Effective Date **4/1/2023**
Next Review Date… **4/1/2024**
Coverage Policy Number **IP0404**

Abrocitinib

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for abrocitinib (Cibinqo®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Abrocitinib (Cibinqo) is considered medically necessary when the following are met:

1. **Atopic Dermatitis, Moderate to Severe.** Individual meets **ALL** of the following criteria (A, B, and C):
    A. Individual is 12 years of age or older
    B. Documentation of **ONE** of the following (i ii or iii):
        i. Individual has had an inadequate response after at least 3 months to **ONE** conventional systemic therapy (for example, methotrexate, azathioprine, cyclosporine, mycophenolate)
        ii. Individual has a contraindication or intolerance to **ALL** conventional systemic therapy

iii. Individual has already tried Dupixent (dupilumab) or Adbry (tralokinumab-ldrm)

C. Medication is prescribed by, or in consultation with, an allergist, immunologist, dermatologist or a prescriber who specializes in atopic dermatitis

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Covered Alternatives:	
Condition	**Criteria**
Atopic Dermatitis	**Preferred Product**

Individual and Family Plan Covered Alternatives:	
Condition	**Criteria**
Atopic Dermatitis	**Preferred Product**

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Abrocitinib (Cibinqo) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Examples of a response to therapy include:

1. **Atopic Dermatitis, Moderate to Severe:** improvement in estimated body surface area affected, erythema, induration/papulation/edema, excoriations, lichenification, a decreased requirement for other topical or systemic therapies for atopic dermatitis, or decrease in itching.

Authorization Duration

Initial approval duration: up to 12 months

Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven including the following (this list may not be all inclusive):

1. **Alopecia.** Insufficient efficacy and safety data to support use in alopecia. Xeljanz is not indicated for this use.[1]

2. **Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (tsDMARD).** Cibinqo is not recommended in combination with biologic immunomodulators or with other potent immunosuppressants such as those used for inflammatory conditions, including other JAKis, such as Rinvoq, Xeljanz/XR, and Olumiant.

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

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

5. **COVID-19 (Coronavirus Disease 2019).** This includes requests for cytokine release syndrome associated with COVID-19.

6. **Vitiligo.** Insufficient efficacy and safety data to support use in vitiligo. Xeljanz is not indicated for this use.[1] A small case series of 10 individuals with vitiligo were treated with JAK inhibitors. Five subjects achieved some repigmentation at sites of either sunlight exposure or low dose nbUVB light. The authors stated that JAK monotherapy does not seem to be effective, but appears to need concurrent nbUVB phototherapy or sunlight exposure. The authors concluded that prospective clinical trials are necessary to evaluate the use of JAK inhibitors in vitiligo. This study was limited by small sample size, retrospective design and no control group.[7]

Background

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).

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.

APPENDIX

Table 1. Approved TNFis for Targeted Indications.

	Rheumatology					Dermatology	Gastroenterology	
	RA	JIA	AS	nr-axSpA	PsA	PsO	CD	UC
Tumor Necrosis Factor Inhibitors								
Cimzia	√	--	√	√	√	√	√	--
Enbrel	√	√	√	--	√	√	--	--
Adalimumab products (Humira, biosimilars)	√	√	√	--	√	√	√	√
Infliximab Products	√	--	√	--	√	√	√	√
Simponi Subcutaneous	√	--	√	--	√	--	--	√
Simponi Aria	√	√	√	--	√	--	--	--

TNFis – Tumor necrosis factor inhibitors; RA – Rheumatoid arthritis; JIA – Juvenile idiopathic arthritis; AS – Ankylosing spondylitis; nr-axSpA – Non-radiographic spondyloarthritis; PsA – Psoriatic arthritis; PsO – Plaque psoriasis; CD – Crohn's disease; UC – Ulcerative colitis.

Table 2. Approved IL-17, IL-23, and IL-12/23 Blockers for Targeted Indications.

	Rheumatology			Dermatology	Gastroenterology	
	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Crohn's Disease	Ulcerative Colitis
Interleukin-17 Blockers						
Cosentyx	√	√	√	√	--	--
Siliq	--	--	--	√	--	--
Taltz	√	√	√	√	--	--
Interleukin-23 Blockers						
Ilumya	--	--	--	√	√	--
Skyrizi Intravenous	--	--	--	--	√#	--
Skyrizi Subcutaneous	--	--	√	√	√^	--
Tremfya	--	--	√	√	--	--
Interleukin-12/23 Blockers						
Stelara Subcutaneous	--	--	√	√	√^	√^
Stelara Intravenous	--	--	--	--	√#	√#

IL – Interleukin; nr-axSpA – Non-radiographic spondyloarthritis; ^ Maintenance dosing only; # Induction dosing only.

Table 3. Approved Oral tsDMARDs for Targeted Indications.

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	Juvenile Idiopathic Arthritis	Ankylosing Spondylitis	nr-axSpA	Psoriatic Arthritis	Plaque Psoriasis	Ulcerative Colitis
Janus Kinases Inhibitors							
Olumiant	√	--	--	--	--	--	--
Opzelura	--	--	--	--	--	--	--
Rinvoq	√	--	√	√	√	--	√
Xeljanz tablets	√	√#	√	--	√	--	√
Xeljanz oral solution	--	√#	--	--	--	--	--
Xeljanz XR	√	--	√	--	√	--	√
Phosphodiesterase Type 4 Inhibitor							
Otezla	--	--	--	--	√	√	--
Sphingosine 1-Phosphate Receptor Modulator							

	Rheumatology					Dermatology	Gastro-enterology
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Ankylosing Spondylitis**	**nr-axSpA**	**Psoriatic Arthritis**	**Plaque Psoriasis**	**Ulcerative Colitis**
Zeposia	--	--	--	--	--	--	√
Tyrosine Kinase 2 Inhibitor							
Sotyktu	--	--	--	--	--	√	--

tsDMARDs – Targeted synthetic disease-modifying antirheumatic drugs; # Indicated in polyarticular JIA.

Table 4. Other Approved Biologics for Targeted Indications.

	Rheumatology		
	Rheumatoid Arthritis	**Juvenile Idiopathic Arthritis**	**Psoriatic Arthritis**
Interleukin-6 Blockers			
Actemra Intravenous	√	√^	--
Actemra Subcutaneous	√	√^	--
Kevzara	√	--	--
Interleukin-1 Blocker			
Kineret	√	--	--
T-Cell Costimulation Modulator			
Orencia Intravenous	√	√#	√
Orencia Subcutaneous	√	√#	√
CD20-Directed Cytolytic Antibody			
Rituximab Intravenous Products	√	--	--

^ Indicated in polyarticular and systemic JIA; # Indicated in polyarticular JIA.