

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2024 P 2273-4
Program	Prior Authorization/Medical Necessity
Medication	Cibinqo [™] (abrocitinib) tablets
P&T Approval Date	4/2022, 7/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Cibinqo is a Janus kinase (JAK) inhibitor indicated for the treatment of adults and pediatric patients 12 years of age and 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.

Limitation of Use:

Cibinqo is not recommended in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

2. Coverage Criteria^a:

A. Atopic Dermatitis

1. Initial Authorization

- a. Cibingo will be approved based on <u>all</u> of the following criteria:
 - (1) Diagnosis of moderate-to-severe chronic atopic dermatitis

-AND-

- (2) **One** of the following:
 - (a) **Both** of the following:
 - i. History of failure, contraindication, or intolerance to <u>two</u> of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication):
 - (a) Medium, high, or very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]
 - (b) Topical calcineurin inhibitor [e.g., pimecrolimus (generic Elidel), tacrolimus (generic Protopic)].
 - (c) Eucrisa (crisaborole)⁴

-AND-

ii. **One** of the following:



a. **Both** of the following^:

• Submission of medical records (e.g., chart notes, laboratory values) documenting a 3 month trial ^b of a systemic drug product for the treatment of atopic dermatitis [examples include, but are not limited to, Adbry (tralokinumab-ldrm), Dupixent (dupilumab), etc.^Ω] (prescription claims history may be used in conjunction as documentation of medication use, dose, and duration)

-AND-

• Physician attests that the patient was not adequately controlled with the documented systemic drug product ^b

-OR-

- b. Physician attests that systemic treatment with <u>both</u> of the following, FDA-approved chronic atopic dermatitis therapies is inadvisable.
 (Document drug and contraindication rationale) ^
 - Adbry (tralokinumab-ldrm)
 - Dupixent (dupilumab)

-OR-

c. Patient has a documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-V-TR 300.29 for specific phobia diagnostic criteria⁵).

-OR-

- (b) **Both** of the following:
 - i. Patient is currently on Cibinqo therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

ii. Patient has <u>not</u> received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from the Pfizer dermatology patient access program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cibinqo*

-AND-

(3) Patient is <u>not</u> receiving Cibinqo in combination with any of the following:



- (a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
- (b) Janus kinase inhibitor [e.g., Rinvoq (upadicitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
- (c) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (4) Prescribed by **one** of the following:
 - (a) Dermatologist
 - (b) Allergist
 - (c) Immunologist
- * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer dermatology patient access program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

2. Reauthorization

- a. Cibingo will be approved based on all of the following criteria:
 - (1) Documentation of positive clinical response to Cibingo therapy

-AND-

- (2) Patient is not receiving Cibingo in combination with any of the following:
 - (a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm), Dupixent (dupilumab)]
 - (b) Janus kinase inhibitor [e.g., Rinvoq (upadicitinib), Xeljanz/XR (tofacitinib), Olumiant (baricitinib), Opzelura (topical ruxolitinib)]
 - (c) Potent immunosuppressant (e.g., azathioprine, cyclosporine, mycophenolate mofetil)

-AND-

- (3) Prescribed by or in consultation with **one** of the following:
 - (a) Dermatologist
 - (b) Allergist
 - (c) Immunologist

