Clinical Guideline

Oscar Clinical Guideline: Cibinqo (abrocitinib) (PG111, Ver. 2)

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.

Summary

Atopic dermatitis (AD) 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 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.

- 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, and biologic agents, such as dupilumab, which targets the interleukin-4 (IL-4)/interleukin-13 (IL-13) pathway.

Cibinqo (abrocitinib) is 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 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.*

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%)**" refers to the percentage of the body covered by atopic dermatitis. It is often used in determining the severity of the disease.

"**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.

"**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.

Medical Necessity Criteria for Initial Authorization

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** of the following:
    a. Involvement of (≥) 10% or more of body surface area***; 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 **ALL** of the following topical therapies for at least 8 weeks each in the past 365 days:
    a. At least two (2) topical corticosteroid (TCS) from medium potency (group III to IV) classes to higher potencies (groups I to II) classes (see **Table 2**)***; and***
    b. Tacrolimus ointment***; and***
    c. Eucrisa (crisaborole) [require members be unable to use, or has tried and failed a medium or higher potency TCS within the past 180 days]***; AND***
5. Cibinqo (abrocitinib) will not be used concomitantly with other JAK inhibitors, biologics (e.g., Dupixent, Adbry, or Rinvoq) in the treatment of atopic dermatitis***; AND***
6. Cibinqo (abrocitinib) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature***; AND***
7. 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 4 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months may be provided for members 12 years of age or older 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** 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, Adbry, or Rinvoq) in the treatment of atopic dermatitis***; AND***

3. Cibinqo (abrocitinib) is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in a compendia of current literature.

Experimental or Investigational / Not Medically Necessary

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, or unproven. Non-covered indications include, but are not limited to, the following:

- Chronic Prurigo / Prurigo Nodularis / Pruritus / Pruritus Chronic / Skin Diseases
- Granuloma annulare lesions
- Psoriasis
- Psoriasis Vulgaris (Plaque Psoriasis)
- Sarcoidosis
- Use for dual therapy with other JAK inhibitors or biologics (e.g., Dupixent, Adbry, or Rinvoq)
- Use as a preventative agent for the development of skin conditions

Appendix

Table 1: Dosage, Retreatment, and Other Considerations

Indication	Initial dose	Subsequent dose	Additional Considerations
Moderate to severe atopic dermatitis	100 mg PO once daily	If an adequate response is not achieved after 12 weeks, 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	If an adequate response is not achieved after 12 weeks, 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: Mild (60 - 89 mL/minute eGFR)	100 mg PO once daily	If an adequate response is not achieved after 12 weeks, the dose of CIBINQO can be doubled	N/A

Renal Impairment: Moderate (30 - 59 mL/minute eGFR)	50 mg PO once daily	If an adequate response is not achieved after 12 weeks, the dose of CIBINQO can be doubled	N/A
Renal Impairment: Severe† (15 - 29 mL/minute eGFR)	Not recommended for use	N/A	N/A
End-Stage Renal Disease† (ESRD) (<15 mL/minute eGFR)	Not recommended for use	N/A	N/A
Hepatic Impairment: Severe	Not recommended for use	N/A	N/A
Taking strong inhibitors of CYP2C19	50 mg PO once daily	If an adequate response is not achieved after 12 weeks, consider increasing the dose to 100 mg PO once daily. Discontinue therapy if inadequate response is seen after dosage increase to 100 mg once daily	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
		Desoximetasone	0.25%	Spray
		Diflorasone diacetate	0.05%	Ointment

		Fluocinonide	0.1%	Cream
		Flurandrenolide	0.05%	Tape
		Halobetasol propionate	0.05% and 0.01%	Cream, Foam, Lotion and Ointment
II	High	Amcinonide	0.1%	Ointment
		Betamethasone dipropionate (augmented)	0.05%	Cream
		Betamethasone dipropionate	0.05%	Ointment
		Desoximetasone	0.25%	Cream and Ointment
		Desoximetasone	0.05%	Gel
		Diflorasone diacetate	0.05%	Cream, and Emollient Cream
		Fluocinonide	0.05%	Cream, Gel, Ointment, and Solution
		Halcinonide	0.1%	Cream, Ointment, and Solution
		Triamcinolone acetonide	0.5%	Ointment
III	Upper Medium	Amcinonide	0.1%	Cream and Lotion
		Betamethasone dipropionate	0.05%	Cream
		Betamethasone valerate	0.12%	Foam
		Betamethasone valerate	0.1%	Ointment
		Fluocinonide	0.05%	Emollient Cream
		Fluticasone propionate	0.005%	Ointment
		Mometasone furoate	0.1%	Ointment
		Triamcinolone acetonide	0.5%	Cream
		Triamcinolone acetonide	0.1%	Ointment
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
		Hydrocortisone valerate	0.2%	Ointment
		Mometasone furoate	0.1%	Cream, Lotion, and Solution
		Triamcinolone acetonide	0.1%	Cream and Spray
V	Lower Medium	Betamethasone dipropionate	0.05%	Lotion
		Betamethasone valerate	0.1%	Cream and Lotion
		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%	Cream and 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
		Desonide	0.05%	Cream, Lotion, and Foam
		Fluocinolone acetonide	0.01%	Cream, Oil, and Solution
		Triamcinolone acetonide	0.025%	Cream and Lotion
VII	Lowest	Hydrocortisone acetate	0.5% and 1%	Cream and Ointment
		Hydrocortisone base	0.5% to 2.5%	Cream, Lotion, Ointment, Solution, and Spray

References

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Clinical Guideline Revision / History Information

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