

PRIOR AUTHORIZATION POLICY

POLICY: Inflammatory Conditions – Cibinqo Prior Authorization Policy

- Cibinqo® (abrocitinib tablets – Pfizer)

REVIEW DATE: 02/07/2024; selected revision 09/11/2024

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

Guidelines for the care and management of atopic dermatitis from the American Academy of Dermatology (2023) and the American Academy of Allergy, Asthma and Immunology (2023) have been updated to address Cibinqo.^{2,3} Systemic therapies are recommended in patients with moderate to severe or widespread disease, in those with impaired quality of life, and those whose atopic dermatitis is refractory to topical therapies. Biologic agents, such as Dupixent® (dupilumab subcutaneous injection) and Adbry® (tralokinumab-ldrm subcutaneous injection), are recommended as initial systemic treatment due to their favorable efficacy and safety profiles compared to traditional systemic therapies (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil). Cibinqo may be considered in adults refractory or intolerant to Dupixent or Adbry.

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 ALL of the following (i, ii, and iii):
 - i. Patient is ≥ 12 years of age; AND

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- ii. Patient meets ONE of the following (a or b):
 - a) Patient has had a 4-month trial of at least ONE systemic therapy; OR
 - b) Patient has tried at least ONE systemic therapy but was unable to tolerate a 4-month trial;
AND
Note: Examples of systemic therapies include Dupixent (dupilumab subcutaneous injection) and Adbry (tralokinumab-ldrm subcutaneous injection). Methotrexate, azathioprine, cyclosporine, and mycophenolate mofetil also count towards trial of a systemic therapy.
 - 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 ALL of 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 Oral Small Molecule Drugs.** The requested medication should not be administered in combination with a biologic used for an inflammatory condition or with a targeted synthetic oral small molecule drug (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of controlled clinical trial data supporting additive efficacy.
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/Xeljanz XR (tofacitinib tablets/ tofacitinib 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; December 2023.
2. 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*. 2023 Nov 3 [Epub ahead of print].
3. Chu DK, Schneider L, Asiniwasis RN, et al. Atopic dermatitis (eczema) guidelines: 2023 American Academy of Allergy, Asthma and Immunology/American College of Allergy, Asthma and Immunology Joint Task Force on Practice Parameters GRADE-and Institute of Medicine-based recommendations. *Ann Allergy Asthma Immunol*. 2023 Dec 18:S1081-1206(23)01455-2.

APPENDIX

* Not an all-inclusive list of indications. 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; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.