

New Hampshire Medicaid Fee-for-Service Program Systemic Immunomodulator Criteria

Approval Date: August 7, 2020

Medications

Brand Names	Generic Names	Dosage Strength	Dosage Form
Actemra®	tocilizumab	80 mg/4 mL, 200 mg/10 mL, 400 mg/20 mL	single-use vial, prefilled syringe
Arava®	leflunomide	10 mg, 20 mg, 100 mg	capsules
Arcalyst®	rilonacept	220 mg	single-use vial
Cimzia®	certolizumab	200 mg	powder for subcutaneous (SC) injection, syringe kits, starter kits
Cosentyx®	secukinumab	150 mg/mL, 150 mg	single-use Sensoready® pen, single-use prefilled syringe, Single-use vial (HCP admin only)
Enbrel®/Mini	etanercept	25mg, 50 mg/mL; Mini 50 mg/mL	SC prefilled syringe, autoinjector, multiuse vials
Entyvio®	vedolizumab	300 mg/20 mL	single-use vial
Humira®	adalimumab	10 mg/0.2 mL, 20 mg/0.4 mL, 40 mg/0.8 mL	SC syringe, single-use pens, starter packages
Ilaris®	canakinumab	180 mg reconstituted to 150 mg/mL	single-use vial
Ilumya™	tildrakizumab-asmn	100 mg/1 mL	subcutaneous solution
Inflectra® (biosimilar to Remicade®)	infliximab-dyyb	100 mg/20 mL	intravenous infusion single-dose vial
Kevzara®	sarilumab	150 mg/1.14 mL, 200 mg/1.14 mL	single-dose pre-filled syringe
Kineret®	anakinra	100 mg/0.67 mL	SC prefilled syringe
Orencia®	abatacept	250 mg	powder for injection, single-dose vial, prefilled syringe, prefilled autoinjector
Olumiant®	baricitinib	1 mg, 2 mg	tablet
Otezla®	apremilast	30 mg, two starter packs	tablet
Remicade®	infliximab	100 mg/20 mL	single-use vial

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Brand Names	Generic Names	Dosage Strength	Dosage Form
Renflexis® (biosimilar to Remicade)	infliximab-abda	100 mg/20 mL	Intravenous (IV) infusion single-dose vial
Rinvoq™	upadacitinib	15 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	single-dose prefilled syringe, SmartJect autoinjector, IV solution
Skyrizi™	risankizumab-rzaa	75 mg/0.83 mL	Subcutaneous solution
Stelara®	ustekinumab	45 mg/0.5 mL, 90 mg/1 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	5 mg tablet, 11 mg tablet (XR)	tablet, ER tablet

Indications

Brand Names	Generic Names	Indications
Actemra®	tocilizumab	<ul style="list-style-type: none"> 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
Arava®	leflunomide	<ul style="list-style-type: none"> Reduction in signs and symptoms of active RA in patients ≥ 18 years old
Arcalyst®	rilonacept	<ul style="list-style-type: none"> Cryopyrin-Associated Periodic Syndromes (CAPS) in patients ≥ 12 years old
Cimzia®	certolizumab	<ul style="list-style-type: none"> Ankylosing spondylitis in patients ≥ 18 years old Moderately to severely active Crohn's Disease in patients ≥ 18 years old Moderately to severely active RA in combination with methotrexate in patients ≥ 18 years old Psoriatic arthritis in patients ≥ 18 years old Moderate to severe plaque psoriasis in patients ≥ 18 years old Non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old
Cosentyx®	secukinumab	<ul style="list-style-type: none"> Moderate to severe plaque psoriasis in patients ≥ 18 years old Ankylosing spondylitis in patients ≥ 18 years old Psoriatic arthritis in patients ≥ 18 years old Non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old
Enbrel®/Mini	etanercept	<ul style="list-style-type: none"> Moderately to severely active RA in patients ≥ 18 years old Moderate to severe JIA in patients ≥ 2 years old (previously listed as JRA) Psoriatic arthritis in patients ≥ 18 years old

