

Cibinqo (abrocitinib)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Atopic dermatitis (AD), commonly known as eczema, is a chronic inflammatory skin disorder that affects approximately 10% of adults and 20% of children worldwide. It is characterized by intense itching, redness, and eczematous lesions, which can be accompanied by skin dryness, scaling, and thickening. The clinical course of AD is characterized by chronic, relapsing episodes over months to years. In mild cases, one may experience intermittent flares that may or may not clear without the use of pharmacological intervention. In more moderate and severe cases, flares rarely clear without pharmacological intervention/therapy. The severity of AD can be classified as mild, moderate, or severe, depending on the extent and intensity of skin inflammation, as well as the impact on the patient's quality of life. Moderate-to-severe AD is defined by the presence of extensive or widespread lesions, intense pruritus, and significant impairment of daily activities, sleep, and mood.

Treatment options for moderate-to-severe AD involve a combination of topical and systemic therapies, tailored to the individual patient's needs and preferences. The goal of treatment is to control inflammation, relieve itching, restore the skin barrier, prevent flares, and improve quality of life.

- Topical treatments for moderate-to-severe AD include corticosteroids, calcineurin inhibitors, and phosphodiesterase-4 (PDE4) inhibitors. These drugs act by reducing inflammation and pruritus and promoting skin healing. However, their long-term use may be limited by adverse effects, such as skin atrophy, telangiectasias, or the potential risk of skin infections or malignancies. In particular, sensitive areas such as the face, skin folds and genitals are at high risk for skin atrophy with topical steroids, and may be an indication for alternative therapy.
- Systemic treatments for moderate-to-severe AD are reserved for patients with inadequate response or contraindications to topical therapies, or those with severe or rapidly worsening disease. The most commonly used systemic agents include oral immunosuppressants, such as cyclosporine, methotrexate, or mycophenolate mofetil; biologic agents, such as dupilumab, which targets the interleukin-4 (IL-4)/interleukin-13 (IL-13) pathway; phototherapy; and, janus kinase (JAK) inhibitors such as Cibinqo (abrocitinib), and Rinvoq (upadacitinib).
- Malignancies have occurred with Cibinqo (abrocitinib); higher rates of lymphomas and lung cancers have been seen in those taking JAK inhibitors versus TNF inhibitors in those with RA.
- Major adverse cardiovascular events (MACE), defined as cardiovascular death, myocardial infarction and stroke, has occurred in those taking Cibinqo (abrocitinib); higher rates have occurred with other JAK inhibitors compared to TNF inhibitors in those with RA.
- Thrombosis has occurred in those with Cibinqo (abrocitinib); there is an increased risk of pulmonary embolism (PE), venous and arterial thrombosis with JAK inhibitors compared to TNF inhibitors.

Cibinqo (abrocitinib) is indicated for the treatment of adults and those 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 the use of those therapies is inadvisable.

Limitations of Use: Cibinqo (abrocitinib) is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, or with other immunosuppressants.

Cibinqo (abrocitinib) has a boxed warning for the following:

- Increased risk of serious bacterial, fungal, viral and opportunistic infections leading to hospitalization or death, including tuberculosis (TB). Cibinqo (abrocitinib) should be discontinued if serious or opportunistic infection occurs. Testing for latent TB before and during therapy is recommended; and if latent TB is detected it should be treated prior to use.
- High rate of all-cause mortality, including sudden cardiovascular death, with another JAK inhibitor versus tumor necrosis factor (TNF) inhibitors in those with rheumatoid arthritis (RA). Cibinqo (abrocitinib) should not be used at this time in those with RA.

Definitions

“Atopic Dermatitis” also known as eczema is a chronic skin condition that makes a person’s skin red, itchy and scaly. Atopic dermatitis (AD) often begins during childhood and persists into adulthood. Some people experience occasional flares followed by periods of improvement or a “waxing and waning” course of the disease.

“Biologics” are a type of medication that are designed to target specific parts of the immune system. Some biologics, such as Dupixent, Adbry, and Rinvoq, are used in the treatment of moderate to severe atopic dermatitis.

“Body Surface Area (BSA%)” is a measure of the total area involved by plaques in relation to the total body surface area. There are a number of different methods, however most clinical trials on plaque psoriasis use the “handprint method”, where the patient’s actual palm/hand size is estimated as 1% of BSA. The head and neck, upper extremities, trunk, and lower extremities (including buttocks) typically correspond to approximately 10%, 20%, 30% and 40% of the BSA, respectively.

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

“Interleukin (IL)-13 cytokine” is a protein secreted by certain cells of the immune system that affects many aspects of chronic airway inflammation.

“Janus kinase 1 (JAK1) inhibitor” is a type of medication that functions by inhibiting the activity of one or more enzymes in the Janus kinase family. This action helps to reduce the inflammatory response that underlies conditions like atopic dermatitis.

