MEDICAL MUTUAL®

Drug Policy

Policy:	Cibinqo (abrocitinib)	Annual Review Date: 12/21/2023 Last Revised Date: 12/21/2023

OVERVIEW

Use of Cibinqo is a Janus kinase (JAK) inhibitor indicated for the treatment of patients 12 years or 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.

POLICY STATEMENT

This policy involves the use of Cibinqo. Prior authorization is recommended for pharmacy benefit coverage of Cibinqo. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

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 be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Atopic Dermatitis.** Approve for the duration noted if the patient meets one of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets the following criteria (i, ii, iii, iv, v and vi):
     - **i.** Patient is ≥ 12 years of age; AND
     - **ii.** Patient has moderate-to-severe atopic dermatitis with at least one of the following (a, b, c, d, or e):
       - **a)** Involvement of at least 10% of body surface area (BSA); OR
       - **b)** Eczema Area and Severity Index (EASI) score of 16 or greater; OR
       - **c)** Investigator's Global Assessment (IGA) score of 3 or more; OR
       - **d)** Scoring Atopic Dermatitis (SCORAD) score of 25 or more; OR
       - **e)** Incapacitation due to AD lesion location; AND
     - **iii.** The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

iv. The patient did not have an adequate response or is intolerant to a 3-month trial of one topical corticosteroid; AND
v. The patient did not have an adequate response or is intolerant to a 3-month trial of one topical calcineurin inhibitor; AND
vi. Patient did not have an adequate response or is intolerant to at least one systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil OR phototherapy)

B) Patient is Currently Receiving Cibinqo. Approve if the patient meets the following (i, ii, and iii):
i. Patient has already received at least 180 days of therapy with Cibinqo; AND
Note: A patient who has received < 180 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.

Initial Approval/ Extended Approval.
A) *Initial Approval: 6 months*
B) *Extended Approval:1 year*

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Cibinqo has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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 an Anti-Interleukin Monoclonal Antibody.** Cibinqo is not recommended in combination with biologic immunomodulators such as Dupixent® (dupilumab subcutaneous injection or Adbry® (tralokinumab-ldrm subcutaneous injection).[1]

3. **Concurrent use with Other Janus Kinase Inhibitors.** Cibinqo is not recommended in combination with other JAKis, such as Rinvoq, Xeljanz/XR, Olumiant.[1]

4. **Concurrent use with Xolair® (omalizumab subcutaneous injection).** Cibinqo is not recommended in combination with biologic immunomodulators such as Xolair.[1]

5. **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

6. **COVID-19 (Coronavirus Disease 2019).** Forward all requests to the Medical Director.
   Note: This includes requests for cytokine release syndrome associated with COVID-19.

7. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Cibinqo® tablets [prescribing information]. New York, NY: Pfizer; January 2022.
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.

APPENDIX

	Mechanism of Action	Examples of Inflammatory Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection)	Inhibition of IL-23	PsA, PsO
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, RA, PsA
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indication (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; DMARDs – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.