Pharmacy Policy Bulletin: J-1193 Cibinqo (abrocitinib) – Commercial and Healthcare Reform	
Number: J-1193	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1193-005	**Original Date:** 04/06/2022
Effective Date: 04/25/2025	**Review Date:** 04/09/2025

Drugs Product(s):	• Cibinqo (abrocitinib)
FDA-Approved Indication(s):	• Treatment of adults and pediatric patients 12 years of age and older 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

Background:	• Cibinqo reversibly inhibits Janus kinase 1 (JAK1) by blocking the adenosine triphosphate (ATP) binding site. Inhibition of JAK1 is thought to modulate multiple cytokines involved in pathophysiology of atopic dermatitis (AD), including interleukin (IL)-4, IL-13, IL-31, IL-22, and thymic stromal lymphopoietin (TSLP). • AD is a chronic, relapsing, pruritic inflammatory skin disease that occurs more commonly in children, but also affects many adults. AD is often associated with elevated serum immunoglobulin E (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Clinical features of AD include pruritus, skin dryness, erythema, oozing and crusting, and lichenification. • Systemic drugs for AD include monoclonal antibodies administered subcutaneously (SC), such as Dupixent (dupilumab) and Adbry (tralokinumab). Other oral systemic therapy includes off-label use of cyclosporine, methotrexate (MTX), mycophenolate mofetil (MMF), or azathioprine (AZA). Oral immunomodulatory therapy is typically reserved for a subset of patients when topical regimens and/or phototherapy do not adequately control the disease, or when quality of life is substantially impacted. • According to the 2023 American Academy of Dermatology (AAD) guidelines for AD, topical corticosteroids are first-line treatment for mild-to-severe AD in all skin areas (strong recommendation, high evidence) along with non-prescription therapies such as moisturizers (strong recommendation, moderate evidence). Initial treatment may be followed by topical calcineurin inhibitors, a topical phosphodiesterase-4 (PDE-4) inhibitor (crisaborole), or a topical JAK inhibitor (ruxolitinib), as alternative treatments due to adverse effects or patient

preference (strong recommendation; high evidence- for all except topical JAK inhibitors: moderate evidence).

- For systemic therapies in AD, the AAD makes strong recommendations for the use of dupilumab, tralokinumab, abrocitinib, baricitinib, and upadacitinib. Conditional recommendations are made in favor of using phototherapy, azathioprine, cyclosporine, methotrexate, and mycophenolate, and against the use of systemic corticosteroids.
- Topical corticosteroids should be avoided if a patient has damaged skin, such as infected skin (unless advised by a doctor), rosacea, acne, and skin ulcers (open sores).
- Severity of atopic dermatitis is defined by the Validated Investigator's Global Assessment (v-IGA)
    - 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.

- Examples of positive clinical response in AD therapy include improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with AD.
- Prescribing Considerations:
    - Cibinqo is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.
    - Cibinqo is not recommended for use in patients with severe renal impairment and end stage renal disease (ESRD) (eGFR ≤ 29 mL/min) including those on renal replacement. A dosage reduction (50 mg once daily) in patients with moderate renal impairment (eGFR 30-59 mL/min) is recommended. Cibinqo 100 mg once daily is recommended in patients with mild renal impairment (eGFR 60-89 mL/min).
    - Increased concentrations of Cibinqo were found in patients who are CYP2C19 poor metabolizers. Dosage reduction of Cibinqo to 50 mg orally daily, or 100 mg orally daily for patients not responding to 50 mg orally daily, is recommended in patients who are known or suspected to be CYP2C19 poor metabolizers based on genotype or previous history/experience with other CYP2C19 substrates, or who are taking strong inhibitors of CYP2C19.
    - Cibinqo has a black box warning for serious infections, mortality, malignancy, major adverse cardiovascular events (MACE), and thrombosis. Cibinqo is contraindicated for use in patients taking

	antiplatelet therapies, except for low-dose aspirin (≤ 81 mg daily), during the first three months of treatment

Approval Criteria

I. Initial Authorization

When a benefit, coverage of Cibinqo may be approved when all of the following criteria are met **(A. through D.)**:

- **A.** The member is 12 years of age or older.
- **B.** The specialist (dermatologist, allergist, or immunologist) submits attestation that the member has a diagnosis of atopic dermatitis (ICD-10: L20) classified as all of the following **(1. and 2.)**:
  - **1.** Moderate-to-severe
  - **2.** Refractory
- **C.** The member meets one (1) of the following criteria **(1. or 2.)**:
  - **1.** The member has experienced therapeutic failure or intolerance to one (1) of the following **(a. or b.)**:
    - **a.** One (1) generic topical corticosteroid
    - **b.** One (1) generic topical calcineurin inhibitor (specifically, tacrolimus or pimecrolimus)
  - **2.** The prescriber submits documentation that the member has severe atopic dermatitis and topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(a. or b.)**:
    - **a.** The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.
    - **b.** Topical therapies are contraindicated due to severely damaged skin.
- **D.** The member has experienced therapeutic failure or intolerance to one (1) systemic therapy for atopic dermatitis, or all systemic therapies are contraindicated.

II. Reauthorization

When a benefit, reauthorization of Cibinqo may be approved when the following criterion is met **(A.)**:

- **A.** The prescriber attests that the member has experienced a positive clinical response to therapy.

III. If the patient has already had a trial of at least one (1) biologic agent for the same indication, the patient is not required to “step back” and try a nonbiologic agent.

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

References:

1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.
2. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics. 2025.
3. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. *J Am Acad Dermatol*. 2023;89(1):e1-e20.
4. Boguniewicz M, Alexis AF, Beck LA, et al. Expert perspectives on management of moderate-to-severe atopic dermatitis: A multidisciplinary consensus addressing current and emerging therapies. *J. Allergy Clin. Immunol*. 2017;5(6):1519-1531.
5. Boguniewicz M, Fonacier L, Guttman-Yassky E, Ong PY, Silverberg J, Farrar JR. Atopic dermatitis yardstick: Practical recommendations for an evolving therapeutic landscape. *Ann Allergy Asthma Immunol*. 2018;120(1):10-22.e2.
6. NHS choices. Topical corticosteroids. Available at: https://www.nhs.uk/conditions/topical-steroids/. Accessed February 4, 2025.
7. International Eczema Council. Validated investigator global assessment scale for atopic dermatitis. Available at: https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf. Accessed February 4, 2025.
8. Davis DMR, Drucker AM, Alikhan A, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. *J Am Acad Dermatol*. 2024;90(2):e43-e56.