

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

**Effective Date: August 15, 2014
Amended Date: January 2, 2025**

Therapeutic Class Code: Z2U

Therapeutic Class Description: Immunomodulatory Agents

Medication
Stelara

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

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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. 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.

2. 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 (not required for Otezla).
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
 - CyclosporineAND

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- 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.

3. Plaque psoriasis (Pediatric): (ages 6 and up)

- Beneficiary has a diagnosis of plaque psoriasis and is a candidate for systemic therapy or phototherapy.
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 or has a contraindication or intolerance to methotrexate.
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
- For ages 6 and up, coverage of non-preferred medications requires a trial and failure of Enbrel or Cosentyx or a clinical reason beneficiary cannot try Enbrel or Cosentyx.

4. Psoriatic arthritis:

- Beneficiary has a documented definitive diagnosis of Psoriatic Arthritis.
AND
- Beneficiary is 6 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 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.
(Note: Coverage of Stelara for this indication for pediatric patients aged 6-17 requires a trial and failure of Cosentyx or a clinical reason beneficiary cannot try Cosentyx.)

5. Ulcerative colitis (Adult):

- Beneficiary has a diagnosis of ulcerative colitis.
AND

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- 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.

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

References

1. Janssen Biotech, Inc. Stelara package insert. Horsham, PA: May 2013. Updated July 2020, July 2022.

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**Medicaid and Health Choice
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Criteria Change Log

08/15/2014	Criteria effective date
02/26/2019	Add for Stelara Plaque Psoriasis (12 and up)
02/01/2021	Add Stelara for ulcerative colitis for Adults
01/02/2025	Age for psoriatic arthritis changed from ≥ 18 to ≥ 6
01/02/2025	Separated out criteria by individual agents