Clinical Policy Title:	abrocitinib
Policy Number:	RxA.752
Drug(s) Applied:	Cibinqo™
Original Policy Date:	04/18/2022
Last Review Date:	04/18/2022
Line of Business Policy Applies to:	All lines of business

Background

Cibinqo™ is a Janus kinase (JAK) inhibitor 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 of Use: Cibinqo™ is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
abrocitinib (Cibinqo™)	Treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with other systemic drug products.	Recommended dosage is 100 mg orally once daily. 200 mg orally once daily is recommended for those patients who are not responding to 100 mg once daily. Moderate renal impairment: 50 mg once daily or 100 mg once daily for those patients who are not responding to 50 mg once daily. CYP2C19 poor metabolizer: 50 mg once daily or 100 mg once daily for those patients who are not responding to 50 mg once daily.	200 mg/day orally.

Dosage Forms

- Tablets: 50 mg, 100 mg, and 200 mg.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Moderate to severe atopic dermatitis (must meet all)**:**

1. Diagnosis of moderate to severe atopic dermatitis (AD);
2. Age ≥18 years of age;
3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist;
4. Documentation of involvement of at least 10% of body surface area;
5. Failure of phototherapy or failure of two of the following (a, b, or c);
   a. A moderate- or higher-potency TCS for at least 2 consecutive weeks;
   b. One non-steroidal topical therapy*: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment and pimecrolimus 1% cream) or Eucrisa®, each used for ≥ 4 weeks;
   c. One or more of the following systemic agents: corticosteroids, azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
6. A trial of at least 16 weeks and inadequate response to Dupixent®;
7. Patient is not receiving Cibinqo™ in combination with other JAK inhibitors, biologic immunomodulators, or other immunosuppressants;
8. Dose does not exceed the following (a or b);
   a. 100-mg per day
   b. 200 mg per day: Confirmation of a trial of at least 12 weeks and inadequate response with the 100 mg dose

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Moderate to severe atopic dermatitis (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 200 mg per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
AD: atopic dermatitis
JAK: janus kinase
MACE: major adverse cardiovascular events
TCS: topical corticosteroids
TCI: topical calcineurin inhibitors
CYP2C19: cytochrome P450 2C19

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Rinvoq®	15 mg orally once daily. If an adequate response is not achieved, consider increasing the dose to 30 mg orally once daily.	30 mg/day orally
Eucrisa®	Apply a thin layer of Eucrisa® twice daily to affected areas.	Specific maximum dosage information not available.
Opzelura™	Apply a thin layer twice daily to affected areas of up to 20% body surface area.	Do not use more than 60 grams per week.
Dupixent®	Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.	600 mg subcutaneously initially, then 300 mg subcutaneously every other week.
Adbry™	600 mg (four 150-mg injections) subcutaneously initially, followed by 300 mg (two 150-mg injections) subcutaneously every other week.	600 mg subcutaneously initially, then 300 mg subcutaneously every other week.
ATOPIC DERMATITIS		
Very High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) twice daily	Varies
clobetasol propionate 0.05% (Temovate®) cream, ointment, gel, solution		
diflorasone diacetate 0.05% cream, ointment		
halobetasol propionate 0.05% (Ultravate®) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) twice daily	Varies
diflorasone 0.05% (Florone®, Maxiflor®, Psorcon E®) cream		
fluocinonide acetonide 0.05% (Lidex®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Kenalog®) cream, ointment		

Medium Potency Topical Corticosteroids		
desoximetasone 0.05% (Topicort®) cream, ointment, gel	Apply topically to the affected area(s) twice daily	Varies
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Kenalog®) cream, ointment		
Low Potency Topical Corticosteroids		
alclometasone 0.05% cream, ointment	Apply topically to the affected varies area(s) twice daily	Varies
desonide 0.05% (Desowen®) cream, ointment, lotion		
fluocinolone acetonide 0.01% (Synalar®) solution		
hydrocortisone 2.5% cream, ointment		
Other Classes of Agents		
tacrolimus (Protopic®), pimecrolimus (Elidel®)	Children ≥ 2 years and adults: Apply a thin layer topically to affected skin twice daily. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa®	Apply to the affected areas twice daily	Varies
cyclosporine	3-6 mg/kg/day orally twice daily	300 mg/day
azathioprine	1-3 mg/kg/day orally once daily	Weight-based
methotrexate	7.5-25 mg/week orally once weekly	25 mg/week
mycophenolate mofetil	1-1.5 orally twice daily	3 g/day
Systemic corticosteroids (e.g. prednisone, prednisolone, triamcinolone)	orally, intramuscular, or parenteral; dose varies	Varies

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

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - Antiplatelet therapies except for low-dose aspirin (≤ 81 mg daily), during the first 3 months of treatment.

  *Contraindications listed reflect direct statements made in the manufacturer's package insert; for additional uses, warnings, and precautions, please refer to clinical guidelines.

- Boxed Warning(s):
  - Serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis.

APPENDIX D: General Information

- Recommended Dosage in CYP2C19 Poor Metabolizers: In patients who are known or suspected to be CYP2C19 poor metabolizers, the recommended dosage of Cibinqo™ is 50 mg once daily. If an adequate response is not achieved with Cibinqo™ 50 mg orally daily after 12 weeks, consider increasing dosage to 100 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily.
- Dosage Modifications due to Strong Inhibitors: In patients taking strong inhibitors of cytochrome P450 (CYP) 2C19 reduce the dosage to 50 mg once daily. If an adequate response is not achieved with Cibinqo™ 50 mg orally daily after 12 weeks, consider increasing dosage to 100 mg orally once daily. Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily.
- Treatment Discontinuation due to Serious Infections or Hematologic Adverse Reactions: Serious or Opportunistic Infections If a patient develops a serious or opportunistic infection, discontinue Cibinqo™ and control the infection. The risks and benefits of treatment with Cibinqo™ should be carefully considered prior to reinitiating therapy with Hematologic Abnormalities Recommendations for Cibinqo™ discontinuation for laboratory abnormalities are summarized in Table 2.

References

1. Cibinqo™ Prescribing Information. NY, NY: Pfizer Laboratories Div. Pfizer Inc.; January 2022. Available at: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=3f6d6fcd-e9f9-42c8-bfa2-bb2cfc9ed258. Accessed March 08, 2022.
2. IPD Analytics Rx Insights_New Drug Review_ Cibinqo™ 01.2022. Available at: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=Cibinqo+%28tablet%29. Accessed March 08, 2022.
3. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Available at: http://www.clinicalkey.com. Accessed March 08, 2022.
4. David M Fleischer, MD; Jeremy Udkoff, MA, Atopic dermatitis: skin care and topical therapies. Seminar in cutaneous medicine and surgery, September 2017, Vol 36, No. 3. Available at: https://nationaleczema.org/wp-content/uploads/2018/03/258887_eprint4.pdf. Accessed March 08, 2022.
5. Dermatitis. Topical calcineurin inhibitors | dermnet nz. Available at: https://dermnetnz.org/cme/dermatitis/topical-calcineurin-inhibitors. Accessed March 08, 2022.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	03/08/2022	04/18/2022