Medications</b>   |                     |   |
|                              | MassHealth   | Phone: 877-433-7643 | Fax: 866-255-7569   |
|                              | Commercial   | Phone: 800-294-5979 | Fax: 888-836-0730   |
|                              | Exchange   | Phone: 855-582-2022 | Fax: 855-245-2134   |
|                              | <b>Medical Specialty Medications (NLX)</b>   |                     |   |
|                              | All Plans  | Phone: 844-345-2803 | Fax: 844-851-0882   |
| <b>Exceptions</b>            | N/A  |                     |   |

**Overview**

Cibinqo® (abrocitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with refractory, moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable.

**Coverage Guidelines**

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Atopic Dermatitis

Prescriber must provide documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is a specialist (i.e., allergist/immunologist or dermatologist) or consult notes from a specialist are provided
3. Member is ≥18 years of age
4. Paid claims or physician documentation of inadequate response or adverse reaction to **ONE** superpotent or potent topical corticosteroid, or contraindication to **ALL** superpotent or potent topical corticosteroids\*
5. Paid claims or physician documentation of inadequate response or adverse reaction to topical tacrolimus or Eucrisa® (crisaborole), or contraindication to both topical tacrolimus and Eucrisa® (crisaborole)

6. Physician documentation of inadequate response, adverse reaction or contraindication to Dupixent® (dupilumab)
7. Appropriate dosing
8. Quantity requested is  $\leq 1$  tablet/day
9. If the request is for the 200 mg tablet, paid claims or physician documentation of member having had an inadequate response (defined as at least 12 weeks of therapy) to the 100-mg dose

*\*Notes:*

- *Trials with topical corticosteroids may be bypassed if the request clearly states that the treatment area is a sensitive area (facial/groin) or the affected area is too widespread*
- *If member has tried systemic immunomodulatory therapy and trial with a superpotent or potent topical corticosteroid has not been documented, the trial may be bypassed*

### **Continuation of Therapy**

Reauthorizations by prescriber will infer a positive response to therapy.

### **Limitations**

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply:

|                        |                        |
|------------------------|------------------------|
| Cibinqo® (abrocitinib) | 30 tablets per 30 days |
|------------------------|------------------------|

### **References**

1. Cibinqo® [package insert]. New York (NY): Pfizer Inc.; 2022 Jan.
2. U.S. FDA Approves Pfizer’s CIBINQO (abrocitinib) for Adults with Moderate-to-Severe Atopic Dermatitis products [press release on the Internet]. Rockville (MD): Food and Drug Administration (US); 2022 Jan 14 [cited 2022 Mar 29]. Available from: <https://www.pfizer.com/news/press-release/press-release-detail/us-fda-approves-pfizers-cibinqor-abrocitinib-adults>
3. Weston WL, Howe W. Atopic dermatitis (eczema): Pathogenesis, clinical manifestations and diagnosis. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2022 [cited 2022 Mar 22]. Available from: <http://www.utdol.com/utd/index.do>
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5. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32.
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7. Simpson EL, Sinclair R, Forman S, Wollenberg A, Aschoff R, Cork M, et al. Efficacy and safety of abrocitinib in adults and adolescents with moderate-to-severe atopic dermatitis (JADE MONO-1): a multicentre, double-blind, randomised, placebo-controlled, phase 3 trial. Lancet. 2020 Jul 25;396(10246):255-266.

8. Silverberg JI, Simpson EL, Thyssen JP, Gooderham M, Chan G, Feeney C, et al. Efficacy and Safety of Abrocitinib in Patients With Moderate-to-Severe Atopic Dermatitis: A Randomized Clinical Trial. *JAMA Dermatol.* 2020 Aug 1;156(8):863-873.
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10. Micromedex<sup>®</sup> Healthcare Series [database on the Internet]. Greenwood Village (CO): Thomson Healthcare; Updated periodically [cited 2022 Mar 29]. Available from: <http://www.thomsonhc.com/>.
11. Pfizer. Study of Abrocitinib Compared With Dupilumab in Adults With Moderate to Severe Atopic Dermatitis on Background Topical Therapy. In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2020- [2022 Mar 29]. Available from: <https://clinicaltrials.gov/ct2/show/NCT04345367>: NCT04345367
12. Pfizer. Study to Evaluate Efficacy and Safety of PF-04965842 With or Without Topical Medications in Subjects Aged 12 Years and Older With Moderate to Severe Atopic Dermatitis (JADE EXTEND). In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2018- [2022 Mar 29]. Available from: <https://clinicaltrials.gov/ct2/show/NCT03422822>: NCT03422822
13. Eichenfield LF, Flohr C, Sidbury R, Siegfried E, Szalai Z, Galus R, et al. Efficacy and Safety of Abrocitinib in Combination With Topical Therapy in Adolescents With Moderate-to-Severe Atopic Dermatitis: The JADE TEEN Randomized Clinical Trial. *JAMA Dermatol.* 2021 Oct 1;157(10):1165-1173.
14. Johns Hopkins University, Duke University, Pfizer. Efficacy of Abrocitinib for Reducing Pruritus in Adults With Prurigo Nodularis and Chronic Pruritus of Unknown Origin. In: *ClinicalTrials.gov* [Internet]. Bethesda (MD): National Library of Medicine (US). 2021- [2022 Mar 29]. Available from: <https://clinicaltrials.gov/ct2/show/NCT05038982>: NCT05038982

### **Review History**

09/21/2022 – Reviewed and Created for September P&T. Matched MH criteria. Effective 11/1/22

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