NC Medicaid
Outpatient Pharmacy
Prior Approval Criteria
Systemic Immunomodulators

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

DRAFT

Therapeutic Class Code: D6A, S2J, S2M, S2Q, Z2U, Z2Z, S2Z, L1A, S2V, Z2V, D6K
Therapeutic Class Description: Injectable Immunomodulators

Medication	~~Generic Code Number(s)~~	~~NDC Number(s)~~
Actemra SQ	~~35486~~	
Actemra Infusion	~~27366, 27367, 27368~~	
Arcalyst	~~99473~~	
Cimzia	~~23471, 99615~~	
Cosentyx	~~37788, 37789~~	
Enbrel	~~23574, 52651, 97724, 98398~~	
Entyvio Infusion	~~36544~~	
Humira	~~18924, 97005, 99439, 37262~~	
Ilaris	~~27445~~	
Ilumya	~~44553~~	
Inflectra Infusion	~~40977~~	
Kevzara	~~43223, 43224~~	
Kineret	~~14867~~	
Olumiant	~~43468~~	
Orencia Infusion	~~26306~~	
Orencia SQ	~~30289, 41656~~	
Otezla	~~36172, 36173, 37765~~	
Remicade Infusion	~~61501~~	
Renflexis	~~43638~~	
Siliq	~~43055~~	
Simponi	~~22533, 22536, 34697, 35001~~	
Simponi Aria Infusion	~~34983~~	
Skyrizi		
Stelara	~~28158, 28159~~	
Stelara Infusion		
Taltz	~~40848, 48049~~	
Tremfya	~~43612~~	
Xeljanz and Xeljanz XR	~~33617, 38086~~	

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.

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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 fora 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 EPSDT provider page: to https://medicaid.ncdhhs.gov

Criteria

1. **Ankylosing Spondylitis**: For Enbrel, Humira, Cosentyx, Inflectra, Cimzia, Simponi, Simponi Aria, Remicade 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.

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, 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, 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, Orencia Infusion and Orencia SQ 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

AND
- 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 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 and Stelara (ages 12 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
- 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.
- For ages 12 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, 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. 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

- 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.

- 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, Inflectra, Cosentyx, Cimzia, Orencia SQ, Orencia Infusion, Otezla, Renflexis, Remicade, Simponi, Simponi Aria, Stelara, Taltz, Xeljanz and Xeljanz XR ONLY

- Beneficiary has a documented definitive diagnosis of psoriatic arthritis

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 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, Cimzia, Inflectra, Kevzara, Kineret, Olumiant, Orencia, Orencia SQ, Remicade, Renflexis, 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, Entyvio, Inflectra, Remicade, Renflexis, 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. 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 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)

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 ONLY

- Beneficiary has a diagnosis of **Non-Radiographic Axial Spondyloarthritis: Cimzia** 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.

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	Enbrel (P)	**Humira (P)**	**Cosentyx (P)**	Actemra Infusion/ Actemra SQ	Arcalyst	Cimzia	Entyvio	Ilaris	Ilumya	Inflectra	Kevzara	Kineret	Olumiant	Orencia/ Orencia SQ	Otezla	Remicade	Renflexis	Siliq	Simponi	Simponi Aria	Stelara	Taltz	Tremfya	Xeljanz/ Xeljanz XR
Anklyosing Spondylitis	**X**	**X**	**X**			X***				X***						X***	X***		X***	X***				
Crohn's Disease (adult)		**X**				X*	X*			X*						X*	X*				X*			
Crohn's Disease (pediatric)		**X**								X*						X*	X*							
Polyarticular Juvenile Idiopathic Arthritis (PJIA)	**X**	**X**		X**										X**										
Systemic Onset Juvenile Idiopathic Arthritis (SJIA)				X				X																
Neonatal Onset Multisystem Inflammatory Disease (NOMID)												X												
Non-Radiographic Axial Spondyloarthritis						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 12 and up)			
Plaque Psoriasis (adult)	**X**	**X**	**X**			X***			X***	X***					X***	X***	X***	X***			X***	X***	X***	

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	Enbrel (P)	**Humira (P)**	**Cosentyx (P)**	Actemra Infusion/ Actemra SQ	Arcalyst	Cimzia	Entyvio	Ilaris	Ilumya	Inflectra	Kevzara	Kineret	Olumiant	Orencia/ Orencia SQ	Otezla	Remicade	Renflexis	Siliq	Simponi	Simponi Aria	Stelara	Taltz	Tremfya	Xeljanz/ Xeljanz XR
Psoriatic Arthritis	**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**
Ulcerative Colitis (adult)		**X**					X*			X*						X*	X*		X*					X*
Ulcerative Colitis (pediatric)																X								
Hidradenitis Suppurativa		**X**																						
Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS)								X																
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																				

*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

References

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4. Swedish Orphan Biovitrum AB. Kineret package insert. Stockholm, Sweden: 2001.
5. Bristol-Myers Squibb Company. Orencia package insert. Princeton, NJ: July 2013. Revised March 2017. Revised June 2017.
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. Revised December 2017.
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14. Novartis Pharmaceuticals Corporation. Cosentyx prescribing information. East Hanover, NJ; January 2015.
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.
17. AbbVie Inc. Humira package insert. North Chicago, IL: updated June 2016 (Uveitis).
18. Regeneron Pharmaceuticals, INC. Arcalyst prescribing information. Tarrytown, NY; September 2016.
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.
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.
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.

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
Xx/xx/xxxx	Add Dx Non-Radiographic Axial Spondyloarthritis for Cimzia
Xx/xx/xxxx	Removed GCN's, add Skyrizi to adult plaque psoriasis, add Stelara Infusion