NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators

Medicaid and Health Choice
Effective Date: August 15, 2014
Amended Date:

DRAFT

Therapeutic Class Code: Z2Z
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.

NC Health Choice (NCHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified. **EPSDT does not apply to NCHC beneficiaries**.

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 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

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

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 ≥ 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 ≥ 18 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 patient 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, 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 patient experienced a disease flare and will require higher dosing; **AND**

  - Patient 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

References

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

Criteria Change Log

08/15/2014	Criteria effective date
06/10/2015	add Otezla and add gcn 37262 for Humira
01/21/2016	add Cosentyx
06/13/2016	add dx Hidradenitis Suppurativa for Humira
10/03/2016	add Xeljanz XR
10/19/2016	add Taltz
06/27/2018	add diagnosis for Ilaris- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS), Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD), and Familial Mediterranean Fever (FMF) add diagnosis for Humira-Uveitis add Arcalyst to criteria coverage add infusion products to clinical coverage criteria- Actemra Infusion, Entyvio Infusion, Orencia Infusion, Remicade Infusion, Simponi Aria Infusion add new dx for Orencia- PHIA, Psoriatic Arthritis add Kevzara to criteria add diagnosis chart add Renflexis add Psoriatic Arthritis DX for coverage-Taltz add Psoriatic Arthritis DX for Xeljanz and Xeljanz XR
02/26/2019	update chart add Simponi Aria for DX Ankylosing Spondylitis, add Enbrel PJIA add Stelara Plaque Psoriasis (12 and up) add Cimzia Plaque Psoriasis adult add Otezla Psoriatic Arthritis remove Renflexis exception add Xeljanz/Xeljanx XR and Renflexis UC adults add Actemra and Actemra SQ to Giant Cell Arteritis and Cytokine Release Syndrome add Tremfya add Olumiant
07/18/2019	add ages for Humira in HS (12 and older) and Uveitis (2 and older) Include Cosentyx as try and fail for Anklyosing Spondylitis, Plaque Psoriasis, and Psoriatic Arthritis add Ilumya for Plaque Psoriasis (adult) update chart add Siliq
11/04/2019	Add Dx Non-Radiographic Axial Spondyloarthritis for Cimzia
12/09/2019	Removed GCN's, add Skyrizi to adult plaque psoriasis, add Stelara Infusion

07/13/2020	Added Taltz to Ankylosing Spondylitis, add Rinvoq ER Added Behcet's Disease for Otezla Updated EPSDT Information Updated table
02/01/2021	Add Stelara for ulcerative colitis for Adults Add Xeljanz XR for ulcerative colitis for adults Add contraindication or intolerance to methotrexate step for plaque psoriasis
02/01/2021	Add Taltz to plaque psoriasis for pediatrics & Non-Radiographic Axial Spondyloarthritis Add Avsola
02/01/2021	Added Cosentyx to Non-Radiographic Axial Spondyloarthritis Added bullet to Non-Radiographic Axial Spondyloarthritis requiring t/f of Cosentyx prior to approval of NP agent Added adult-onset Still's disease (AOSD) criteria for Ilaris Added Tremfya to psoriatic arthritis Added Enspryng & Uplinza for Neuromyelitis Optica Spectrum Disorder (NMOSD) to policy Age for Stelara for pediatric plaque psoriasis changed from 12 to 6
02/01/2021	Added Simponi Aria & Xeljanz to Polyarticular Juvenile Idiopathic Arthritis Updated age for Simponi Aria for Psoriatic Arthritis
10/1/21	Added Deficiency of Interleukin-1 Receptor Antagonist (DIRA) for Arcalyst and Kineret
xx/xx/xxxx	Separated out criteria by individual agents
xx/xx/xxxx	Added Cibinqo