Pharmacy Medical Necessity Guidelines:
Targeted Immunomodulators Self-administration

Effective: October 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Brand Name	AD	AS	CD	JIA	nr-axSpA	PsA	PsO	RA	UC	Other
Actemra SC	-	-	-	X	-	-	-	X	-	Giant cell arteritis Systemic Sclerosis-Associated Interstitial Lung Disease
Adalimumab-adbm	-	X	X	X (pJIA)	-	X	X	X	X	
Adalimumab-fkjp	-	X	X	X (pJIA)	-	X	X	X	X	
Avtozma SC	-	-	-	x	-	-	-	x	-	Giant cell arteritis Systemic Sclerosis-Associated Interstitial Lung Disease
Cimzia	-	X	X	x (pJIA)	X	X	X	X	-	
Cosentyx	-	X	-	-	X	X	X	-	-	Enthesitis-related arthritis Hidradenitis suppurativa
Enbrel	-	X	-	X (pJIA)	-	X	X	X	-	
Hadlima	-	X	X	X (pJIA)	-	X	X	X	X	
Kevzara	-	-	-	X (pJIA)	-	-	-	X	-	Polymyalgia rheumatica
Kineret	-	-	-	-	-	-	-	X	-	Cryopyrin-associated periodic syndromes Deficiency of interleukin-1 receptor antagonist
Olumiant	-	-	-	-	-	-	-	X	-	Alopecia areata
Orencia SC	-	-	-	X (pJIA)	-	X	-	X	-	
Otezla	-	-	-	-	-	X	X	-	-	Oral ulcers associated with Behçet's Disease
Rinvoq	X	X	X	X (pJIA)	X	X	-	X	X	
Siliq	-	-	-	-	-	-	X	-	-	
Simponi SC	-	X	-	-	-	X	-	X	X	
Skyrizi	-	-	X	-	-	X	X	-	-	
Sotyktu	-	-	-	-	-	X	X	-	-	
Taltz	-	X	-	-	X	X	X	-	-	
Tremfya	-	-	X	-	-	X	X	-	X	
Tyenne SC	-	-	-	X	-	-	-	X	-	Giant cell arteritis
Xeljanz	-	X	-	X (pJIA)	-	X	-	X	X	
Starjemza SC	-	-	X	-	-	X	X	-	X	

AD=atopic dermatitis, AS=ankylosing spondylitis, CD=Crohn's disease, JIA=juvenile idiopathic arthritis, nr-ax SpA=non-radiogrphic axial spondyloarthritis, pJIA=polyarticular course juvenile idiopathic arthritis, PsA=psoriatic arthritis, PsO=plaque psoriasis, RA=rheumatoid arthritis, SC=subcutaneous, sJIA=systemic juvenile idiopathic arthritis, UC=ulcerative colitis

COVERAGE GUIDELINES

PREFERRED PRODUCTS

1. Adalimumab-adbm, Adalimumab-fkjp, and Hadlima (adalimumab-bwwd)

The plan may authorize coverage of Adalimumab-adbm, Adalimumab-fkjp, or Hadlima for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to a prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
    b. Contraindication to non-steroidal anti-inflammatory drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is at least 6 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least two (2) of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
    b. Contraindication to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate
    c. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
    d. Previous treatment with a biologic agent indicated for the requested use.
    e. Patient is new to the plan and stable on the requested agent

Hidradenitis Suppurativa

1. Documented diagnosis of hidradenitis suppurativa

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is at least 12 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Inadequate response to at least three (3) of the following conventional treatments:
        i. Local hygiene and ordinary hygiene
        ii. Weight reduction in patients who are obese
        iii. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate)
        iv. Application of warm compresses with sodium chloride solution or Burow's solution
        v. Laser hair removal
        vi. Cessation of cigarette smoking
        vii. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
    b. Patient is new to the plan and stable on the requested agent

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
    b. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to one traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is at least 18 years of age or older

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least one (1) traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 5 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
    b. Contraindication to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate
    c. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease

d. Previous treatment with a biologic agent indicated for the requested use e.
e. Patient is new to the plan and stable on the requested agent

Uveitis

1. Documented diagnosis of uveitis (non-infectious intermediate, posterior or panuveitis)

AND

2. Prescribed by or in consultation with an ophthalmologist, ocular immunologist, rheumatologist)

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or inability to tolerate conventional therapy (e.g., periocular, intraocular, or systemic corticosteroids; immunosuppressants)
    b. Patient is new to the plan and stable on the requested agent

