New Hampshire Medicaid Fee-for-Service Program

Systemic Immunomodulator Criteria

Approval Date: January 26, 2023

Medications

Brand Names	Generic Names	Dosage Strength	Dosage Form
Actemra®	tocilizumab	80 mg/4 mL, 162 mg/0.9 mL, 200 mg/ 10 mL, 400 mg/20 mL	single-use vial, prefilled syringe, ACTPen®
Arava®	leflunomide	10 mg, 20 mg, 100 mg	capsules
Arcalyst®	rilonacept	220 mg	single-use vial
Avsola®	infliximab-axxq	100 mg	intravenous infusion single-dose vial
Cimzia®	certolizumab	200 mg	powder for subcutaneous (SC) injection, syringe kits, starter kits
Cosentyx®	secukinumab	75 mg/0.5mL, 150 mg/mL	single-use Sensoready® pen, single-use prefilled syringe, Single-use vial (HCP admin only)
Enbrel®/Mini	etanercept	25mg/0.5 mL, 50 mg/mL; Mini 50 mg/mL	prefilled syringe, autoinjector, single-use vials
Entyvio®	vedolizumab	300 mg/20 mL	single-use vial
Humira®	adalimumab	10 mg/0.1 mL, 20 mg/0.2 mL, 40 mg/ 0.4 mL, 40 mg/0.8 mL, 80 mg/0.8 mL	syringe, single-use pens, starter packages
Ilaris®	canakinumab	150 mg/mL	single-use vial
Ilumya®	tildrakizumab-asmn	100 mg/mL	syringe
Inflectra® (biosimilar to Remicade®)	infliximab-dyyb	100 mg	intravenous infusion single-dose vial
Kevzara®	sarilumab	150 mg/1.14 mL, 200 mg/1.14 mL	single-dose pre-filled syringe, pen
Kineret®	anakinra	100 mg/0.67 mL	prefilled syringe
Olumiant®	baricitinib	1 mg, 2 mg, 4 mg	tablet
Orencia®	abatacept	50 mg/0.4 mL, 87.5 mg/0.7mL, 125 mg/ mL, 250 mg	powder for injection, single-dose vial, prefilled syringe, prefilled autoinjector
Otezla®	apremilast	30 mg	tablet, titration pack
Remicade®	infliximab	100 mg	single-use vial

Brand Names	Generic Names	Dosage Strength	Dosage Form
Renflexis® (biosimilar to Remicade)	infliximab-abda	100 mg	single-dose vial
Rinvoq®	upadacitinib	15 mg, 30 mg, 45 mg	ER tablet
Siliq®	brodalumab	210 mg/1.5 mL	single-dose pre-filled syringe
Simponi®/ Simponi Aria®	golimumab	50 mg/0.5 mL, 50 mg/4 mL, 100 mg/mL	single-dose prefilled syringe, SmartJect autoinjector vial
Skyrizi™	risankizumab-rzaa	75 mg/0.83 mL, 150 mg/mL, 360 mg/ 2.4 mL, 600 mg/10 mL	prefilled syringe, auto-injector, single-dose vial
Sotyktu™	deucravacitinib	6 mg	tablet
Spevigo®	spesolimab-sbzo	450 mg/7.5 mL	single-dose vial
Stelara®	ustekinumab	45 mg/0.5 mL, 90 mg/mL, 130 mg/26 mL	single-use vial, prefilled syringe
Taltz®	ixekizumab	80 mg/mL	prefilled syringe, prefilled auto-injector
Tremfya®	guselkumab	100 mg/mL	single-dose prefilled syringe single-dose One-Press patient-controlled injector
Xeljanz®/XR	tofacitinib	1 mg/mL 5 mg, 10 mg tablet 11 mg, 22 mg tablet (XR)	solution, tablet, ER tablet

