Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Targeted Immunomodulators – Skilled Administration

Effective: January 1, 2027

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 Medicaid-Medicare 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

Autoimmune diseases are conditions in which the body's immune response attacks or otherwise reacts to a normally functioning body part in an adverse manner. Conditions include, but are not limited to, ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, and ulcerative colitis. Various biologic medications classes are Food and Drug Administration approved and recommended by treatment guidelines based on well-established efficacy and safety. Mechanisms of action include, but are not limited to, integrin receptor antagonists, phosphodiesterase 4 inhibitors, tumor necrosis factor inhibitors, interleukin antagonists, Janus kinase inhibitors, and tyrosine kinase 2 inhibitors.

Coverage criteria for infliximab products is based on Local Coverage Determination (LCD) Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394).

Food and Drug Administration - Approved Indications:

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

*Zymfentra is indicated for the maintenance treatment of moderately to severely active ulcerative colitis and Crohn's disease following treatment with an infliximab product administered intravenously.

Clinical Guideline Coverage Criteria

Actemra, Avtozma, Tofidence, and Tyenne Intravenous

The plan may authorize coverage of Actemra, Avtozma, Tofidence, or Tyenne when the following criteria are met:

Cytokine Release Syndrome

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

AND

2. Patient is 2 years of age and older

Giant Cell Arteritis

Initial Authorization Criteria

1. Documented diagnosis of giant cell arteritis

AND

2. Patient is 18 years of age or older

AND

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

AND

4. Documentation of history of failure to a systemic corticosteroid, unless contraindicated (*Note: Document drug, date and duration of trial*)

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of giant cell arteritis

AND

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

AND

4. Prescribed by a rheumatologist or neurologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Juvenile Idiopathic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of **one (1)** of the following:
    a. Active polyarticular juvenile idiopathic arthritis
    b. Active systemic juvenile idiopathic arthritis

AND

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

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of **one (1)** of the following:
    a. Active polyarticular juvenile idiopathic arthritis
    b. Active systemic juvenile idiopathic arthritis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Prescribed by a rheumatologist

AND

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

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Cosentyx Intravenous

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

Ankylosing spondylitis

Initial Authorization Criteria

1. Documented diagnosis of active ankylosing spondylitis

AND

2. Prescribed by a rheumatologist

AND

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

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active ankylosing spondylitis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Non-radiographical Axial Spondyloarthritis

Initial Authorization Criteria

1. Documented diagnosis of active non-radiographic axial spondyloarthritis with objective signs of inflammation

AND

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

AND

3. Prescribed by a rheumatologist

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least 12 months

AND

2. Documented diagnosis of active non-radiographic axial spondyloarthritis with objective signs of inflammation

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    a. Dactylitis
    b. Enthesitis
    c. Axial disease
    b. Active skin and/or nail involvement

AND

3. Prescribed by a rheumatologist or dermatologist

AND

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

AND

5. Documentation of failure to a minimum three (3) month supply of at least **one (1)** disease-modifying anti-rheumatic drug (e.g., methotrexate, sulfasalazine, cyclosporine), unless contraindicated or clinically significant adverse effects are experienced (*Note: Document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

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

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Entyvio Intravenous

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

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's disease

AND

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

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic dug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

3. Prescribed by a gastroenterologist

AND

4. Documentation of history of failure to **one (1)** of the following medications, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic dug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ilumya

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

Plaque Psoriasis

Initial Authorization Criteria

1. Documented diagnosis of moderate to severe plaque psoriasis

AND

2. Documentation of **one (1)** of the following:
    a. Greater than or equal to 3% body surface area involvement
    b. Severe scalp psoriasis
    c. Palmoplantar, facial, or genital involvement

AND

3. Prescribed by a dermatologist

AND

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

AND

5. Documentation of failure to a minimum three (3) month supply of at least **one (1)** of the following traditional systemic agents, unless contraindicated or clinically significant adverse effects are experienced: methotrexate, cyclosporine, acitretin, or phototherapy *(Note: Document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderately to severe plaque psoriasis