2. Enbrel (etanercept)

The plan may authorize coverage of Enbrel for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to a prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
    b. Contraindication to non-steroidal anti-inflammatory drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. The patient is new to the plan and has been stable on the requested agent

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 4 years of age or older

AND

4. Documentation of **one (1) of the following:**
    a. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
    b. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least one (1) traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is at least 2 years of age or older

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least one (1) traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

3. Simponi

The plan may authorize coverage of Simponi for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to a prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
    b. Contraindication to non-steroidal anti-inflammatory drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 18 years of age or older

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least one (1) traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
    b. Contraindication to all traditional disease modifying antirheumatic drugs
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Documentation of **one (1)** of the following:
    a. Patient is at least 18 years of age or older
    b. Patient weighs at least 15 kilograms

AND

4. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
    b. Contraindication to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate
    c. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan and stable on the requested agent

4. Starjemza (ustekinumab-hmny)

The plan may authorize coverage of Starjemza for Member when **ALL** of the following criteria are met:

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to at least two (2) of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
    b. Contraindication to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate
    c. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
    d. Previous treatment with a biologic agent indicated for the requested use.
    e. Patient is new to the plan and stable on the requested agent

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 6 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
    b. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
    c. Previous treatment with a biologic agent indicated for the requested use
    d. Patient is new to the plan and stable on the requested agent

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 6 years of age or older

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
    b. Contraindication to corticosteroids, 5-aminosalycylates, 6-mercaptopurine, and methotrexate
    c. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
    d. Previous treatment with a biologic agent indicated for the requested use e.
    e. Patient is new to the plan and stable on the requested agent

NONPREFERRED PRODUCTS

1. Actemra (tocilizumab), Avtozma (tocilizumab-anoh), Tyenne (tocilizumab-bavi)

The plan may authorize coverage of Actemra, Avtozma, or Tyenne for Members when **ALL** of the following criteria are met:

Giant Cell Arteritis

1. Documented diagnosis of giant cell arteritis

AND

2. Prescribed by or in consultation with a rheumatologist or neurologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to a systemic corticosteroid
    b. Contraindication to systemic corticosteroids
    c. Patient is new to the plan and stable on Actemra

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all, traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, or Hadlima
    b. Patient is new to the plan and stable on the requested medication and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use

ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi

b. Patient is new to the plan and stable on the requested medication and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Systemic Juvenile Idiopathic Arthritis

1. Documented diagnosis of systemic juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to one (1) traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
    b. Contraindication to all traditional disease modifying antirheumatic drugs

Systemic Sclerosis-Associated Interstitial Lung Disease

1. Documented diagnosis of systemic sclerosis-associated interstitial lung disease

AND

2. Prescribed by or in consultation with a rheumatologist or pulmonologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation to **one (1)** of the following:
    a. Inadequate response or adverse reaction to at least two (2) of the following agents: mycophenolate mofetil, cyclophosphamide, or azathioprine
    b. Contraindication to mycophenolate mofetil, cyclophosphamide, or azathioprine

2. Cimzia (certolizumab)

The plan may authorize coverage of Cimzia for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. One of the following:

1. Inadequate response or adverse reaction to at least two (2), or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
3. Previous treatment with a biologic agent indicated for the requested use

ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, or Starjemza

b. Patient is new to the plan and stable on a Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to one prescription strength nonsteroidal anti-inflammatory drug
   b. Contraindication to nonsteroidal anti-inflammatory drugs

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   1. Both of the following:
      i. One of the following:
         1 Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
         2 Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
         3 Previous treatment with a biologic agent indicated for the requested use
      ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Starjemza
   2. Patient is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Both of the following:
      i. One of the following:
         1. Inadequate response or adverse reaction to one (1), or contraindication to all, traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
         2. Previous treatment with a biologic agent indicated for the requested use

ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, or Hadlima

b. Patient is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
   b. Patient is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
   a. Both of the following:
      i. One of the following:
         1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
         2. Previous treatment with a biologic agent indicated for the requested use
      ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
   b. Patient is new to the plan and stable on Cimzia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

3. Cosentyx (secukinumab)

The plan may authorize coverage of Cosentyx for Members when **ALL** of the following criteria are met:

Ankylosing spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
   a. Both of the following:
      i. One of the following:
         1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
         2. Previous treatment with a biologic agent indicated for the requested use
      ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
   b. Patient is new to the plan and stable on Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Enthesitis-related Arthritis