“No evidence of” indicates that the reviewer has not identified any records of the specified item or condition within the submitted materials or claims history. In the absence of such evidence, the member is considered eligible. If any evidence of the item or condition is present upon review of the request, the member does not qualify.

“Topical Corticosteroids (TCS)” are steroid medications applied to the skin. They are used to reduce inflammation and suppress the immune response in conditions like atopic dermatitis.

“[s]” indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Moderate-to-Severe Atopic Dermatitis

The Plan considers Cibinqo (abrocitinib) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with a dermatologist, allergist, or immunologist; *AND*
2. The member is 12 years of age or older; *AND*
3. The member has a documented diagnosis of moderate to severe atopic dermatitis *AND ONE* (1) of the following:
 - a. Involvement of equal to or greater than (\geq) 10% or more of body surface area (BSA); *or*
 - b. Involvement of sensitive body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas); *AND*
4. The member is unable to use, or has adequately tried and failed *TWO* (2) of the following therapies for at least 8 weeks each in the past 365 days^[s]:
 - a. At least one (1) topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see [Appendix A, Table 2](#)); *and/or*
 - b. Tacrolimus ointment; *and/or*
 - c. Eucrisa (crisaborole); *AND*
5. The member has no evidence of concomitant use of antiplatelet therapy (except for aspirin \leq 81 mg daily), during the first 3 months of treatment with Cibinqo (abrocitinib); *AND*
6. Cibinqo (abrocitinib) will not be used concomitantly with other JAK inhibitors (e.g., Rinvoq [upadacitinib]), or biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab], or Ebglyss [lebrikizumab]) for the treatment of atopic dermatitis; *AND*
7. Cibinqo (abrocitinib) is being prescribed at a dose and frequency that is within FDA approved labeling *OR* is supported by compendia or evidence-based published dosing guidelines for the requested indication; *AND*

8. Clinical chart documentation is provided for review to validate the above listed requirements.

If the above prior authorization criteria are met, Cibinqo (abrocitinib) will be approved for up to 4-months.^[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Moderate-to-Severe Atopic Dermatitis

The Plan considers Cibinqo (abrocitinib) medically necessary when recent chart documentation (within the past 4-months) is provided showing ALL of the following criteria are met:

1. The member is responding positively to Cibinqo (abrocitinib) treatment based upon the prescriber's assessment as demonstrated by ONE (1) of the following:
 - a. Decreased disease activity (e.g., a reduction in BSA%); *or*
 - b. Symptomatic improvement (e.g., redness, itching, oozing/crusting); *AND*
2. Cibinqo (abrocitinib) will not be used concomitantly with other JAK inhibitors, biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab], Ebglyss [lebrikizumab], or Rinvoq [upadacitinib]) for the treatment of atopic dermatitis; *AND*
3. Cibinqo (abrocitinib) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.^[s]

Experimental or Investigational or Unproven / Not Medically Necessary^[s]

Cibinqo (abrocitinib) for any other indication apart from atopic dermatitis is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, unproven, or not medically necessary. Non-covered indications include, but are not limited to, the following:

- Chronic Prurigo / Prurigo Nodularis / Pruritus / Pruritus Chronic / Skin Diseases. Only one non-randomized study assessing the impact of Cibinqo (abrocitinib) on prurigo nodularis and chronic pruritus of unknown origin was identified. The study was limited by being non-randomized, open-label, lacking placebo or comparator group, and its small sample size (n=20). While it was found that Cibinqo (abrocitinib) was effective, larger, high-quality randomized studies are needed to support this indication.

- Granuloma annulare lesions. No clinical trials have supported the safety and efficacy of Cibinqo (abrocitinib) for the management of granuloma annulare lesions. One study is currently active (NCT05650736) but results have not yet been published.
- Psoriasis or Psoriasis Vulgaris (Plaque Psoriasis). One only phase-II randomized study assessed the impact of Cibinqo (abrocitinib) on those with moderate-to-severe psoriasis. While the outcome was favorable for Cibinqo (abrocitinib), it's small sample size (n=59) and short follow-up period (4 weeks) are limitations, and further studies are needed to support the safety and efficacy of Cibinqo (abrocitinib) for this indication.
- Rheumatoid Arthritis. JAK inhibitors are associated with higher rates of all-cause mortality, including sudden cardiovascular death, compared to tumor necrosis factor (TNF) inhibitors in those with rheumatoid arthritis (RA). The boxed warning for Cibinqo (abrocitinib) explicitly states it is not approved in those with RA.
- Sarcoidosis. No clinical trials have supported the safety and efficacy of Cibinqo (abrocitinib) for the management of sarcoidosis. One study is currently completed (NCT05696795) but results have not yet been published (the study will be limited by its small sample size [n=10], lack of masking and a comparator group).
- Use for dual therapy with other JAK inhibitors or biologics (e.g., Dupixent [dupilumab], Adbry [tralokinumab], or Rinvoq [upadacitinib]).
- Use as a preventative agent for the development of skin conditions.

