

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators- Cibinqo Effective Date: August 1, 2025**

Therapeutic Class Code: ZZZ

Therapeutic Class Description: Immunomodulatory Agents (Janus Kinase Inhibitors)

Medication
Cibinqo

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary’s physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary’s right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider’s documentation shows that the requested service is medically necessary “to correct or ameliorate a defect, physical or mental illness, or a condition” [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary’s health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.

IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators- Cibinqo Effective Date: August 1, 2025**

addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:

<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents>

1. Atopic Dermatitis:

Criteria for Initial Approval:

- Beneficiary has a diagnosis of moderate-to-severe atopic dermatitis (AD) defined by ≥ 1 of the following:
 - Involvement of $\geq 10\%$ of body surface area (BSA); OR
 - Eczema Area and Severity Index (EASI) score of ≥ 16 ; OR
 - Investigator's Global Assessment (IGA) score of ≥ 3 ; OR
 - Scoring Atopic Dermatitis (SCORAD) score of ≥ 25 ; OR
 - Pruritus Numerical Rating Scale (NRS) score of ≥ 4 ; OR
 - Incapacitation due to AD lesion location (head and neck, palms, soles, or genitalia); **AND**
- Beneficiary is ≥ 12 years of age; **AND**
- Beneficiary did NOT respond adequately (or is not a candidate) to a 3-month minimum trial of topical agents (e.g., corticosteroids, calcineurin inhibitors [e.g., tacrolimus or pimecrolimus], crisaborole); **AND**
- Beneficiary did NOT respond adequately (or is not a candidate*) to a 3-month minimum trial of phototherapy (e.g., Psoralens with UVA light [PUVA], UVB); **AND**
- Beneficiary did NOT respond adequately (or is not a candidate) to a 3-month minimum trial of ≥ 1 systemic agent (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil, dupilumab, tralokinumab-ldrm); **AND**
- Beneficiary individual risks and benefits have been considered prior to initiating or continuing therapy in those at higher risk for malignancy and/or major adverse cardiovascular events (MACE); **AND**
- Beneficiary is NOT considered to be at high risk for thrombosis; **AND**
- Beneficiary has been evaluated and screened for the presence of viral hepatitis prior to initiating treatment in accordance with clinical guidelines; **AND**
- Beneficiary has been considered and screened for the presence of latent tuberculosis infection; **AND**
- Beneficiary will NOT receive live vaccines during therapy; **AND**
- Will NOT be used in combination with other monoclonal antibody biologics (e.g., tezepelumab, omalizumab, mepolizumab, reslizumab, benralizumab, dupilumab, tralokinumab) or other non-biologic agents (e.g., apremilast, baricitinib, tofacitinib, upadacitinib); **AND**
- Beneficiary is NOT on concomitant antiplatelet therapies during the first 3 months of treatment (Note: excludes the use of low-dose aspirin [≤ 81 mg daily]); **AND**
- Beneficiary does NOT have severe hepatic impairment (e.g., Child-Pugh C) or severe renal impairment (eGFR < 30 mL/min); **AND**
- Beneficiary will avoid concomitant therapy with all of the following:
 - Coadministration with strong CYP2C19 inhibitors (e.g., amitriptyline, fluconazole, imipramine,); if therapy is unavoidable, the beneficiary will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**
 - Coadministration with moderate to strong CYP2C19 and CYP2C9 inhibitors (e.g., fluconazole,

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators- Cibinqo Effective Date: August 1, 2025**

- fluvoxamine, voriconazole); **AND**
- Coadministration with strong CYP2C19 inducers (e.g., enzalutamide, rifampin) or CYP2C9 inducers (e.g., rifampin, carbamazepine, enzalutamide)

Procedures

- Approve for up to 6 months.
- Coverage of one injectable immunomodulator at a time

**Examples of contraindications to phototherapy (PUVA or UVB) include the following:*

- Xeroderma pigmentosum
- Pregnancy or lactation (PUVA only)
- Lupus Erythematosus
- History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage (PUVA only), or treatment with arsenic or ionizing radiation
- Immunosuppression in an organ transplant patient (UVB only)
- Photosensitizing medications (PUVA only)
- Severe liver, renal, or cardiac disease (PUVA only)

Criteria for Renewal:

- Beneficiary must continue to meet the above criteria; **AND**
- Disease response as indicated by improvement in signs and symptoms compared to baseline in ≥ 1 of the following: pruritus, the amount of surface area involvement, EASI, IGA, SCORAD, and/or NRS; **AND**
 - Beneficiary has achieved clear or almost clear skin defined as achievement of an IGA 0/1 or EASI-75 at week 16; **OR**
 - Beneficiary has had an inadequate response to standard doses of therapy after an adequate trial of ≥ 12 weeks **OR** beneficiary experienced a disease flare and will require higher dosing; **AND**
 - Beneficiary requires an increase in dose, in accordance with prescribing information recommended dosages (e.g., up to 200 mg daily)
- Beneficiary has NOT experienced a myocardial infarction or stroke; **AND**
- Beneficiary has NOT experienced any treatment-restricting adverse effects (serious infections [e.g., fungal, viral, or other opportunistic infections], tuberculosis, virus reactivation [e.g., herpes zoster, Hepatitis B, Hepatitis C], malignancy and lymphoproliferative disorders [e.g., lymphomas, non-melanoma skin cancer, or other solid tumors], major adverse cardiovascular events [MACE], thrombosis [e.g., pulmonary embolism, deep vein thrombosis, arterial thrombosis], lymphopenia, thrombocytopenia, neutropenia, anemia, lipid elevation, etc.).

Procedures

- Approve for up to 6 months.
- Coverage of one injectable immunomodulator at a time

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators**

**Medicaid
Effective Date: August 15, 2014
Amended Date:**

References

1. Cibinco [package insert]. New York, NY; Pfizer; January 2022.

**NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators**

Medicaid

Effective Date: August 15, 2014

Amended Date:

Criteria Change Log

08/01/2025

Criteria effective date