1. Documented diagnosis of enthesitis-related arthritis

AND

2. Patient is at least 4 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documented inadequate response to optimal doses of methotrexate for at least three months or the provider has indicated clinical inappropriateness with methotrexate

Hidradenitis Suppurativa

1. Documented diagnosis of hidradenitis suppurativa

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is at least 12 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. Inadequate response to at least three (3) of the following conventional treatments:
            1. Local hygiene and ordinary hygiene
            2. Weight reduction in patients who are obese
            3. Use of ordinary soaps and antiseptic and antiperspirant agents (e.g., aluminum chloride hexahydrate)
            4. Application of warm compresses with sodium chloride solution or Burow's solution
            5. Laser hair removal
            6. Cessation of cigarette smoking
            7. Medical anti-inflammatory or antiandrogen therapy such as oral or topical antibiotics, intralesional triamcinolone, spironolactone, or finasteride
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, or Hadlima
    b. Patient is new to the plan and stable on a Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to one prescription strength nonsteroidal anti-inflammatory drug
    b. Contraindication to nonsteroidal anti-inflammatory drugs

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 6 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
            2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate

3. Previous treatment with a biologic agent indicated for the requested use
   ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Starjemza
b. Patient is new to the plan and stable on Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
   b. Patient is new to the plan and stable on Cosentyx and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

4. Kevzara (sarilumab)

The plan may authorize coverage of Kevzara for Members when **ALL** of the following criteria are met:

Polymyalgia Rheumatica

1. Documented diagnosis of polymyalgia rheumatica

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
   a. Inadequate response to corticosteroids
   b. Patient cannot tolerate corticosteroid taper

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Both of the following:
      i. One of the following:
         1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
         2. Previous treatment with a biologic agent indicated for the requested use
      ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
   b. Patient is new to the plan and stable on Kevzara and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient weighs at least 63 kilograms

AND

4. Documentation of **one (1)** of the following:

a. Both of the following:
    i. One of the following:
        1. Inadequate response or adverse reaction to one (1), or contraindication to all, traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
        2. Previous treatment with a biologic agent indicated for the requested use
    ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, or Hadlima
b. Patient is new to the plan and stable on Kevzara and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

5. Kineret (anakinra)
The plan may authorize coverage of Kineret for Members when **ALL** of the following criteria are met:

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

1. Documented diagnosis of deficiency of interleukin-1 receptor antagonist

Neonatal-Onset Multisystem Inflammatory Disease (NOMID)

1. Documented diagnosis of neonatal-onset multisystem inflammatory disease

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Kineret and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

6. Olumiant (baricitinib)
The plan may authorize coverage of Olumiant for Members when **ALL** of the following criteria are met:

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Olumiant and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

7. Orencia (abatacept)
The plan may authorize coverage of Orencia for Members when **ALL** of the following criteria are met:

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular or systemic juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following
        i. One of the following:
            1. Inadequate response or adverse reaction to one, or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, or Hadlima
    b. Patient is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Orencia and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

8. Otezla (apremilast)
The plan may authorize coverage of Otezla for Members when **ALL** of the following criteria are met:

Behçet's Disease

1. Documented diagnosis of Behçet's disease

AND

2. Documentation of active oral ulcers

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Patient is at least 18 years of age or older

AND

5. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to two (2) of the following agents: azathioprine, colchicine, corticosteroids (topical or systemic), or sucralfate
    b. Contraindication to all of the following: azathioprine, colchicine, corticosteroids (topical or systemic), or sucralfate

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Documentation of both of the following:
    a. Patient is 6 years of age or older
    b. Patient weights at least 20 kg

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
            2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Starjemza
    b. Patient is new to the plan and stable on Otezla and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Documentation of one (1) of the following:
    a. Patient is 18 years of age or older
    b. Both of the following:
        i. Patient is 6 years of age or older
        ii. Patient weighs at least 20 kilograms

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Otezla and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

9. Rinvoq (upadacitinib)

The plan may authorize coverage of Rinvoq for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:

i. One of the following:
    1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
    2. Previous treatment with a biologic agent indicated for the requested use
ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi

b. Patient is new to the plan and stable on Rinvoq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Atopic Dermatitis

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

4. Documentation the patient's condition meets **one (1)** of the following:
    a. Body Surface Area (BSA) of at least 10%
    b. Eczema Area and Severity Index EASI score of at least 16
    c. Investigator's Global Assessment/Physician Global Assessment (IGA/PGA) score of at least 3