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific



benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

Table 1: Relative potencies of topical corticosteroids³

Very high potency	Class	Drug	Dosage Form	Strength (%)
Clobetasol propionate Cream, foam, ointment 0.05		Augmented betamethasone	Ointment, gel	0.05
Difflorasone diacetate	Vary biala	dipropionate		
Halobetasol propionate Cream, ointment 0.05			Cream, foam, ointment	0.05
Amcinonide	potency	Diflorasone diacetate	Ointment	0.05
Augmented betamethasone dipropionate Cream, lotion 0.05		Halobetasol propionate	Cream, ointment	0.05
High Potency Desoximetasone Gel Desoximetasone Gel Desoximetasone Gel Desoximetasone Gel Diflorasone diacetate Cream, gel, ointment, solution O.05		Amcinonide	Cream, lotion, ointment	0.1
Desoximetasone Cream, ointment 0.25			Cream, lotion	0.05
Desoximetasone Gel 0.05		Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
Diflorasone diacetate		Desoximetasone	Cream, ointment	0.25
Fluocinonide	High Potency	Desoximetasone	Gel	0.05
Halcinonide		Diflorasone diacetate	Cream	0.05
Mometasone furoate Ointment 0.1		Fluocinonide	Cream, gel, ointment, solution	0.05
Triamcinolone acetonide Cream, ointment 0.5		Halcinonide	Cream, ointment	0.1
Betamethasone valerate Cream, foam, lotion, ointment 0.1		Mometasone furoate	Ointment	0.1
Medium potency Clocortolone pivalate Cream 0.1 Pluocinolone acetonide Cream, ointment 0.05 Flurandrenolide Cream, ointment, lotion 0.05 Fluticasone propionate Cream 0.05 Fluticasone propionate Ointment 0.005 Mometasone furoate Cream, lotion 0.1 Triamcinolone acetonide Cream, ointment, lotion 0.1 Hydrocortisone butyrate Cream, ointment, solution 0.1 Hydrocortisone probutate Cream 0.1 Hydrocortisone valerate Cream, ointment 0.2 Prednicarbate Cream, ointment 0.05 Low potency Alclometasone dipropionate Cream, ointment 0.05 Low potency Desonide Cream, ointment 0.05 Fluocinolone acetonide Cream, ointment 0.05 Cream, solution 0.01 Hydrocortisone Cream, solution 0.01		Triamcinolone acetonide	Cream, ointment	0.5
Medium potency Desoximetasone Cream 0.05 Fluocinolone acetonide Cream, ointment 0.025 Fluricasone propionate Cream, ointment, lotion 0.05 Fluticasone propionate Ointment 0.005 Mometasone furoate Cream, lotion 0.1 Triamcinolone acetonide Cream, ointment, lotion 0.1 Hydrocortisone butyrate Cream, ointment, solution 0.1 Hydrocortisone probutate Cream, ointment, solution 0.1 Hydrocortisone valerate Cream, ointment 0.2 Prednicarbate Cream, ointment 0.05 Low potency Alclometasone dipropionate Cream, ointment 0.05 Low potency Desonide Cream, gel, foam, ointment 0.05 Fluocinolone acetonide Cream, solution 0.01 Lowest Hydrocortisone Cream, solution 0.01		Betamethasone valerate	Cream, foam, lotion, ointment	0.1
Medium potency Fluocinolone acetonide Cream, ointment 0.025 Flurandrenolide Cream, ointment, lotion 0.05 Fluticasone propionate Cream 0.05 Fluticasone propionate Ointment 0.005 Mometasone furoate Cream, lotion 0.1 Triamcinolone acetonide Cream, ointment, lotion 0.1 Hydrocortisone butyrate Cream, ointment, solution 0.1 Hydrocortisone probutate Cream 0.1 Hydrocortisone valerate Cream, ointment 0.2 Prednicarbate Cream, ointment 0.05 Low potency Desonide Cream, ointment 0.05 Low potency Desonide Cream, gel, foam, ointment 0.05 Lowest Fluocinolone acetonide Cream, solution 0.01 Lowest Hydrocortisone Cream lotion aintment solution 0.25, 0.5, 1		Clocortolone pivalate	Cream	0.1
Flurandrenolide Cream, ointment, lotion 0.05 Fluticasone propionate Cream 0.005 Fluticasone propionate Ointment 0.005 Mometasone furoate Cream, lotion 0.1 Triamcinolone acetonide Cream, ointment, lotion 0.1 Lower-medium potency Hydrocortisone butyrate Cream, ointment, solution 0.1 Hydrocortisone probutate Cream 0.1 Hydrocortisone valerate Cream, ointment 0.2 Prednicarbate Cream 0.1 Alclometasone dipropionate Cream, ointment 0.05 Low potency Desonide Cream, ointment 0.05 Fluocinolone acetonide Cream, solution 0.01 Lowest Dexamethasone Cream 0.1 Hydrocortisone Cream lotion ointment 0.05 Cream lotion ointment solution 0.25 0.5 1		Desoximetasone		0.05
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Fluticasone propionate Cream 0.05 Fluticasone propionate Ointment 0.005 Mometasone furoate Cream, lotion 0.1 Triamcinolone acetonide Cream, ointment, lotion 0.1 Lower-medium potency Hydrocortisone butyrate Cream, ointment, solution 0.1 Hydrocortisone probutate Cream 0.1 Hydrocortisone valerate Cream, ointment 0.2 Prednicarbate Cream 0.1 Alclometasone dipropionate Cream, ointment 0.05 Low potency Desonide Cream, gel, foam, ointment 0.05 Fluocinolone acetonide Cream, solution 0.01 Lowest Hydrocortisone Cream 0.1 Hydrocortisone Cream 0.1 Example 1 on 1 o		Flurandrenolide	Cream, ointment, lotion	0.05
Mometasone furoateCream, lotion0.1Triamcinolone acetonideCream, ointment, lotion0.1Lower-medium potencyHydrocortisone butyrateCream, ointment, solution0.1Hydrocortisone probutateCream0.1Hydrocortisone valerateCream, ointment0.2PrednicarbateCream0.1Alclometasone dipropionateCream, ointment0.05Low potencyDesonideCream, gel, foam, ointment0.05Fluocinolone acetonideCream, solution0.01LowestDexamethasoneCream lotion ointment solution0.25, 0.5, 1	potency		Cream	
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Lower-medium potencyHydrocortisone butyrateCream, ointment, solution0.1Hydrocortisone probutateCream0.1Hydrocortisone valerateCream, ointment0.2PrednicarbateCream0.1Alclometasone dipropionateCream, ointment0.05Low potencyDesonideCream, gel, foam, ointment0.05Fluocinolone acetonideCream, solution0.01LowestDexamethasoneCream0.1HydrocortisoneCream lotion ointment solution0.25, 0.5, 1				
Lower- medium potency		Triamcinolone acetonide	Cream, ointment, lotion	0.1
Hydrocortisone probutate Cream 0.1	medium	Hydrocortisone butyrate	Cream, ointment, solution	0.1
Prednicarbate Cream, ointment 0.2				
Alclometasone dipropionate Cream, ointment 0.05 Low potency Desonide Cream, gel, foam, ointment 0.05 Fluocinolone acetonide Cream, solution 0.01 Lowest Dexamethasone Cream 0.1 Hydrocortisone Cream lotion ointment solution 0.25, 0.5, 1			Cream, ointment	
Low potency Desonide Cream, gel, foam, ointment 0.05 Fluocinolone acetonide Cream, solution 0.01 Lowest Dexamethasone Cream 0.1 Hydrocortisone Cream lotion ointment solution 0.25, 0.5, 1		Prednicarbate	Cream	0.1
Fluocinolone acetonide Cream, solution 0.01 Lowest Dexamethasone Cream 0.1 Hydrocortisone Cream lotion ointment solution 0.25, 0.5, 1	Low potency	Alclometasone dipropionate	*	0.05
Lowest Dexamethasone Cream 0.1 Hydrocortisone Cream lotion ointment solution 0.25 0.5 1			Cream, gel, foam, ointment	0.05
Lowest Hydrocortisone Cream lotion ointment solution 0.25.0.5.1		Fluocinolone acetonide	Cream, solution	0.01
Hydrocortisone (Freem lotion outment solution 1975 1951)	Lowest potency	Dexamethasone	Cream	0.1
notency 11 discording Cream, rotton, officiality, solution 0.25, 0.5, 1		Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
Hydrocortisone acetate Cream, ointment 0.5-1		Hydrocortisone acetate	Cream, ointment	0.5-1

