

**NC Division of Medical Assistance  
 Outpatient Pharmacy  
 Prior Approval Criteria  
 Systemic Immunomodulators**

**Medicaid and Health Choice  
 Amended Date:**

**DRAFT**

**Therapeutic Class Code:** D6A, S2J, S2M, S2Q, Z2U, Z2Z, S2Z, **L1A, S2V**

**Therapeutic Class Description:** Injectable Immunomodulators

Medication	Generic Code Number(s)	NDC Number(s)
Actemra SQ	35486	
Cimzia	23471, 99615	
Enbrel	23574, 52651, 97724, 98398	
Humira	18924, 97005, 99439	
Ilaris	27445	
Kineret	14867	
Orencia SQ	30289	
Simponi	22533, 22536, 34697, 35001	
Stelara	19903, 28158, 28159	
Xeljanz	33617	
Otezla	36172, 36173, 37765	
<b>Cosentyx</b>	<b>37788, 37789</b>	

**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.

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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**

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at <http://www.ncdhhs.gov/dma/epsdt/>.

**Criteria**

**Ankylosing spondylitis: For Enbrel, Humira, and Simponi, and Cimzia ONLY.**

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

**Crohn's disease For Cimzia, and Humira ONLY.**

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

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**Juvenile idiopathic arthritis: For Actemra SO, Enbrel, Humira, and Orencia SO ONLY.**

Beneficiary has a diagnosis of juvenile idiopathic 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 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 JIA subtype enthesitis related arthritis

OR

Beneficiary has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g. arthritis of the hip, radiographic damage)

**Systemic Onset JIA: For Kineret, Ilaris, and Actemra SO ONLY.**

Beneficiary has a diagnosis of juvenile idiopathic 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

OR

Beneficiary has systemic arthritis with active systemic features and features of poor prognosis, as determined by the prescribing physician (e.g. arthritis of the hip, radiographic damage)

**Cryopyrin-Associated Periodic Syndromes: For Kineret ONLY.**

Beneficiary has a diagnosis of neonatal-onset multisystem inflammatory disease or Cryopyrin-Associated Periodic Syndromes.

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

**Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): For Ilaris ONLY.**

**Beneficiary has a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)**

**AND**

**Beneficiary is not on another injectable biologic immunomodulator.**

**AND**

**Beneficiary has been considered and screened for the presence of latent tuberculosis infection.**

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**AND**

**Beneficiary has been tested with Hep B SAG and Core Ab**

**Plaque psoriasis: For Enbrel, Humira, and Stelara ONLY.**

Beneficiary has a diagnosis of plaque psoriasis.

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.

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 systemic therapy (methotrexate, cyclosporine, Soriatane) for plaque psoriasis or beneficiary has contraindications to these treatments.

**Plaque psoriasis: For Otezla and Cosentyx.**

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 experienced a therapeutic failure/inadequate response with 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

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

Beneficiary has a documented inadequate response or inability to take both Enbrel and Humira.

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**Psoriatic arthritis: For Enbrel, Humira, and Simponi ONLY.**

Beneficiary has a diagnosis of psoriatic 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

Beneficiary is unable to receive methotrexate due to contraindications or intolerabilities.

OR

Beneficiary has clinical evidence of severe or rapidly progressing disease

**Psoriatic arthritis: For Otelza ONLY**

Beneficiary has a documented definitive diagnosis of psoriatic arthritis

AND

Beneficiary is 18 years of age or older

AND

Beneficiary has a documented inadequate response or inability to take methotrexate

AND

Beneficiary has a documented inadequate response or inability to take both Enbrel and Humira.

**Rheumatoid arthritis For Cimzia, Enbrel, Humira, Kineret, Orencia SO, Simponi and Xeljanz and Actemra SO (tocilizumab) ONLY**

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

**Ulcerative colitis: For Humira, and Simponi ONLY.**

Beneficiary has a diagnosis of ulcerative colitis.

AND

Beneficiary is not on another injectable biologic immunomodulator.

AND

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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

**Procedures**

- Approve for up to 12 months.
- Prior authorization request forms will be accepted when submitted by mail or facsimile telecommunication methods only.
- Coverage of one injectable immunomodulators at a time.
- Cimzia, Simponi, Stelara and Xeljanz are not approvable in ages 17 years and younger.
- Enbrel can be used in ages 2 years and older.
- Humira can be used in ages 4 years and older in patients that weight at least 15 kg.
- Orencia SQ can be used in ages 6 years and older.

**References**

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4. Swedish Orphan Biovitrum AB. Kineret package insert. Stockholm, Sweden: 2001.
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6. Janssen Biotech, Inc. Simponi package insert. Horsham, PA: May 2013.
7. Janssen Biotech, Inc. Stelara package insert. Horsham, PA: May 2013.
8. Pfizer. Xeljanz package insert. New York: September 2013.
9. Bos JD, Hagens C, Das PK, et al. Predominance of “memory” T cells (CD4+, CDw29+) over “naïve” T cells (CD4+, CD45R+) in both normal and diseased human skin. Arch Dermatol Res 1989; 281:24-30.
10. Ellis C, Krueger GG. Treatment of chronic plaque psoriasis by selective targeting of memory effector T lymphocytes. N Engl J Med 2001; 345:248-255.
11. Fredriksson T, Pettersson U. Severe psoriasis--oral therapy with a new retinoid. Dermatologica 1978; 157:238-244.
12. Celgene Corporation. Otezla prescribing information. Summit, NJ.; September 2014.
13. Novartis Pharmaceuticals Corporation. Ilaris prescribing information. East Hanover, NJ.; October 2014.
14. Novartis Pharmaceuticals Corporation. Cosentyx prescribing information. East Hanover, NJ.; January 2015.