AND

5. Documentation of **one (1)** of the following:
    a. Trial and failure of at least one medium to very high topical corticosteroid
    b. Contraindication to medium to very high topical corticosteroid

AND

6. Documentation of **one (1)** of the following:
    a. Trial and failure of at least one topical immunomodulator
    b. Contraindication to topical immunomodulator

AND

7. Documentation of **one (1)** of the following:
    a. Trial and failure of Eucrisa (crisaborole)
    b. Contraindication to Eucrisa (crisaborole)

AND

8. For Members at least 18 years of age, documentation of **one (1)** of the following:
    a. Trial and failure with or intolerance to at least one of the following systemic immunosuppressive therapies: azathioprine, cyclosporine, or methotrexate
    b. Contraindication to all of the following systemic immunosuppressive therapies: azathioprine, cyclosporine, and methotrexate

Reauthorization Criteria

1. Documented diagnosis of moderate to severe atopic dermatitis

AND

2. Patient is at least 12 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist, allergist, or immunologist

AND

4. Documentation the Member has experienced a therapeutic response as defined by **one (1)** of the following:
    a. Reduction in body surface area involvement relative to pretreatment baseline
    b. Improvement in atopic dermatitis symptoms as evidenced by marked improvements in symptoms such as pruritus, xerosis, crusting, or lichenification
    c. Reduction in the use of other or systemic therapies

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least two (2), or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
            2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, or Starjemza
    b. Patient is new to the plan and stable on a Rinvoq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Inadequate response or adverse reaction to one prescription strength nonsteroidal anti-inflammatory drug
    b. Contraindication to nonsteroidal anti-inflammatory drugs

Polyarticular Course Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following
        i. One of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all, traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, or Hadlima
    b. Patient is new to the plan and stable on Rinvoq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza

b. Patient is new to the plan and stable on Rinvoq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Rinvoq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least two (2), or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
            2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on a Rinvoq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

10. Siliq (brodalumab)

The plan may authorize coverage of Siliq for Members when **ALL** of the following criteria are met:

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. All of the following:
        i. One of the following:

1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
3. Previous treatment with a biologic agent indicated for the requested use

ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Otezla or Starjemza

iii. Trial and failure with, or contraindication to Cosentyx

b. Patient is new to the plan and stable on Siliq and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

11. Skyrizi (risankizumab-rzaa)

The plan may authorize coverage of Skyrizi for Members when **ALL** of the following criteria are met:

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Both of the following:
      i. One of the following:
         1. Inadequate response or adverse reaction to at least two, or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6-mercaptopurine, or methotrexate
         2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
         3. Previous treatment with a biologic agent indicated for the requested use

      ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, or Starjemza

   b. Patient is new to the plan and stable on a Skyrizi and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 6 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Both of the following:
      i. One of the following:
         1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
         2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
         3. Previous treatment with a biologic agent indicated for the requested use

      ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Starjemza

   b. Patient is new to the plan and stable on Skyrizi and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Skyrizi and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age

AND

4. Documentation of **one (1)** of the following:
    a. All of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least two (2), or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
            2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Skyrizi and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

12. Sotyktu (deucravacitinib)

The plan may authorize coverage of Sotyktu for Member when **ALL** of the following criteria are met:

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
            2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Starjemza
    b. Patient is new to the plan and stable on Sotyktu and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Sotyktu and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

13. Taltz (ixekizumab)

The plan may authorize coverage of Taltz for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. All of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
        iii. Trial and failure with or contraindication to Cosentyx
    b. Patient is new to the plan and stable on Taltz and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of non-radiographic axial spondyloarthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One (1) of the following:
            1. Inadequate response or adverse reaction one prescription strength nonsteroidal anti-inflammatory drug
            2. Contraindication to nonsteroidal anti-inflammatory drugs
        ii. Trial and failure with or contraindication to Cosentyx
    b. Patient is new to the plan and stable on Taltz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Patient is 6 years of age or older

AND

4. Documentation of **one (1)** of the following:

a. All of the following:
    i. One (1) of the following:
        1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
        2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
        3. Previous treatment with a biologic agent indicated for the requested use
    ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Otezla or Starjemza
    iii. Trial and failure with, or contraindication to Cosentyx
b. Patient is new to the plan and stable on Taltz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
        ii. Trial and failure with, or contraindication to Cosentyx
    b. Patient is new to the plan and stable on Taltz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

