

DRAFT

Therapeutic Class Code: S2J

Therapeutic Class Description: Anti-inflammatory Tumor Necrosis Factor Inhibitors

Medication

Simlandi

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

- 1. 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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2. **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 Coverage for Simlandi:

1. **Ankylosing Spondylitis (adults):**

- Beneficiary has a diagnosis of Ankylosing Spondylitis.

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 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

2. **Crohn's Disease (adults):**

- Beneficiary has a diagnosis of moderate to severe Crohn's Disease.

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

3. **Crohn's Disease (pediatric ages 6 and older):**

- Beneficiary has a diagnosis of moderate to severe Crohn's Disease.

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.

4. **Polyarticular Juvenile Idiopathic Arthritis (PJIA) (ages 2 and older):**

- Beneficiary has a diagnosis of Polyarticular Juvenile Idiopathic Arthritis.

AND

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- 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 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.
5. **Plaque psoriasis (adults):**
- 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 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 (not required for Otezla).
 - 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
6. **Psoriatic arthritis (adults):**
- Beneficiary has a documented definitive diagnosis of Psoriatic Arthritis.
 - AND
 - Beneficiary is 18 years of age or older.
 - 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 has a documented inadequate response or inability to take methotrexate.
 - AND

7. **Rheumatoid arthritis (adults):**

- 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 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

8. **Ulcerative colitis (adults):**

- Beneficiary has a diagnosis of ulcerative colitis.

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

9. **Hidradenitis Suppurativa (adults):**

- Beneficiary has a diagnosis of Hidradenitis Suppurativa (moderate to severe).

AND

- Beneficiary is 18 years of age or older.

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

10. **Uveitis (UV) (adults):**

- Beneficiary has a diagnosis of non-infectious intermediate, posterior panuveitis

AND

- Beneficiary is not 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

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Procedures

- Approve for up to 12 months.
- Coverage of one injectable 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. Simlandi [package insert]. Parsippany, NJ; Teva Pharmaceuticals; February 2025.

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Criteria Change Log

xx/xx/xxxx	New Criteria