Brand Names	Generic Names	Indications
		<ul style="list-style-type: none"> ▪ Ankylosing spondylitis in patients ≥ 18 years old ▪ Moderate to severe chronic plaque psoriasis in patients ≥ 4 years old
Entyvio®	vedolizumab	<ul style="list-style-type: none"> ▪ Moderately to severely active Crohn's disease in patients ≥ 18 years old ▪ Moderately to severely active ulcerative colitis in patients ≥ 18 years old
Humira®	adalimumab	<ul style="list-style-type: none"> ▪ Reduction in signs and symptoms of active RA in patients ≥ 18 years old ▪ Moderate to severe chronic plaque psoriasis in patients ≥ 18 years old ▪ JIA in patients ≥ 2 years old (previously listed as JRA) ▪ Psoriatic arthritis in patients ≥ 18 years old ▪ Ankylosing spondylitis in patients ≥ 18 years old ▪ Moderately to severely active Crohn's disease in patients ≥ 6 years old ▪ Moderately to severely active ulcerative colitis in patients ≥ 18 years old ▪ Hidradenitis suppurativa in patients ≥ 12 years old ▪ Uveitis in patients ≥ 2 years old
Ilaris®	canakinumab	<ul style="list-style-type: none"> ▪ JIA in patients ≥ 2 years old (previously listed as JRA) ▪ CAPS in patients ≥ 4 years old, including: <ul style="list-style-type: none"> – 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	<ul style="list-style-type: none"> ▪ Moderate to severe plaque psoriasis in patients ≥18 years old
Inflectra® (biosimilar to Remicade)	infliximab-dyyb	<ul style="list-style-type: none"> ▪ Ankylosing spondylitis in patients ≥ 18 years old ▪ Fistulizing Crohn's disease in patients ≥ 18 years old ▪ Moderately to severely Crohn's disease in patients ≥ 6 years old ▪ Chronic severe Plaque psoriasis 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 ulcerative colitis in patients ≥ 6 years old
Kevzara®	sarilumab	<ul style="list-style-type: none"> ▪ Moderately to severely active RA with or without methotrexate in patients ≥ 18 years old who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs)
Kineret®	anakinra	<ul style="list-style-type: none"> ▪ Moderately to severely active RA in patients ≥ 18 years old ▪ Chronic infantile neurological, cutaneous, and articular syndrome
Orencia®	abatacept	<ul style="list-style-type: none"> ▪ Moderately to severely active RA in patients ≥ 18 years old ▪ JIA in patients ≥ 2 years old (previously listed as JRA) ▪ Psoriatic arthritis (PsA) in patients ≥ 18 years old
Olumiant®	baricitinib	<ul style="list-style-type: none"> ▪ Moderately to severely active RA in patients ≥ 18 years old
Otezla®	apremilast	<ul style="list-style-type: none"> ▪ PsA in patients ≥ 18 years old ▪ Plaque psoriasis in patients ≥ 18 years old ▪ Oral ulcers associated with Behçet's disease in patients ≥ 18 years old
Remicade®	infliximab	<ul style="list-style-type: none"> ▪ Moderately to severely active RA in patients ≥ 18 years old in combination with methotrexate

Brand Names	Generic Names	Indications
		<ul style="list-style-type: none"> ▪ PsA in patients ≥ 18 years old ▪ Ankylosing spondylitis in patients ≥ 18 years old ▪ Chronic severe plaque psoriasis in patients ≥ 18 years old ▪ Moderately to severely active Crohn's disease in patients ≥ 6 years old ▪ Fistulizing Crohn's disease in patients ≥ 18 years old ▪ Moderately to severely active ulcerative colitis in patients ≥ 6 years old
Renflexis® (biosimilar to Remicade)	infliximab-abda	<ul style="list-style-type: none"> ▪ Ankylosing spondylitis in patients ≥ 18 years old ▪ Fistulizing Crohn's disease in patients ≥ 18 years old ▪ Moderately to severely Crohn's disease in patients ≥ 6 years old ▪ Chronic severe plaque psoriasis 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 ulcerative colitis in patients ≥ 6 years old
Rinvoq™	upadacitinib	<ul style="list-style-type: none"> ▪ Moderately to severely active rheumatoid arthritis in patients ≥ 18 years old
Siliq®	brodalumab	<ul style="list-style-type: none"> ▪ Moderate to severe plaque psoriasis in adult patients
Simponi®/ Simponi Aria®	golimumab	<ul style="list-style-type: none"> ▪ Moderately to severely active RA in patients ≥ 18 years old, in combination with methotrexate ▪ Active PsA in adults, alone or in combination with methotrexate ▪ Active ankylosing spondylitis (AS) in patients ≥ 18 years old ▪ Moderately to severely active ulcerative colitis in patients ≥ 18 years old
Skyrizi™	risankizumab-rzaa	<ul style="list-style-type: none"> ▪ Moderate to severe plaque psoriasis in patients ≥ 18 years old
Stelara®	ustekinumab	<ul style="list-style-type: none"> ▪ Moderate to severe plaque psoriasis in patients ≥ 12 years old ▪ Psoriatic arthritis in patients ≥ 18 years old ▪ Moderately to severely active Crohn's disease in patients ≥ 18 years old who have: <ul style="list-style-type: none"> – 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 ulcerative colitis in patients ≥ 18 years old
Taltz®	ixekizumab	<ul style="list-style-type: none"> ▪ Moderate to severe plaque psoriasis in patients ≥ 6 years old ▪ Active Ankylosing Spondylitis (AS) in patients ≥ 18 years old ▪ Active non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation in patients ≥ 18 years old ▪ Active psoriatic arthritis (PsA) in patients ≥ 18 years old
Tremfya®	Guselkumab	<ul style="list-style-type: none"> ▪ Moderate to severe plaque psoriasis in patients ≥ 18 years old
Xeljanz®/XR	tofacitinib	<ul style="list-style-type: none"> ▪ Moderately to severely active RA in patients ≥ 18 years old alone or in combination with methotrexate or other DMARDS ▪ Psoriatic arthritis in patients ≥ 18 years old ▪ Moderate to severe ulcerative colitis in patients ≥ 18 years old

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 an 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) (all of the following must be met):
 - 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 (all of 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:
 - a. Must have a previous failure on a topical psoriasis agent
6. Psoriatic arthritis:
 - a. Trial and failure required with methotrexate first or in combination with methotrexate if appropriate
7. Rheumatoid arthritis:
 - a. Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (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 Rx 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® request 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 (PA).

References

Available upon request.

Revision History

Reviewed by	Reason for Review	Date Approved
Pharmacy & 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

Reviewed by	Reason for Review	Date Approved
DUR Board	Revision	03/12/2019
Commissioner Designee	Approval	04/05/2019
DUR Board	Revision	10/28/2019
Commissioner Designee	Approval	12/03/2019
DUR Board	Revision	06/30/2020
Commissioner Designee	Approval	08/07/2020