NC Medicaid Outpatient Pharmacy Prior Approval Criteria Systemic Immunomodulators	Medicaid and Health Choice Effective Date: August 15, 2014 Amended Date:

DRAFT

Therapeutic Class Code: S2J
Therapeutic Class Description: Immunomodulatory Agents

Medication
Renflexis

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.

Criteria for approval

1. Ankylosing Spondylitis:

- Beneficiary has a diagnosis of Ankylosing Spondylitis.
  AND
- Beneficiary is not on another injectable 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 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
- Coverage of non-preferred medications require a trial and failure of Cosentyx, Enbrel or Humira or a clinical reason beneficiary cannot try Cosentyx, Enbrel or Humira.

2. Crohn's Disease (Adult):

- Beneficiary has a diagnosis of moderate to severe Crohn's Disease.
  AND
- Beneficiary is not on another injectable 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

- Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira.

3. Crohn's Disease (Pediatric):

- Beneficiary has a diagnosis of moderate to severe Crohn's Disease.
  AND
- Beneficiary is not on another injectable 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
- Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira.

4. Plaque psoriasis (adult):

- Beneficiary has a documented definitive diagnosis of moderate-to-severe Chronic Plaque Psoriasis
  AND
- Beneficiary is 18 years of age or older.
  AND
- Beneficiary is not on another injectable 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 has body surface area (BSA) involvement of at least 3%.
  OR
- Beneficiary has involvement of the palms, soles, head and neck, or genitalia, causing disruption in normal daily activities and/or employment.
  AND
- Beneficiary has failed to respond to, or has been unable to tolerate phototherapy and **ONE** of the following medications or beneficiary has contraindications to these treatments:
  - Soriatane (acitretin)
  - Methotrexate
  - Cyclosporine

  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.
  AND
- Beneficiaries, Providers, and Pharmacies utilizing Siliq must be registered appropriately in the Siliq Risk Evaluation and Mitigation Strategy Program (REMS program).

5. Psoriatic arthritis:

- Beneficiary has a documented definitive diagnosis of Psoriatic Arthritis.
  AND
- Beneficiary is 18 years of age or older (OR 2 years or older for Simponi Aria).

AND
- Beneficiary is not on another injectable 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 has a documented inadequate response or inability to take methotrexate.
  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.

6. Rheumatoid arthritis:
- Beneficiary has a diagnosis of Rheumatoid Arthritis.
  AND
- Beneficiary is not on another injectable 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 has experienced a therapeutic failure/inadequate response with methotrexate or at least one disease modifying antirheumatic drug (e.g. leflunomide, hydroxychloroquine, minocycline, sulfasalazine).
  OR
- Beneficiary is unable to receive methotrexate or disease modifying antirheumatic drug due to contraindications or intolerabilities.
  OR
- Beneficiary has clinical evidence of severe or rapidly progressing disease.
  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.

7. Ulcerative colitis (Adult):
- Beneficiary has a diagnosis of ulcerative colitis.
  AND
- Beneficiary is not on another injectable 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
- 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. Merck Sharp and Dohme, Corporation, Renflexis Prescribing Information. Whitehouse Station, NJ: April 2017.

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
10/1/2021	Added Deficiency of Interleukin-1 Receptor Antagonist (DIRA) for Arcalyst and Kineret
xx/xx/xxxx	Separated out criteria by individual agents