

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

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

DRAFT

Therapeutic Class Code: D6K, S2J, S2M, S2Q, Z2U, Z2Z, S2Z, L1A, S2V, Z2V, D6K, Z27

Therapeutic Class Description: Immunomodulatory Agents

Medication	Medication	Medication
Actemra SQ	Ilumya	Siliq
Actemra Infusion	Inflectra Infusion	Simponi
Arcalyst	Kevzara	Simponi Aria Infusion
Avsola Infusion	Kineret	Skyrizi
Cimzia	Olumiant	Stelara
Cosentyx	Orencia Infusion	Stelara Infusion
Enbrel	Orencia SQ	Taltz
Enspryng	Otezla	Tremfya
Entyvio Infusion	Remicade Infusion	Uplizna
Humira	Renflexis	Xeljanx and Xeljanx XR
Ilaris	Rinvoq ER	

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 (NHC) 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 NHC 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.

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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

1. Ankylosing Spondylitis: For Enbrel, Humira, Cosentyx, Avsola Cimzia, Inflectra, Simponi, Simponi Aria, Remicade, Taltz, and Renflexis 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.

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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):** For Humira, Avsola, Cimzia, Entyvio, Inflectra, Stelara, Stelara Infusion Remicade and Renflexis 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
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):** For Humira, Avsola, Inflectra, Remicade, and Renflexis 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
AND
 - Coverage of non-preferred medications require a trial and failure of Humira or a clinical reason beneficiary cannot try Humira
- 4. Polyarticular Juvenile Idiopathic Arthritis (PJIA):** For Enbrel, Humira, Actemra SQ, Actemra Infusion, **Simponi Aria**, Orencia Infusion, Orencia SQ, and **Xeljanz** ONLY.
- Beneficiary has a diagnosis of Polyarticular 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 PJIA subtype enthesitis related arthritis

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

5. Systemic Onset Juvenile Idiopathic Arthritis.(SJIA): For Actemra Infusion, Actemra SQ and Ilaris ONLY.

- Beneficiary has a diagnosis of Systemic Juvenile Idiopathic arthritis
- AND
- Beneficiary is not on another injectable biologic immunomodulator.
- AND
- Beneficiary has a diagnosis of Systemic Juvenile Idiopathic arthritis
- 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)

6. Neonatal Onset Multisystem Inflammatory Disease (NOMID): For Kineret ONLY.

- Beneficiary has a diagnosis of neonatal-onset multisystem inflammatory 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

7. Cryopyrin-Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS): For Arcalyst and 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.
- AND
- Beneficiary has been tested with Hep B SAG and Core Ab

8. Plaque psoriasis (Pediatric): For Enbrel, Stelara (ages 6 and up), and Taltz (ages 6 and up) ONLY.

- 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

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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
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 a clinical reason beneficiary cannot try Enbrel.

9. Plaque psoriasis (adult): For Enbrel, Humira, Cosentyx, Avsola, Cimzia, Ilumya, Inflectra, Otezla, Remicade, Renflexis, Siliq, Skyrizi, Stelara, Taltz, and Tremfya ONLY.

- 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 (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
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).

10. Psoriatic arthritis: For Enbrel, Humira, Cosentyx, Avsola, Cimzia, Inflectra, Orencia SQ, Orencia Infusion, Otezla, Renflexis, Remicade, Simponi, Simponi Aria, Stelara, Taltz, Tremfya, Xeljanz and

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Xeljanz XR ONLY

- 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 (not required for Otezla).
- AND
- Beneficiary has been tested with Hep B SAG and Core Ab (not required for Otezla).
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.

11. Rheumatoid arthritis: For Enbrel, Humira, Actrema Infusion, Actemra SQ, Avsola, Cimzia, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Orencia SQ, Remicade, Renflexis, Rinvoq ER, Simponi, Simponi Aria, Xeljanz and Xeljanz XR 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
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.

12. Ulcerative colitis (Adult): For Humira, Avsola, Entyvio, Inflectra, Remicade, Renflexis, Stelara, Simponi, Xeljanz and Xeljanz XR ONLY.

- 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.

