NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Rinvoq ER **Effective Date: July 13, 2020**
Systemic Immunomodulators **Amended Date: August 12, 2026**

Therapeutic Class Code: Z2Z
Therapeutic Class Description: Immunomodulatory Agents

Medication
Rinvoq ER and Rinvoq LQ

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

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. **Rheumatoid arthritis:** (18 years of age and older)
   - Beneficiary has a diagnosis of Rheumatoid Arthritis.
     AND
   - Beneficiary is not on another biologic immunomodulator.
     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 is NOT considered to be at high risk for thrombosis
     AND
   - Beneficiary has experienced a therapeutic failure/inadequate response, with at least one Tumor Necrosis Factor Blocker
     OR
   - Beneficiary is unable to receive Tumor Necrosis Factor Blockers due to contraindications or intolerabilities.
     OR
   - Beneficiary has clinical evidence of severe or rapidly progressing disease.

2. **Psoriatic arthritis:** (2 years of age and older)
   - Beneficiary has a documented definitive diagnosis of Psoriatic Arthritis.
     AND
   - Beneficiary is not on another biologic immunomodulator.
     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 is NOT considered to be at high risk for thrombosis
     AND
   - Beneficiary has experienced a therapeutic failure/inadequate response with at least one Tumor Necrosis Factor Blocker
     OR
   - Beneficiary is unable to receive Tumor Necrosis Factor Blockers due to contraindications or intolerabilities.

3. **Ulcerative Colitis:** (18 years of age and older)

- Beneficiary has a diagnosis of ulcerative colitis.
  AND
- Beneficiary is not on another 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 Tumor Necrosis Factor Blockers due to contraindications or intolerabilities.

4. **<u>Ankylosing Spondylitis:</u>** (18 years of age and older)
   - Beneficiary has a diagnosis of Ankylosing Spondylitis.
     AND
   - Beneficiary is not on another 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 inadequate symptom relief from treatment with at least two NSAIDS.
     OR
   - Beneficiary is unable to receive treatment with NSAIDS due to contraindications.
     OR

- Beneficiary has clinical evidence of severe or rapidly progressing disease.
  AND
- Beneficiary has experienced a therapeutic failure/inadequate response with at least one Tumor Necrosis Factor Blocker
  OR
- Beneficiary is unable to receive Tumor Necrosis Factor Blockers due to contraindications or intolerabilities.

5. **Atopic Dermatitis:** (age 12 years of age weighing at least 40 kg)

- 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 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 is not on another biologic immunomodulator;
  AND
- Beneficiary has been tested with Hep B SAG and Core Ab
  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)

**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)*

6. **Non-radiographic axial spondyloarthritis (nr-axSpA):** (18 years of age and older)
   - Beneficiary has a diagnosis of Non-Radiographic Axial Spondyloarthritis;
     AND
   - Beneficiary is not on another 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 failed an adequate trial of a Non-Steroidal Anti-Inflammatory Drug (NSAID) unless contraindicated;
     AND
   - Beneficiary has experienced a therapeutic failure/inadequate response with at least one Tumor Necrosis Factor Blocker OR Beneficiary is unable to receive Tumor Necrosis Factor Blockers due to contraindications or intolerabilities;

7. **Crohn's Disease:** (18 years and older)
   - Beneficiary has a diagnosis of moderately to severely active Crohn's Disease.
     AND
   - Beneficiary is not on another 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 Tumor Necrosis Factor Blockers due to contraindications or intolerabilities.

8. <u>Polyarticular Juvenile Idiopathic Arthritis (PJIA)</u>: (2 years of age and older)

- Beneficiary has a diagnosis of Polyarticular Juvenile Idiopathic Arthritis.
  AND
- Beneficiary is not on another biologic immunomodulator.
  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 is NOT considered to be at high risk for thrombosis
  AND
- Beneficiary has tried one systemic corticosteroid (e.g. prednisone, methylprednisolone) or methotrexate, leflunomide or sulfasalazine with inadequate response or is unable to take these therapies due to contraindications.
  OR
- Beneficiary has PJIA subtype enthesitis related arthritis.

9. <u>Giant Cell Arteritis:</u> (18 years of age and older)

- Beneficiary has a diagnosis of Giant Cell Arteritis.
  AND
- Beneficiary is not on another biologic immunomodulator.
  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 is NOT considered to be at high risk for thrombosis

Procedures

- Approve for up to 12 months.
- Coverage of one immunomodulator at a time
- Preferred Drug List (PDL) criteria also apply if requested medication is on the PDL. (ex. try and fail preferred(s)first or a clinical reason the preferred(s) cannot be tried or other criteria as noted on the PDL).

References

1. AbbVie, Inc., Rinvoq Prescribing Information. North Chicago, IL: August 2019. Updated April 2025.

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Criteria Change Log

07/13/2020	Criteria effective date
01/02/2025	Separated out criteria by individual agents Criteria changed to require step through ≥ 1 TNF blocker, rather than methotrexate or ≥ 1 DMARD Added criteria for psoriatic arthritis
08/12/2026	Lowered age for psoriatic arthritis Added the following indications: Ulcerative Colitis, Ankylosing Spondylitis, Polyarticular Juvenile Idiopathic Arthritis, Non-radiographic axial spondyloarthritis, Atopic Dermatitis, Crohn's Disease, Giant Cell Arteritis added Rinvoq LQ. Changed to coverage of one immunomodulator at a time from one injectable immunomodulator at a time