Indications

Brand Names	Generic Names	Indications
Actemra®	tocilizumab	• Reduction in signs and symptoms of active rheumatoid arthritis (RA) in patients ≥ 18 years old • Juvenile idiopathic arthritis (JIA) in patients ≥ 2 years old (previously listed as Juvenile Rheumatoid Arthritis [JRA]) • Systemic onset juvenile chronic arthritis in patients ≥ 2 years old • Giant cell arteritis in patients ≥ 18 years old • Systemic sclerosis-associated interstitial lung disease in patients ≥ 18 years old
Arava®	leflunomide	• Reduction in signs and symptoms of active RA in patients ≥ 18 years old
Arcalyst®	rilonacept	• Cryopyrin-associated periodic syndromes (CAPS) in patients ≥ 12 years old • Deficiency of Interleukin-1 Receptor Antagonist (DIRA) in patients weighing ≥ 10 kg • Recurrent pericarditis in patients ≥ 12 years old
Avsola®	infliximab-axxq	• Ankylosing spondylitis (AS) in patients ≥ 18 years old • Fistulizing Crohn's disease (CD) in patients ≥ 18 years old • Moderately to severely Crohn's disease in patients ≥ 6 years old • Chronic severe plaque psoriasis (PP) in patients ≥ 18 years old • Psoriatic arthritis (PsA) in patients ≥ 18 years old • Moderately to severely RA in patients ≥18 years old in combination with methotrexate

Brand Names	Generic Names	Indications
		• Moderately to severely ulcerative colitis (UC) in patients ≥ 6 years old
Cimzia®	certolizumab	• AS in patients ≥ 18 years old • Moderately to severely active CD in patients ≥ 18 years old • Moderately to severely active RA in patients ≥ 18 years old • PsA in patients ≥ 18 years old • Moderate to severe PP in patients ≥ 18 years old • Non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old
Cosentyx®	secukinumab	• Moderate to severe PP in patients ≥ 6 years old • AS in patients ≥ 18 years old • PsA in patients ≥ 2 years old • Non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old • Active enthesitis-related arthritis in patients ≥ 4 years old
Enbrel®/Mini	etanercept	• Moderately to severely active RA in patients ≥ 18 years old • Moderate to severe JIA in patients ≥ 2 years old (previously listed as JRA) • PsA in patients ≥ 18 years old • AS in patients ≥ 18 years old • Moderate to severe chronic PP in patients ≥ 4 years old
Entyvio®	vedolizumab	• Moderately to severely active CD in patients ≥ 18 years old • Moderately to severely active UC in patients ≥ 18 years old
Humira®	adalimumab	• Reduction in signs and symptoms of active RA in patients ≥ 18 years old • Moderate to severe chronic PP in patients ≥ 18 years old • JIA in patients ≥ 2 years old (previously listed as JRA) • PsA in patients ≥ 18 years old • AS in patients ≥ 18 years old • Moderately to severely active CD in patients ≥ 6 years old • Moderately to severely active UC in patients ≥ 5 years old • Hidradenitis suppurativa in patients ≥ 12 years old • Uveitis in patients ≥ 2 years old
Ilaris®	canakinumab	• JIA and Still's Disease in patients ≥ 2 years old (previously listed as JRA) • CAPS in patients ≥ 4 years old, including: – Familial cold autoinflammatory syndrome (FCAS) – Muckle-Wells syndrome (MWS) • Tumor necrosis factor receptor-associated periodic syndrome (TRAPS) in adult and pediatric patients • Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD) in adult and pediatric patients • Familial Mediterranean fever (FMF) in adult and pediatric patients
Ilumya®	tildrakizumab-asmn	• Moderate to severe PP in patients ≥ 18 years old