Appendix A

Table 1: Dosage, Retreatment, and Other Considerations

Indication	Initial dose	Subsequent dose	Additional Considerations
Moderate to severe atopic dermatitis	100 mg PO once daily	Consider increasing the dose to 200 mg PO once daily	Complete any necessary immunizations, including herpes zoster vaccinations, prior to Cibinqo (abrocitinib) initiation
Adults who are CYP2C19 poor metabolizers	50 mg PO once daily	Consider increasing the dose to 100 mg PO once daily. Discontinue use of the drug if an adequate response is not achieved with the 100 mg dose	N/A
Renal Impairment: Moderate (30 - 59 mL/minute eGFR)	50 mg PO once daily	If an adequate response is not achieved may increase to 100 mg daily	N/A
Renal Impairment: Severe or End Stage Renal Disease† (less	Use is not recommended	N/A	N/A

than 30 mL/minute eGFR)			
Hepatic Impairment: Severe (Child-pugh C)	Use is not recommended	N/A	N/A

†Severe Renal Impairment and End-Stage Renal Disease include patients on renal replacement therapy.

Table 2: Topical Corticosteroid Potency

NOTE: The following chart is only for approximate comparative purposes. Please check product-specific information to best assess product potency, which can also be affected by a multitude of factors (e.g., formulation, site of application, member and disease-specific factors)

Group	Potency	Steroid	Strength	Dosage Form
I	Very High	Betamethasone dipropionate (augmented)	0.05%	Gel, Lotion, and Ointment
		Clobetasol propionate	0.05%	Cream, Emollient Cream, Foam, Gel, Lotion, Ointment, Spray, and Solution
		Diflorasone diacetate	0.05%	Ointment
		Fluocinonide	0.1%	Cream
		Flurandrenolide	0.05%	Tape
		Halobetasol propionate	0.05%	Cream, Foam, Lotion and Ointment
II	High	Amcinonide	0.1%	Ointment
		Betamethasone dipropionate (augmented)	0.05%	Cream
		Betamethasone dipropionate	0.05%	Ointment
		Clobetasol propionate	0.025%	Cream
		Desoximetasone	0.25%	Cream, Ointment and Spray
		Desoximetasone	0.05%	Gel
		Diflorasone diacetate	0.05%	Cream, Emollient Cream, and Ointment
		Fluocinonide	0.05%	Cream, Gel, Ointment, and Solution
		Halcinonide	0.1%	Cream, Ointment, and Solution

		Halobetasol propionate	0.01%	Lotion
III	Upper Medium	Amcinonide	0.1%	Cream and Lotion
		Betamethasone dipropionate	0.05%	Cream
		Betamethasone valerate	0.12%	Foam
		Betamethasone valerate	0.1%	Ointment
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinonide	0.05%	Emollient Cream
		Fluticasone propionate	0.005%	Ointment
		Mometasone furoate	0.1%	Ointment
		Triamcinolone acetonide	0.5%	Cream
IV	Medium	Betamethasone dipropionate	0.05%	Spray
		Clocortolone pivalate	0.1%	Cream
		Desoximetasone	0.05%	Cream and Ointment
		Fluocinolone acetonide	0.025%	Ointment
		Flurandrenolide	0.05%	Ointment
		Fluticasone propionate	0.05%	Cream
		Hydrocortisone valerate	0.2%	Ointment
		Mometasone furoate	0.1%	Cream, Lotion, and Solution
		Triamcinolone acetonide	0.1%	Cream, Dental Paste, Ointment, and Spray
V	Lower Medium	Betamethasone dipropionate	0.05%	Lotion
		Betamethasone valerate	0.1%	Cream
		Desonide	0.05%	Gel and Ointment
		Fluocinolone acetonide	0.025%	Cream
		Fluocinolone acetonide	0.01%	Shampoo
		Flurandrenolide	0.05%	Cream and Lotion

		Fluticasone propionate	0.05%	Lotion
		Hydrocortisone butyrate	0.1%	Cream, Lotion, Ointment, and Solution
		Hydrocortisone probutate	0.1%	Cream
		Hydrocortisone valerate	0.2%	Cream
		Prenicarbate	0.1%	Emollient Cream and Ointment
		Triamcinolone acetonide	0.1%	Lotion
		Triamcinolone acetonide	0.025%	Ointment
VI	Low	Alclometasone dipropionate	0.05%	Cream and Ointment
		Betamethasone valerate	0.1%	Lotion
		Desonide	0.05%	Cream, Lotion, and Foam
		Fluocinolone acetonide	0.01%	Cream, Oil, Shampoo and Solution
		Triamcinolone acetonide	0.025%	Cream and Lotion
VII	Lowest	Hydrocortisone acetate	1% to 2.5%	Cream, Lotion, and Ointment
		Hydrocortisone base	0.5% to 2.5%	Cream, Gel, Liquid, Lotion, Ointment, Solution, and Spray

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