^b For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

[^] Tried/failed alternative(s) are supported by FDA labeling.

^{*}Eucrisa requires prior authorization.



Table 2: Systemic immunomodulatory agents recommended by the 2014 American Academy of Dermatology guidelines for the treatment of refractory atopic dermatitis $^{\Omega,4}$

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('vic	losporine
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Azathioprine

Methotrexate

Mycophenolate mofetil

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

- 1. Cibinqo [package insert]. New York, NY: Pfizer Inc.; December 2023.
- 2. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
- 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):116-32.
- 4. Sidbury R, Davis DM, Cohen DE, 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 Aug;71(2):327-49.
- 5. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Arlington, VA: American Psychiatric Publishing. 2013.

Program	Prior Authorization/Medical Necessity – Cibinqo (abrocitnib)		
Change Control			
4/2022	New program		
7/2022	Removed age requirement from initial authorization criteria for atopic		
	dermatitis. Updated state mandate footnote to include Mississippi.		
3/2023	Updated background to reflect expanded indication for patients 12 years		
	of age and older. Updated step requirement to generic Elidel and		
	Protopic and removed footnote. Updated reference.		
3/2024	Annual review. Clarified topical steroid potency in atopic dermatitis		
	with no change to clinical intent or coverage criteria. Updated state		
	mandate footnote and reference.		