Brand Names	Generic Names	Indications
Inflectra® (biosimilar to Remicade)	infliximab-dyyb	• AS in patients ≥ 18 years old • Fistulizing CD in patients ≥ 18 years old • Moderately to severe CD in patients ≥ 6 years old • Chronic severe PP in patients ≥ 18 years old • PsA in patients ≥ 18 years old • Moderately to severely RA in patients ≥ 18 years old in combination with methotrexate • Moderately to severely UC in patients ≥ 6 years old
Kevzara®	sarilumab	• Moderately to severely active RA in patients ≥ 18 years old who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs)
Kineret®	anakinra	• Moderately to severely active RA in patients ≥ 18 years old • Neonatal-Onset Multisystem Inflammatory Disease (NOMID) • Treatment of Deficiency of Interleukin-1 Receptor Antagonist (DIRA)
Orencia®	abatacept	• Moderately to severely active RA in patients ≥ 18 years old • JIA in patients ≥ 2 years old (previously listed as JRA) • PsA in patients ≥ 18 years old • Acute graft versus host disease (aGVHD) in combination with a calcineurin inhibitor and methotrexate in patients ≥ 2 years old undergoing hematopoietic stem cell transplantation
Olumiant®	baricitinib	• Moderately to severely active RA in patients ≥ 18 years old • Severe alopecia areata in patients ≥ 18 years old
Otezla®	apremilast	• PsA in patients ≥ 18 years old • PP in patients ≥ 18 years old • Oral ulcers associated with Behçet's disease in patients ≥ 18 years old
Remicade®	infliximab	• Moderately to severely active RA in patients ≥ 18 years old in combination with methotrexate • PsA in patients ≥ 18 years old • AS in patients ≥ 18 years old • Chronic severe PP in patients ≥ 18 years old • Moderately to severely active CD in patients ≥ 6 years old • Fistulizing CD in patients ≥ 18 years old • Moderately to severely active UC in patients ≥ 6 years old
Renflexis® (biosimilar to Remicade)	infliximab-abda	• AS in patients ≥ 18 years old • Fistulizing CD in patients ≥ 18 years old • Moderately to severely CD in patients ≥ 6 years old • Chronic severe PP in patients ≥ 18 years old • PsA in patients ≥ 18 years old • Moderately to severely RA in patients ≥18 years old in combination with methotrexate • Moderately to severely UC in patients ≥ 6 years old
Rinvoq®	upadacitinib	• Moderately to severely active RA in patients ≥ 18 years old • PsA in patients ≥ 18 years old • Moderate to severe atopic dermatitis in patients ≥ 12 years old*

Brand Names	Generic Names	Indications
		• Moderately to severely active UC in patients ≥ 18 years old • Non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old who have had an inadequate response or intolerance to TNF blocker therapy
Siliq®	brodalumab	• Moderate to severe PP in adult patients
Simponi®/ Simponi Aria®	golimumab	• Moderately to severely active RA in patients ≥ 18 years old, in combination with methotrexate • Active PsA in patients ≥ 2 years old • Active AS in patients ≥ 18 years old • Moderately to severely active UC in patients ≥ 18 years old • JIA in patients ≥ 2 years old
Skyrizi®	risankizumab-rzaa	• Moderate to severe PP in patients ≥ 18 years old • PsA in patients ≥ 18 years old • Moderately to severely active CD in patients ≥ 18 years old
Sotyktu™	deucravacitinib	• Moderate to severe PP in patients ≥ 18 years old
Spevigo®	spesolimab-sbzo	• Generalized pustular psoriasis (GPP) in patients ≥ 18 years old
Stelara®	ustekinumab	• Moderate to severe PP in patients ≥ 6 years old • PsA in patients ≥ 18 years old • Moderately to severely active CD in patients ≥ 18 years old who have: – Failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker; or – Failed or were intolerant to treatment with one or more TNF blockers • Moderately to severely active UC in patients ≥ 18 years old
Taltz®	ixekizumab	• Moderate to severe PP in patients ≥ 6 years old • Active AS in patients ≥ 18 years old • Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old • Active PsA in patients ≥ 18 years old
Tremfya®	guselkumab	• Moderate to severe PP in patients ≥ 18 years old • PsA in patients ≥ 18 years old
Xeljanz®/XR	tofacitinib	• Moderately to severely active RA in patients ≥ 18 years old alone or in combination with methotrexate or other DMARDS • PsA in patients ≥ 18 years old • Moderate to severe UC in patients ≥ 18 years old • Active AS in patients ≥ 18 years old

***For requests for Rinvoq™ (upadacitinib) for Atopic Dermatitis, use Atopic Dermatitis Criteria.**

Criteria for Approval

Prior authorization will only be granted for the approved FDA indications listed above **AND** must be prescribed by a rheumatologist, gastroenterologist, or dermatologist based on the approved FDA indication.

