Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Targeted Immunomodulators Skilled Administration

Effective: October 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☐ Tufts Health Plan Commercial products; Fax 617-673-0988

Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration - Approved Indications

Disease State	Cosentyx IV	Entyvio IV	Ilumya	Infliximab (Avsola*, Inflectra*, Infliximab*, Remicade, Renflexis*)	Omvoh IV	Orencia IV	Simponi Aria	Skyrizi IV	Tocilizumab IV (Actemra, Avtozma Tofidence, Tyenne)	Tremfya IV	Ustekinumab IV (Imuldosa, Otulfi, Pyzchiva, Selarsdi, Starjemza, Stelara, Steqeyma, Wezlana, Yesintek)
AS	X	-	-	X	-	-	X	-	-	-	-
CD	-	X	-	X	X	-	-	X	-	X	X
CRS	-	-	-	-	-	-	-	-	X (Actemra IV)	-	-
GCA	-	-	-	-	-	-	-	-	X	-	-
GVHD	-	-	-	-	-	X	-	-	-	-	-
nr-axSpA	X	-	-	-	-	-	-	-	-	-	-
PsO	-	-	X	X	-	-	-	-	-	-	-
pJIA	-	-	-	-	-	X	X	-	X	-	-
PsA	X	-	-	X	-	X	X	-	-	-	-
RA	-	-	-	X	-	X	X	-	X	-	-
sJIA	-	-	-	-	-	-	-	-	X	-	-

UC	-	X	-	X	X	-	X	-	-	X	X

AS=ankylosing spondylitis, CD=Crohn's Disease, CRS=Cytokine Release Syndrome, GCA=Giant Cell Arteritis, GVHD= Prophylaxis for Acute Graft versus Host Disease, IV=intravenous, nr-axSpA=Non-radiographic Axial Spondyloarthritis, PsO=plaque psoriasis, pJIA=polyarticular Juvenile Idiopathic Arthritis, PsA=Psoriatic Arthritis, RA=Rheumatoid Arthritis, sJIA= Systemic Juvenile Idiopathic Arthritis, UC=ulcerative colitis

IV=intravenous

*Preferred products

Clinical Guideline Coverage Criteria

The plan may authorize coverage of a Targeted Immunomodulator Skilled Administration medication for a Member when **ALL** of the following criteria are met:

Actemra, Avtozma, Tofidence, and Tyenne Intravenous

Cytokine Release Syndrome

1. Documented diagnosis of severe or life-threatening chimeric antigen receptor T cell-induced cytokine release syndrome

AND

2. Patient is 2 years of age or older

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 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 the requested medication prior to enrollment

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 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 medication

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is 18 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 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 medication

Avsola, Inflectra, Infliximab, Remicade, Renflexis

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is 18 years of age or older

AND

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

AND

5. If the request is for Remicade, documentation of **one (1)** of the following:
    a. Previous failure of or clinical inappropriateness of treatment with all infliximab biosimilars
    b. Patient is new to the plan and stable on Remicade and the prescribing physician has documented that changing to an infliximab biosimilar would result in adverse clinical outcomes

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 6 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on the requested agent prior to enrollment

AND

5. If the request is for Remicade, documentation of **one (1)** of the following:
    a. Previous failure of or clinical inappropriateness of treatment with all infliximab biosimilars
    b. Patient is new to the plan and stable on Remicade and the prescribing physician has documented that changing to an infliximab biosimilar 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 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 or the provider has indicated clinical inappropriateness with all of the following: Soriatane (acitretin), cyclosporine, or methotrexate
    b. Previous treatment with a biologic agent indicated for the requested use

c. Patient is new to the plan and stable on the requested agent

AND

5. If the request is for Remicade, documentation of **one (1)** of the following:
    a. Previous failure of or clinical inappropriateness of treatment with all infliximab biosimilars
    b. Patient is new to the plan and stable on Remicade and the prescribing physician has documented that changing to an infliximab biosimilar would result in adverse clinical outcomes

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is 18 years of age or older

AND

4. If the request is for Remicade, documentation of **one (1)** of the following:
    a. Previous failure of or clinical inappropriateness of treatment with all infliximab biosimilars
    b. Patient is new to the plan and stable on Remicade and the prescribing physician has documented that changing to an infliximab biosimilar 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 18 years of age or older

AND

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

AND

5. If the request is for Remicade, documentation of **one (1)** of the following:
    a. Previous failure of or clinical inappropriateness of treatment with all infliximab biosimilars
    b. Patient is new to the plan and stable on Remicade and the prescribing physician has documented that changing to an infliximab biosimilar would result in adverse clinical outcomes