AND

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

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as reduction in body surface area affected by plaque psoriasis from baseline

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of plaque psoriasis such as itching, redness, flaking, scaling, burning, cracking, or pain

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Infliximab Products (Avsola, Inflectra, Infliximab, Remicade, Renflexis, Zymfentra)

Ankylosing spondylitis

Initial Authorization Criteria

1. Documented diagnosis of active ankylosing spondylitis

AND

2. Prescribed by a rheumatologist

AND

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

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active ankylosing spondylitis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of **one (1)** of the following:
    a. Moderately to severely active Crohn's disease
    b. Fistulizing Crohn's disease

AND

2. Prescribed by a gastroenterologist

AND

3. Documentation of **one (1)** of the following:
    a. For moderately to severely active Crohn's disease, patient is at least 6 years of age
    b. For fistulizing Crohn's disease, patient is at least 18 years of age

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of **one (1)** of the following:
    a. Moderately to severely active Crohn's disease
    b. Fistulizing Crohn's disease

AND

3. Documentation of **one (1)** of the following:
    a. For moderately to severely active Crohn's disease, patient is at least 6 years of age
    b. For fistulizing Crohn's disease, patient is at least 18 years of age

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Plaque Psoriasis

Initial Authorization Criteria

1. Documented diagnosis of chronic severe (i.e., extensive and/or disabling) plaque psoriasis

AND

2. Documentation of **one (1)** of the following:
    a. Greater than or equal to 3% body surface area involvement
    b. Severe scalp psoriasis
    c. Palmoplantar, facial, or genital involvement

AND

3. Prescribed by a dermatologist

AND

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

AND

5. Documentation of failure to a minimum 30-day supply (14-day supply for topical corticosteroids) to **one (1)** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced: corticosteroid, vitamin D analog, tazarotene, calcineurin inhibitor *(Note: Document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of moderately to severe plaque psoriasis

AND

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

AND

4. Prescribed by a dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined as reduction in body surface area affected by plaque psoriasis from baseline

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of plaque psoriasis such as itching, redness, flaking, scaling, burning, cracking, or pain

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Prescribed by a rheumatologist or dermatologist

AND

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

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

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

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Prescribed by a rheumatologist

AND

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

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    a. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Approved Compendia and Off-Label Uses

1. Documentation of **one (1)** of the following:
    a. **ALL** of the following
        i. Diagnosis of Behcet's Disease
        ii. Use of the requested medication for the management of clinical manifestations of Behcet's disease (e.g., severe ocular involvement, major organ involvement, severe gastrointestinal or neurological involvement, joint or mucocutaneous involvement)
        iii. Inadequate response to initial therapy
    b. **Both** of the following:
        i. Diagnosis of pyoderma gangrenosum
        ii. Coexisting inflammatory bowel disease
    c. **Both** of the following:
        i. Diagnosis of sarcoid
        ii. Disease refractory to treatment with steroids and other standard drug regimens
    d. **Both** of the following:
        i. Severe immune-related colitis
        ii. No response to treatment with high-dose steroids within one week of initiation of treatment
    e. **Both** of the following:
        i. Diagnosis of microscopic colitis
        ii. Refractory disease as evidenced by a lack of response to standard pharmacologic therapy

Omvoh Intravenous

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

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's Disease

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial*):
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Orencia Intravenous

The plan may authorize coverage of Orencia Intravenous for a Member when **ALL** the following criteria are met

Polyarticular Juvenile Idiopathic Arthritis

Initial Authorization Criteria

6. Documented diagnosis of active polyarticular juvenile idiopathic arthritis

AND

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

AND

8. Prescribed by a rheumatologist

AND

9. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

10. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active polyarticular juvenile idiopathic arthritis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Prophylaxis for Acute Graft versus Host Disease

Initial Authorization Criteria

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 of use in combination with a calcineurin inhibitor (e.g., cyclosporine, tacrolimus) and methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least 12 months