14. Tremfya (guselkumab)

The plan may authorize coverage of Tremfya for Members when **ALL** of the following criteria are met:

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least two (2), or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
            2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, or Starjemza
    b. Patient is new to the plan and stable on a Tremfya and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Prescribed by or in consultation with a dermatologist

AND

3. Documentation of **one (1)** of the following:
    a. Patient is 18 years of age or older
    b. Both of the following:
        i. Patient is 6 years of age or older
        ii. Patient weighs at least 40 kilograms

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response to phototherapy and at least one (1) of the following agents: Soriatane (acitretin), cyclosporine, or methotrexate
            2. Contraindication to phototherapy and all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Starjemza
    b. Patient is new to the plan and stable on Tremfya and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Documentation of **one (1)** of the following:
    a. Patient is 18 years of age or older
    b. Both of the following:
        i. Patient is 6 years of age or older
        ii. Patient weighs at least 40 kilograms

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Tremfya and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least two (2), or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6- mercaptopurine, or methotrexate
            2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on a Tremfya and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

15. Xeljanz (tofacitinib)

The plan may authorize coverage of Xeljanz for Members when **ALL** of the following criteria are met:

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Patient is at least 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

AND

4. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Xeljanz and the prescribing physician has documented that changing to a preferred product would result in adverse clinical outcomes

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    c. Both of the following
        i. One of the following:
            1. Inadequate response or adverse reaction to one (1), or contraindication to all, traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, or Hadlima
    d. Patient is new to the plan and stable on Xeljanz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist or dermatologist

AND

3. Patient is 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on Xeljanz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least one (1), or contraindication to all traditional disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
            2. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with two (2), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Enbrel, Hadlima, or Simponi
    b. Patient is new to the plan and stable on Xeljanz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. The prescribing physician is a gastroenterologist

AND

3. Patient is at least 18 years of age or older

AND

4. Documentation of **one (1) of the following**:
    a. Both of the following:
        i. One of the following:
            1. Inadequate response or adverse reaction to at least two, or contraindication to all of the following: Corticosteroids, 5-aminosalycylates, 6-mercaptopurine, or methotrexate
            2. The patient is moderate to high risk as evidenced by deep ulcers on colonoscopy, long segments of small and/or large bowel involvement, perianal disease, extra-intestinal manifestations (e.g., fever, weight loss, abdominal pain, intermittent nausea/vomiting), history of bowel resections, or recent hospitalization for the disease
            3. Previous treatment with a biologic agent indicated for the requested use
        ii. Trial and failure with one (1), or contraindication to all of the following: Adalimumab-adbm, Adalimumab-fkjp, Hadlima, Simponi or Starjemza
    b. Patient is new to the plan and stable on a Xeljanz and the prescribing physician has documented that changing to the preferred products would result in adverse clinical outcomes

LIMITATIONS

- Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response and will not be considered for prior authorization.
- For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
- Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
- Documentation of a Member having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products.
- The plan will not authorize coverage of Olumiant for the treatment of alopecia.
- For the treatment of atopic dermatitis, initial coverage of Rinvoq will be authorized for 6 months. Reauthorization of Rinvoq for atopic dermatitis will be provided in 12-month intervals.

CODES

None

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APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

