NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Xeljanz **Effective Date: August 15, 2014**
Systemic Immunomodulators **Amended Date: January 2, 2025**

Therapeutic Class Code: Z2Z
Therapeutic Class Description: Immunomodulatory Agents

Medication
Xeljanz tablets
Xeljanz oral solution

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.

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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

Criteria for approval

1. **Ankylosing Spondylitis: (Xeljanz tablets)**
- Beneficiary has a diagnosis of Ankylosing Spondylitis.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  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 considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab.
  AND
- Beneficiary will NOT receive live vaccines during therapy
  AND
- Beneficiary has tried at least one Tumor Necrosis Factor Blocker with inadequate response or is unable to take these therapies due to intolerance or contraindications.
  AND
- Coverage of non-preferred medications require a trial and failure of Cosentyx, Enbrel or Humira or a clinical reason beneficiary cannot try either Cosentyx, Enbrel or Humira.

2. **Polyarticular Juvenile Idiopathic Arthritis (PJIA)**: (Xeljanz tablets, Xeljanz oral solution)
- Beneficiary has a diagnosis of Polyarticular Juvenile Idiopathic Arthritis.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  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 considered and screened for the presence of latent tuberculosis infection.

AND
- Beneficiary has been tested with Hep B SAG and Core Ab.
  AND
- Beneficiary will NOT receive live vaccines during therapy
  AND
- Beneficiary has tried at least one Tumor Necrosis Factor Blocker with inadequate response or is unable to take these therapies due to intolerance or contraindications.
  AND
- Coverage of non-preferred medications require a trial and failure of Enbrel or Humira or a clinical reason beneficiary cannot try Enbrel or Humira.

3. **Psoriatic arthritis: (Xeljanz tablets)**
- Beneficiary has a documented definitive diagnosis of Psoriatic Arthritis.
  AND
- Beneficiary is 18 years of age or older.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  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 considered and screened for the presence of latent tuberculosis infection.
- AND
- Beneficiary has been tested with Hep B SAG and Core Ab.
  AND
- Beneficiary will NOT receive live vaccines during therapy
  AND
- Beneficiary has a documented inadequate response, intolerance or contraindication to at least one Tumor Necrosis Factor Blocker
  AND
- Coverage of non-preferred medications require a trial and failure of Cosentyx, Enbrel or Humira or a clinical reason beneficiary cannot try either Cosentyx, Enbrel or Humira.

4. **Rheumatoid arthritis:** (Xeljanz tablets)
- Beneficiary has a diagnosis of Rheumatoid Arthritis.
  AND
- Beneficiary is not on another injectable biologic immunomodulator.
  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 considered and screened for the presence of latent tuberculosis infection.
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab.
  AND
- Beneficiary will NOT receive live vaccines during therapy
  AND
- Beneficiary has experienced a therapeutic failure/inadequate response with at least one Tumor Necrosis Factor Blocker
  OR
- Beneficiary is unable to receive Necrosis Factor Blocker due to contraindications or intolerabilities.
  AND
- Coverage of non-preferred medications require a trial and failure of Enbrel or Humira or a clinical reason beneficiary cannot try either Enbrel or Humira.

5. **Ulcerative colitis (Adult):** (Xeljanz tablets)
   - Beneficiary has a diagnosis of ulcerative colitis.
     AND
   - Beneficiary is not on another injectable biologic immunomodulator.
     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 considered and screened for the presence of latent tuberculosis infection.
     AND
   - Beneficiary has been tested with Hep B SAG and Core Ab.
     AND
   - Beneficiary will NOT receive live vaccines during therapy
     AND
   - Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira.

Procedures

- Approve for up to 12 months.
- Coverage of one injectable immunomodulator at a time.

References

1. Pfizer. Xeljanz package insert. New York: September 2013. Revised December 2017. Updated September 2020. Updated December 2021.

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Criteria Change Log

08/15/2014	Criteria effective date
06/27/2018	add Psoriatic Arthritis DX for Xeljanz
02/26/2019	add Xeljanz for UC adults
02/01/2021	Add Xeljanz to Polyarticular Juvenile Idiopathic Arthritis
01/02/2025	Separated out criteria by individual agents Replaced step through methotrexate or DMARD with step through TNF blocker Added criteria for ankylosing spondylitis Added Xeljanz oral solution to pJIA Added criteria bullets re: MACE, thrombosis & live vaccine use