PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Cibinqo Prior Authorization Policy
- Cibinqo® (abrocitinib tablets – Pfizer)

REVIEW DATE: 02/15/2023

OVERVIEW

Cibinqo, a Janus kinase inhibitor (JAKi), is indicated for treatment of refractory, moderate to severe **atopic dermatitis** in patients ≥ 12 years of age whose disease is not adequately controlled with other systemic drug products (including biologics) or when those therapies are not advisable.[1] Cibinqo is not recommended for use in combination with other JAKis, biologic immunomodulators, or with other immunosuppressants.

Guidelines

US-based atopic dermatitis guidelines do not address Cibinqo.[2-4] Phototherapy, followed by systemic therapy, is generally used if initial topical treatments have failed to adequately control the signs and symptoms of disease.[2,4] A variety of systemic agents have been used off-label for treatment of atopic dermatitis, including cyclosporine, azathioprine, methotrexate, and mycophenolate mofetil. Biological guidelines from the European Academy of Allergy and Clinical Immunology (2021) also do not address Cibinqo.[5,6] Dupixent® (dupilumab subcutaneous injection) is recommended for use in patients ≥ 6 years of age with atopic dermatitis not adequately controlled with topical prescription therapies or when those therapies are not advisable (moderate to severe disease in patients ≥ 12 years of age; severe disease in patients 6 to 11 years of age).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Cibinqo. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Cibinqo as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Cibinqo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

All reviews for use of Cibinqo for COVID-19 and/or cytokine release syndrome associated with COVID-19 will be forwarded to the Medical Director.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Cibinqo is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Atopic Dermatitis.** Approve for the duration noted if the patient meets one of the following (A or B):
   - **A)** Initial Therapy. Approve for 3 months if the patient meets the following criteria (i, ii, and iii):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient meets one of the following (a or b):

a) Patient has had a 3-month trial of at least ONE traditional systemic therapy; OR
b) Patient has tried at least ONE traditional systemic therapy but was unable to tolerate a 3-month trial; AND
Note: Examples of traditional systemic therapies include methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil. A patient who has already tried Dupixent (dupilumab subcutaneous injection) or Adbry (tralokinumab-ldrm subcutaneous injection) is not required to "step back" and try a traditional systemic agent for atopic dermatitis.

iii. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

B) Patient is Currently Receiving Cibinqo. Approve for 1 year if the patient meets the following (i, ii, and iii):

i. Patient has already received at least 90 days of therapy with Cibinqo; AND
Note: A patient who has received < 90 days of therapy or who is restarting therapy with Cibinqo should be considered under Initial Therapy.

ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating Cibinqo) in at least one of the following: estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, and/or a decreased requirement for other topical or systemic therapies for atopic dermatitis; AND

iii. Compared with baseline (prior to receiving Cibinqo), patient experienced an improvement in at least one symptom, such as decreased itching.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Cibinqo is not recommended in the following situations:

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD).** Cibinqo is not recommended in combination with biologic immunomodulators or with other immunosuppressants such as those used for inflammatory conditions (see Appendix for examples).[1]

2. **Concurrent Use with a Biologic Immunomodulator.** Cibinqo is not recommended in combination with biologic immunomodulators.[1]
Note: Examples include Adbry (tralokinumab-ldrm subcutaneous injection), Cinqair (reslizumab intravenous), Dupixent (dupilumab subcutaneous injection), Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), Tezspire (tezepelumab-ekko subcutaneous injection), and Xolair (omalizumab subcutaneous injection).

3. **Concurrent Use with Other Janus Kinase Inhibitors (JAKis).** Cibinqo is not recommended in combination with other JAKis, such as Rinvoq (upadacitinib tablets), Xeljanz/XR (tofacitinib tablets/extended-release tablets), Olumiant (baricitinib tablets).[1]

4. **Concurrent Use with Other Potent Immunosuppressants** (e.g., azathioprine, cyclosporine).[1] Coadministration with other potent immunosuppressive drugs has the risk of added immunosuppression and has not been evaluated.

5. **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.
Note: This includes requests for cytokine release syndrome associated with COVID-19.
6. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; February 2023.
2. Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. *J Allergy Clin Immunol*. 2013;131:295-299.
3. Eichenfield LF, Tom WL, Berger TG, 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;71(1):116-132.
4. Sidbury R, et al. Guidelines of care for the management of atopic dermatitis Section 3. Management and treatment with phototherapy and systemic agents. *J Am Acad Dermatol*. 2014;71(2):327-349.
5. Agache I, Akdis CA, Akdis M, et al. EAACI biologicals guidelines-dupilumab for children and adults with moderate to severe atopic dermatitis. *Allergy*. 2021;76(4):988-1009.
6. Wollenberg A, Christen-Zach S, Taieb A, et al. ETFAD/EADV eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. *J Eur Acad Dermatol Venereol*. 2020;34(12):2717-2744.

Type of Revision	Summary of Changes	Review Date
New Policy	--	01/26/2022
Selected Revision	**Atopic Dermatitis:** The requirement that a patient has had a previous trial of a conventional systemic therapy for atopic dermatitis was changed from a 4-month trial to a 3-month trial. The exception for a patient who was unable to tolerate a 4-month trial of a traditional systemic therapy was changed to an intolerance to a 3-month trial.	03/23/2022
Annual Revision	**Atopic Dermatitis:** To align with the updated labeling, a requirement that the patient is ≥ 12 years of age was added for initial therapy (previously was ≥ 18 years of age). **Conditions Not Recommended for Approval:** Concurrent Use with a Biologic Immunomodulator was added as a Condition Not Recommended for Approval. Concurrent Use with Xolair (omalizumab subcutaneous injection) and Concurrent Use with an Anti-Interleukin Monoclonal Antibody were removed (not needed).	02/15/2023

APPENDIX

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; TYK2 – Tyrosine kinase 2.