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 6 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on the requested agent prior to enrollment

AND

5. If the request is for Remicade, documentation of **one (1)** of the following:

a. Previous failure of or clinical inappropriateness of treatment with all infliximab biosimilars
b. Patient is new to the plan and stable on Remicade and the prescribing physician has documented that changing to an infliximab biosimilar would result in adverse clinical outcomes

Cosentyx Intravenous

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is 18 years of age or older

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 has been stable on Cosentyx Intravenous prior to enrollment

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

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

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

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

Entyvio Intravenous

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. 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
   b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
   c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
   d. Previous treatment with a biologic agent indicated for the requested use
   e. Patient is new to the plan has been stable on Entyvio Intravenous prior to enrollment

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on Entyvio Intravenous prior to enrollment

Ilumya

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 or adverse reaction 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 Ilumya prior to enrollment

Omvoh Intravenous

Crohn's Disease

1. Documented diagnosis of Crohn's Disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on the requested agent prior to enrollment

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on the requested agent prior to enrollment

Orencia Intravenous

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 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 Orencia Intravenous prior to enrollment

Prophylaxis for Acute Graft Versus Host Disease

1. Documented diagnosis of acute graft versus host disease

AND

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

AND

3. Documentation the patient is undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated-donor

AND

4. Documentation Orencia Intravenous will be used in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

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 one, or contraindication to all disease modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)
b. Previous treatment with a biologic agent indicated for the requested use
c. Patient is new to the plan and stable on Orencia intravenous

Simponi Aria

Ankylosing Spondylitis

1. Documented diagnosis of ankylosing spondylitis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is 18 years of age or older

AND

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

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 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to one (1) 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 has been stable on Simponi Aria prior to enrollment

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Prescribed by or in consultation with a rheumatologist

AND

3. Patient is 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 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
   a. Inadequate response or adverse reaction to one 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 has been stable on Simponi Aria prior to enrollment

Skyrizi Intravenous

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on Skyrizi Intravenous prior to enrollment

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on Skyrizi Intravenous prior to enrollment

Starjemza Intravenous

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 2 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on Starjemza Intravenous prior to enrollment

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    f. 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
    g. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    h. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    i. Previous treatment with a biologic agent indicated for the requested use
    j. Patient is new to the plan has been stable on Starjemza Intravenous prior to enrollment

Imuldosa, Otulfi, Pzychiva, Selsardi, Steqemya, Wezlana, Yesintek Intravenous

In addition to the coverage criteria for Yesintek, the plan may authorize coverage of Imuldosa, Otulfi, Pzychiva, Selsardi, Stelara, Steqemya, Wezlana, or Yesintek Intravenous for Members when the following criteria are met:

1. Documentation of one (1) of the following:
    a. Previous trial and failure with, contraindication to, or clinical inappropriateness to treatment with Starjemza
    b. Patient is new to the plan and stable on the requested agent prior to enrollment
    c. The prescribing physician has documented that changing to a preferred product would result in an adverse clinical outcome

Tremfya Intravenous

Crohn's disease

1. Documented diagnosis of Crohn's disease

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of **one (1)** of the following:
    a. 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
    b. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
    c. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
    d. Previous treatment with a biologic agent indicated for the requested use
    e. Patient is new to the plan has been stable on Tremfya intravenous prior to enrollment

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Prescribed by or in consultation with a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

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

g. Inadequate response or adverse reaction to at least two of the following: Corticosteroids, a 5-aminosalicylates, 6-mercaptopurine, or methotrexate
h. Contraindication to corticosteroids, 5-aminosalicylates, 6-mercaptopurine, and methotrexate
i. Previous treatment with a biologic agent indicated for the requested use
j. Patient is new to the plan has been stable on Tremfya intravenous prior to enrollment

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.
- Approval of tocilizumab for intravenous injection for cytokine release syndrome will be limited to **one (1)** month.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J3247	Injection, secukinumab, IV, 1 mg
J2267	Injection, mirikizumab-mrkz, 1 mg
J0129	Injection, abatacept, per 10 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1628	Injection, guselkumab, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q5099	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Injection, infliximab-adba-biosimilar, (renflexis), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg
Q5135	Injection, tocilizumab-aazg (tyenne) biosimilar, 1 mg
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q0238	Injection, tocilizumab-aazg, for hospitalized adult patients with covid-19 who are receiving systemic corticosteroidsand require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ecmo) only, 1 mg
Q5138	Injection, ustekinumab-auub (wezlana), biosimilar, intravenous, 1 mg
Q5156	Injection, tocilizumab-anoh (avtozma), biosimilar, 1 mg
Q9997	Injection, ustekinumab-ttwe (pyzchiva), intravenous, 1 mg
Q9998	Injection, ustekinumab-aekn (selarsdi), biosimilar, 1mg
Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg

Note: Medical billing codes may not be used for Actemra, Avtozma, Tyenne, Cosentyx, Orencia, Simponi, Stelara, Tremfya or Imuldosa, Otulfi, Pzychiva, Selsardi, Starjemza, Steqemya, Wezlana, or Yesintek injections for subcutaneous use. These formulations must be obtained via the Member's pharmacy benefit.

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Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- November 14, 2023: Updated title of Medical Necessity Guideline from “Anti-inflammatory Agents” to “Targeted Immunomodulators Skilled Administration.” Added Skyrizi Intravenous to the Medical Necessity Guideline with coverage criteria in Crohn's disease. Coverage of Skyrizi Intravenous for Plaque Psoriasis and Psoriatic Arthritis from Anti-inflammatory Agents has been retired since the drug is not FDA-approved for these indications. Removed coverage criteria for Stelara IV for plaque psoriasis and psoriatic arthritis since the formulation is not FDA-approved for these indications. Removed immunosuppressants as a prerequisite for Actemra IV for Giant Cell Arteritis. Removed non-biologic prerequisites from psoriatic arthritis throughout the Medical Necessity Guideline. Removed step through Humira and Enbrel for shared indications throughout Medical Necessity Guideline. Expanded specialty provider requirements to “prescribed by or consultation with” throughout the Medical Necessity Guideline. Added age requirements throughout the Medical Necessity Guideline. Updated prerequisite criteria for ankylosing spondylitis throughout Medical Necessity Guideline. Added "Previous treatment with a biologic agent indicated for the requested use" as a prerequisite option for ankylosing spondylitis, Crohn's disease, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, systemic juvenile idiopathic arthritis, and ulcerative colitis. Remove the Limitations Maximal doses of methotrexate are defined as 15 to 25 mg per week depending on the patient’s tolerance, and Documentation of a Member having a needle phobia does not qualify as a medically acceptable contraindication or clinical inappropriateness to injectable products (eff 2/1/24).
- December 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024.
- February 13, 2024: Added Cosentyx Intravenous to the Medical Necessity Guideline (eff 3/1/24).
- March 12, 2024: Added Omvoh and Tofidence to the Medical Necessity Guideline. Administrative update to add C code C9166 (eff 4/1/2024).
- July 1, 2024: Administrative update: Removed expired C Codes C9166 and C9168 and added J Codes J3247 and J2267 as part of Quarterly HCPC code updates (eff 7/1/24).
- September 10, 2024: Added Tyenne to the Medical Necessity Guideline. Added coverage criteria for Skyrizi IV for supplemental indication in ulcerative colitis. Modified the Limitation to address the approval duration of all tocilizumab for intravenous injections for cytokine release syndrome (eff 10/1/24).
- October 8, 2024: Added Tremfya IV to the Medical Necessity Guideline (eff 11/1/24).
- March 11, 2025: Added coverage criteria for Omvoh IV’s supplemental indication in Crohn’s Disease. Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 4/1/25).
- April 8, 2025: Added coverage criteria for Tremfya IV’s supplemental indication in Crohn’s disease (eff 5/1/25).
- August 12, 2025: Added Avtozma to the Medical Necessity Guideline (eff 9/1/25). Added Imuldosa, Otulfi, Pzychiva, Selsardi, Steqemya, Wezlana and Yesintek Intravenous to the Medical Necessity Guideline (eff 11/1/25).
- October 2025: Administrative update to HCPCs Codes: Added Code, Q5156 (Avtozma) to guideline effective 10/1/25.
- April 2026: Administrative update: Removed Carelink from the template. Added HCPCS code, Q0238 (Tyenne) to guideline, effective 4/1/26. Added HCPCs codes for Steqeyma (Q5099) and Pyzchiva (Q9997) with an effective date

of 9/1/25.

- July 14, 2026: Effective 10/1/26, added Starjemza to the Medical Necessity Guideline and updated coverage criteria for Crohn's disease to include pediatric patients 2 years of age and older based on expanded indication. Updated coverage criteria for non-preferred ustekinumab products to include Yesintek.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

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