Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	July 8, 2022

Cibinqo™ (abrocitinib)

LENGTH OF AUTHORIZATION: 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age.
- Patient must have a diagnosis of refractory moderate-to-severe atopic dermatitis (AD).
- Patient has had a trial of at least
    - one preferred medium to very-high potency topical corticosteroid and experienced inadequate response or intolerance.
    - one preferred topical calcineurin inhibitor (Elidel, Protopic) and experienced inadequate response or intolerance.
- Patient did NOT respond adequately (or is not a candidate) to
    - a 3-month minimum trial of phototherapy.
    - a 3-month minimum trial of ≥ 1 preferred systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab).
- Patient individual risks and benefits have been considered prior to initiating or continuing therapy in those at higher risk for malignancy and/or major adverse cardiovascular events (MACE).
- Patient is NOT considered to be at high risk for thrombosis and does NOT have an active infection, including clinically important localized infections.
- Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment.
- Cibinqo will NOT be used in combination with other monoclonal antibody biologics (e.g., tezepelumab, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab, tralokinumab) or other non-biologic agents (e.g., apremilast, baricitinib, tofacitinib, upadacitinib).

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of improved clinical response (clinical reduction in pruritus and flares).
- Patient has NOT experienced any treatment-restricting adverse effects (serious infections [e.g., fungal, viral, or other opportunistic infections], tuberculosis, virus reactivation [e.g., herpes zoster, Hepatitis B, Hepatitis C), malignancy and lymphoproliferative disorders [e.g., lymphomas, non-melanoma skin cancer, or other solid tumors], MACE, thrombosis [e.g., pulmonary embolism, deep vein thrombosis, arterial thrombosis], lymphopenia, thrombocytopenia, neutropenia, anemia, lipid elevation, etc.).
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Available as 50 mg, 100 mg, and 200 mg tablets.

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- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/