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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

13. Ulcerative colitis (Pediatric): For Avsola, Remicade ONLY

- 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

14. Hidradenitis Suppurativa: For Humira ONLY (ages 12 and older)

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

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

15. Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS): Ilaris ONLY

- Beneficiary has a diagnosis of Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)

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

16. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD): Ilaris ONLY

- Beneficiary has a diagnosis of Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)

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

17. Familial Mediterranean Fever (FMF): Ilaris ONLY

- Beneficiary has a diagnosis of Familial Mediterranean Fever (FMF)

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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

18. Non-infectious Intermediate Posterior Panuveitis: Humira ONLY (ages 2 and older)

- Beneficiary has a diagnosis of Non-infectious Intermediate Posterior Panuveitis

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

19. Giant Cell Arteritis: Actemra and Actemra SQ ONLY

- Beneficiary has a diagnosis of Giant Cell Arteritis

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

20. Cytokine Release Syndrome: Actemra and Actemra SQ ONLY

- Beneficiary has a diagnosis of Cytokine Release Syndrome

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

21. Non-Radiographic Axial Spondyloarthritis: Cimzia, Cosentyx, and Taltz ONLY

- Beneficiary has a diagnosis of Non-Radiographic Axial Spondyloarthritis

AND

- Beneficiary is not on another injectable biologic immunomodulator.

AND

- Beneficiary has failed an adequate trial of a Non-Steroidal Anti-Inflammatory Drug (NSAID) unless contraindicated.

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 Cosentyx

22. Oral Ulcers associated with Behcet's Disease: Otezla ONLY

- Beneficiary has a documented diagnosis of Behcet's disease
AND
- Beneficiary is 18 years of age or older
AND
- Beneficiary is not on another injectable biologic immunomodulator.

23. Adult Onset Still's Disease: Ilaris ONLY

- Beneficiary has a diagnosis of Adult Onset Still'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
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)

24. Neuromyelitis Optica Spectrum Disorder (NMOSD): Uplizna and Enspryng

- Beneficiary has a diagnosis of Neuromyelitis Optica Spectrum Disorder
AND
- Beneficiary is anti-aquaporin-4 (AQP4) antibody positive
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

Procedures

- Approve for up to 12 months.
- Coverage of one injectable immunomodulator at a time.

	Enbrel (P)	Humira (P)	Cosentyx (P)	Actemra Infusion/ Actemra SQ	Arcalyst	Avsola	Cimzia	Enspryng	Entyvio	Ilaris	Ilumya	Inflectra	Kevzara	Kineret	Olumiant	Orencia/ Orencia SQ	Otezla	Remicade	Renflexis	Rinvoq ER	Siliq	Simponi	Simponi Aria	Skyrizi	Stelara	Stelara Infusion	Taltz	Tremfya	Uplizna	Xeljanz/ Xeljanz XR
Ankylosing Spondylitis	X	X	X			X***	X***					X***						X***	X***			X***	X***				X***			
Crohn's Disease (adult)		X				X*	X*		X*			X*						X*	X*						X*	X*				
Crohn's Disease (pediatric)		X				X*						X*						X*	X*											
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	X	X		X**												X**							X**							X**
Systemic Onset Juvenile Idiopathic Arthritis (SJIA)				X						X																				
Neonatal Onset Multisystem Inflammatory Disease (NOMID)														X													X			
Non-Radiographic Axial Spondyloarthritis			X				X*																				X*			
Cryoprin Associated Periodic Syndromes (CAPS) including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS)					X					X																				
Plaque Psoriasis (pediatric)	X																								X* (ages 6 and up)		X* (ages 6 and up)			
Plaque Psoriasis (adult)	X	X	X			X***	X***				X***	X***					X***	X***	X***		X***			X***	X***		X***	X***		
Psoriatic Arthritis	X	X	X			X***	X***					X***				X***	X***	X***	X***			X***	X***		X***		X***	X***		X***
Rheumatoid Arthritis	X	X		X**		X**	X**					X**	X**	X**	X**	X**		X**	X**	X**		X**	X**							X**
Ulcerative Colitis (adult)		X				X*			X*			X*						X*	X*			X*								X*
Ulcerative Colitis (pediatric)						X*												X												
Hidradenitis Suppurativa		X																												
Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)										X																				