1. February 14, 2023: Added coverage criteria for Rinvoq's supplemental indication in non-radiographic axial spondyloarthritis (effective March 1, 2023). Added Sotyktu to the Medical Necessity Guideline (effective March 1, 2023).
2. July 11, 2023: Added coverage criteria for Rinvoq's supplemental indication in Crohn's disease ankylosing spondylitis, and ulcerative colitis. Added coverage criteria for Skyrizi's supplemental indication in Crohn's disease. Administrative edit to add back in a Limitation noting that Olumiant will not be authorized for the treatment of alopecia (effective August 1, 2023).
3. December 12, 2023: Changed name from "Targeted Immunomodulators-Biological Agents" to "Targeted Immunomodulators-Self-administered" Minor wording updates. Added age requirements and provider specialty requirements throughout the Medical Necessity Guideline; provider specialty requirements updated to "prescribed by or in consultation with", and for Psoriatic arthritis expanded specialty requirements to dermatologist and rheumatologist. For ankylosing spondylitis, added nonsteroidal anti-inflammatory drugs as a prerequisite option. Updated non-biologic prerequisites to DMARDs for juvenile idiopathic arthritis. Removed non-biologic prerequisites from psoriatic arthritis coverage criteria. Removed Documentation of objective signs of inflammation from Non-radiographic Axial Spondyloarthritis. Removed The Member has tried and failed treatment with another biologic agent FDA-approved for the requested indication from Uveitis and HS for Humira. Removed Documentation of Hurley Stage II or III disease with at least three abscesses or inflammatory nodules" from HS. Giant cell arteritis prerequisites updated and continuity of care was added. For Rinvoq for atopic dermatitis, expanded requirements to demonstrate moderate to severe atopic dermatitis and removed notes specifying treatment failure definition. Removed the Limitation: Maximal doses of methotrexate are defined as 15 to 25 mg per week depending on the patient's tolerance. Added coverage criteria for Cosentyx's supplemental indication for hidradenitis suppurativa. Expanded age requirements of Enbrel for psoriatic arthritis to at least 2 years of age based on the expanded indication. Added coverage criteria for Kevzara's supplemental indication in polymyalgia rheumatica. Expanded age requirements of Orencia SC for psoriatic arthritis to at least 2 years of age based on expanded indication (eff 3/1/2024).
4. February 13, 2024: Moved Simponi and Stelara to preferred status. Added Adalimumab-adbm, Adalimumab-fkjp, and Hadlima to the Medical Necessity Guideline as preferred products. Removed Humira from the Medical Necessity Guideline (eff 4/1/2024). Coverage criteria for Taltz and Siliq for the indications ankylosing spondylitis, non-radiographic axial spondyloarthritis, plaque psoriasis, psoriatic arthritis, respectively, updated to include a step through Cosentyx (eff 5/1/2024).
5. June 11, 2024: Added criteria for Rinvoq's supplemental indication for Polyarticular Juvenile Idiopathic Arthritis. Updated age requirements for Rinvoq for PsA based on expanded indication (eff 7/1/24).
6. September 10, 2024: Updated age requirements for Otezla for plaque psoriasis based on the expanded indication. Added coverage criteria for Skyrizi's supplemental indication in ulcerative colitis. Added Tyenne SC to the Medical Necessity Guideline (eff 10/1/24).
7. October 8, 2024: Added coverage criteria for Tremfya for the supplemental indication in ulcerative colitis (eff 11/1/24).
8. December 10, 2024: Added coverage criteria for Cimzia for the polyarticular juvenile idiopathic arthritis (eff 1/1/25).
9. April 8, 2025: Added coverage criteria for Tremfya for the supplemental indication in Crohn's disease (eff 5/1/25).
10. August 12, 2025: Added Avtozma to the Medical Necessity Guideline (eff 9/1/25). Removed Stelara from the Medical Necessity Guideline. Added Yesintek to the Medical Necessity Guideline (eff 11/1/25).
11. July 14, 2026: Effective 10/1/26, added Starjemza and removed Yesintek to the Medical Necessity Guideline. Updated coverage criteria to replace Yesintek with Starjemza for step through requirements for the following products: Cosentyx (plaque psoriasis, psoriatic arthritis), Cimzia (Crohn's disease, plaque psoriasis, psoriatic arthritis), Orencia (psoriatic arthritis), Otezla (psoriatic arthritis), Rinvoq (Crohn's disease, psoriatic arthritis, ulcerative colitis), Siliq (plaque psoriasis), Skyrizi (Crohn's disease, plaque psoriasis, psoriatic arthritis, ulcerative colitis), Sotyktu (plaque psoriasis), Taltz (plaque psoriasis, psoriatic arthritis), Tremfya (Crohn's disease, plaque psoriasis, psoriatic arthritis, ulcerative colitis), Xeljanz (psoriatic arthritis, ulcerative colitis). Updated coverage criteria for the following products based on expanded indication: Starjemza (pediatric patients 2

years of age and older for Crohn's disease), Simponi (adults and pediatrics weighing at least 15 kg for ulcerative colitis), Cosentyx (pediatric patients 12 years of age and older for ankylosing spondylitis and hidradenitis suppurativa), Otezla (pediatric patients 6 years of age and older weighing at least 20 kg), Skyrizi (pediatric patients 6 years of age and older for plaque psoriasis), Tremfya (pediatric patients 6 years of age and older weighing at least 40 kg for plaque psoriasis and psoriatic arthritis), Xeljanz (pediatric patients 2 years of age and older for psoriatic arthritis). Added coverage criteria for Kevzara for polyarticular juvenile idiopathic arthritis and for Sotyktu for psoriatic arthritis.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic. Provider Services