Clinical Policy: Abrocitinib (Cibinqo)

Reference Number: ERX.SPA.474
Effective Date: 06.01.22
Last Review Date: 05.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Abrocitinib (Cibinqo™) 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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ≥ 18 years;
4. Failure of all of the following (a, b, and c), unless contraindicated or clinically significant adverse effects are experience:
   a. Two formulary medium to very high potency topical corticosteroids, each used for ≥ 2 weeks;
   b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa®;
      **These agents may require prior authorization*
   c. One systemic agent used for ≥ 3 months: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
5. Cibinqo is not prescribed concurrently with another biologic immunomodulators (e.g. Adbry™, Dupixent®) or a JAK inhibitor (Olumiant®, Rinvoq®, Cibinqo®, Opzelura™);
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.

Approval duration: 6 months

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Atopic Dermatitis (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
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. If request is for a dose increase, new 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.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
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 and may require prior authorization.

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution		
triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment		
Medium Potency Topical Corticosteroids		
desoximetasone 0.05% (Topicort ®) cream, ointment, gel	Apply topically to the affected area(s) BID	Varies
fluocinolone acetonide 0.025% (Synalar®) cream, ointment		
mometasone 0.1% (Elocon®) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment		
Low Potency Topical Corticosteroids		
alclometasone 0.05% (Aclovate®) cream, ointment	Apply topically to the affected area(s) BID	Varies
desonide 0.05% (Desowen®) cream, ointment, lotion		
fluocinolone acetonide 0.01% (Synalar®) solution		
hydrocortisone 2.5% (Hytone®) cream, ointment		
Other Classes of Agents		
Protopic® (tacrolimus), Elidel® (pimecrolimus)	Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa® (crisaborole)	Apply to the affected areas BID	Varies
cyclosporine	3-6 mg/kg/day PO BID	300 mg/day
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® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): antiplatelet therapies except for low-dose aspirin (≤ 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) 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, Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), and Six Area, Six Sign Atopic Dermatitis (SASSAD) severity score.

Appendix E: EASI Scale

- 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
Atopic dermatitis	100 PO QD 200 mg PO QD is recommended for those patients who are not responding to 100 mg QD	200 mg/ day

VI. Product Availability

Tablets: 50 mg, 100 mg, 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. Accessed January 30, 2022.
2. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dematitis. *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

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.