	Enbrel (P)	Humira (P)	Cosentyx (P)	Actemra Infusion/ Actemra SQ	Arcalyst	Avsola	Cimzia	Enspryng	Entyvio	Ilaris	Ilumya	Inflectra	Kevzara	Kineret	Olumiant	Orencia/ Orencia SQ	Otezla	Remicade	Renflexis	Rinvoq ER	Siliq	Simponi	Simponi Aria	Skyrizi	Stelara	Stelara Infusion	Taltz	Tremfya	Uplizna	Xeljanz/ Xeljanz XR
Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)										X																				
Familial Mediterranean Fever (FMF)										X																				
Non-Infectious Intermediate Posterior Panuveitis		X																												
Giant Cell Arteritis				X																										
Cytokine Release Syndrome				X																										
Behcet's Disease																	X													
Adult Onset Still's Disease										X																				
Neuromyelitis Optica Spectrum Disorder (NMOSD)								X																					X	

*Trial and failure of Humira before coverage of non-preferred agent

** Trial and failure of Enbrel or Humira before coverage of non-preferred agent

*Trial and Failure of Enbrel before coverage of non-preferred

***Trial and failure of either Cosentyx, Enbrel or Humira before coverage of non-preferred agent

*Trial and Failure of Cosentyx before coverage of non-preferred

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14. Novartis Pharmaceuticals Corporation. Cosentyx prescribing information. East Hanover, NJ; January 2015. Updated June 2020
15. Eli Lilly and Company. Taltz prescribing information. Indianapolis, IN 46285: March 2016. Updated 12/2017
16. Novartis Pharmaceuticals Corporation. Ilaris prescribing information. East Hanover, NJ: September 2016. Updated June 2020
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19. Genentech Inc. Actemra Prescribing Information. San Fransisco CA: revised May 2018.
20. Takeda Pharmaceuticals America. Entyvio Prescribing Information. Deerfield IL: May 2014.
21. Pfizer Labs, Inc. Inflectra Prescribing Information. New York, NY: August 2016.
22. Janssen Biotech, Inc. Remicade Prescribing Information. Horsham, PA: October 2015.
23. Janssen Biotech, Inc. Simponi Aria Prescribing Information. Horsham, PA: January 2017. **Updated September 2020.**
24. Sanofi-Aventis, US, LLC, Kevzara Prescribing information. Bridgewater, NJ: May 2017.
25. Merck Sharp and Dohme, Corporation, Renflexis Prescribing Information. Whitehouse Station, NJ: April 2017.
26. Janssen Biotech, INC., Tremfya Prescribing Information. Horsham, PA: July 2017. Updated July 2020
27. Lilly, USA, LLC., Olumiant Prescribing Information. Indianapolis, IN: May 2018.
28. Sun Pharma Global, FZE. Inc. Ilumya Prescribing Information. Cranbury, NJ: August 2018.
29. Valeant Pharmaceuticals of North America, LLC., Siliq Prescribing Information. Bridgewater, NJ: February 2017.
30. AbbVie, Inc., Skyrizi Prescribing Information. North Chicago, IL: April 2019.
31. AbbVie, Inc., Rinvoq Prescribing Information. North Chicago, IL: August 2019.
32. Amgen, Inc. Avsola Prescribing Information. Thousand Oaks, CA rev. December 2019.

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33. Genetech, Inc. Enspryng Prescribing Information. South San Francisco, CA; August 2020.
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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/Xeljanz 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 Ankylosing 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

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

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

Xx/xx/xx	Added Taltz to Ankylosing Spondylitis, add Rinvoq ER Added Behcet's Disease for Otezla Updated EPSDT Information Updated table
Xx/xx/xx	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
Xx/xxxx	Add Taltz to plaque psoriasis for pediatrics & Non-Radiographic Axial Spondyloarthritis Add Avsola
Xx/xxxx	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
Xx/xx/xxxx	Added Simponi Aria & Xeljanz to Polyarticular Juvenile Idiopathic Arthritis Updated age for Simponi Aria for Psoriatic Arthritis