1. Ankylosing spondylitis:
    a. Trial and failure required with a nonsteroidal anti-inflammatory drugs (NSAID).
2. Juvenile idiopathic arthritis (JIA) (previously listed as JRA):
    a. Trial and failure of, contraindication, or adverse reaction to methotrexate.
3. Moderately to severely active Crohn's disease (CD):
    a. Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids).
4. Moderately to severely active ulcerative colitis (UC) (all the following must be met):
    a. Trial and failure of a compliant regimen of oral or rectal aminosalicylates (e.g., sulfasalazine or mesalamine) for two consecutive months; **AND**
    b. Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe ulcerative colitis) unless contraindicated, or intravenous corticosteroids (for severe and fulminant ulcerative colitis or failure to respond to oral corticosteroids); **AND**
    c. Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months.
5. Moderate to severe chronic plaque psoriasis (PP):
    a. Must have a previous failure on a topical psoriasis agent.
6. Psoriatic arthritis (PsA):
    a. Trial and failure required with methotrexate first or in combination with methotrexate if appropriate.
7. Rheumatoid arthritis (RA):
    a. Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (e.g., sulfasalazine, hydroxychloroquine, minocycline).

Length of Approval:

1. Initial three months for Crohn's disease or ulcerative colitis.
2. One year for all other indications.
3. One-year renewal dependent upon medical records supporting response to therapy and review of prescription history.

Criteria for Denial

1. Moderate to severe heart failure (New York Heart Association [NYHA] Functional Class III/IV).
2. Live vaccines should not be given concurrently.
3. Presence of active infections.
4. Current or recent malignancy.
5. Concomitant treatment with azathioprine or 6-mercaptopurine due to increased risk of fatal hepatosplenic T-cell lymphomas (for Remicade®, Avsola®, Inflectra®, and Renflexis® requests only).
6. Pregnancy (for Arava® request only).
7. Concomitant use with other systemic immunomodulators.
8. Concurrent diagnosis of irritable bowel syndrome (for Cosentyx® only).

Non-preferred drugs on the Preferred Drug List (PDL) require additional prior authorization.

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
Pharmacy and Therapeutic Committee	New	11/06/2008
Commissioner	Approval	12/01/2008
DUR Committee	Revision	03/22/2010
Commissioner	Approval	04/30/2010
DUR Committee	Revision	03/23/2011
Commissioner	Approval	06/07/2011
DUR Board	Revision	05/12/2015
Commissioner	Approval	06/30/2015
DUR Board	Revision	05/31/2016
Commissioner	Approval	06/18/2016
DUR Board	Revision	10/11/2016
Commissioner	Approval	11/22/2016
DUR Board	Revision	10/24/2017
Commissioner	Approval	12/05/2017
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019

Reviewed by	Reason for Review	Date Approved
DUR Board	Revision	10/28/2019
Commissioner Designee	Approval	12/03/2019
DUR Board	Revision	06/30/2020
Commissioner Designee	Approval	08/07/2020
DUR Board	Revision	12/15/2020
Commissioner Designee	Approval	02/24/2021
DUR Board	Revision	06/08/2021
Commissioner Designee	Approval	08/13/2021
DUR Board	Revision	06/02/2022
Commissioner Designee	Approval	07/12/2022
DUR Board	Revision	12/13/2022
Commissioner Designee	Approval	01/26/2023