AND

2. Documented diagnosis of acute graft versus host disease

AND

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

AND

4. Documentation of use in combination with a calcineurin inhibitor and methotrexate

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Prescribed by a rheumatologist or dermatologist

AND

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

AND

5. Documentation of failure to a minimum three (3) month supply of at least **one (1)** disease-modifying anti-rheumatic drug (e.g., methotrexate, sulfasalazine, cyclosporine), unless contraindicated or clinically significant adverse effects are experienced (*Note: Document drug, date and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

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

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Prescribed by a rheumatologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined

by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Simponi Aria

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

Ankylosing spondylitis

Initial Authorization Criteria

1. Documented diagnosis of active ankylosing spondylitis

AND

2. Prescribed by a rheumatologist

AND

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

AND

4. Documentation of history of failure to **one (1)** prescription strength non-steroidal anti-inflammatory drug (e.g., celecoxib, diclofenac, ibuprofen, naproxen, meloxicam), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active ankylosing spondylitis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Polyarticular Juvenile Idiopathic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of active polyarticular juvenile idiopathic arthritis

AND

2. Prescribed by a rheumatologist

AND

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

AND

4. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of active moderately to severely active polyarticular juvenile idiopathic arthritis

AND

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

AND

4. Prescribed by a rheumatologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Psoriatic Arthritis

Initial Authorization Criteria

1. Documented diagnosis of psoriatic arthritis

AND

2. Documentation of **one (1)** of the following:
    a. Actively inflamed joints
    b. Dactylitis
    c. Enthesitis
    d. Axial disease
    e. Active skin and/or nail involvement

AND

3. Prescribed by a rheumatologist or dermatologist

AND

4. Patient is 2 years of age or older

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been receiving the requested medication for at least six (6) months

AND

2. Documented diagnosis of active psoriatic arthritis

AND

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

AND

4. Prescribed by a rheumatologist or dermatologist

AND

5. Submission of medical charts documenting the patient experienced a beneficial clinical response defined improvement from baseline in at least **one (1)** of the following:
    a. Body surface area affected by psoriatic arthritis
    b. Total active (swollen and tender) joint count

AND

6. Submission of medical charts documenting that compared to baseline, the patient has experienced an improvement in at least one symptom of psoriatic arthritis such as joint pain, morning stiffness, fatigue, joint or tendon sheath swelling

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Rheumatoid Arthritis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

2. Documentation of use in combination with methotrexate

AND

3. Prescribed by a rheumatologist

AND

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

AND

5. Documentation of history of failure to **one (1)** traditional disease modifying antirheumatic drug (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial)*

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the Member has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active rheumatoid arthritis

AND

3. Documentation of use in combination with methotrexate

AND

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

AND

5. Prescribed by a rheumatologist

AND

6. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

7. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Skyrizi Intravenous

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

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's disease

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trials):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic dug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Prescribed by a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. *5*-aminosalycyclate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Tremfya Intravenous

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

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's disease

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trials):*
    a. Corticosteroid
    b. 5-aminosalycylate

c. 6-mercaptopurine
d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic dug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Prescribed by a gastroenterologist

AND

3. Patient is 18 years of age or older

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. *5*-aminosalycyclate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ustekinumab Products (Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, Steqeyma, Wezlana, Yesintek)

The plan may authorize coverage of an ustekinumab product when **ALL** of the following criteria are met:

Crohn's Disease

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active Crohn's disease

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trials):*
    a. Corticosteroid
    b. 5-aminosalycylate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic dug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active Crohn's disease

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Ulcerative Colitis

Initial Authorization Criteria

1. Documented diagnosis of moderately to severely active ulcerative colitis

AND

2. Prescribed by a gastroenterologist

AND

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

AND

4. Documentation of history of failure to **one (1)** of the following, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial):*
    a. Corticosteroid
    b. *5*-aminosalycyclate
    c. 6-mercaptopurine
    d. Methotrexate

AND

5. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Reauthorization Criteria

1. Documentation the patient has been established on the requested medication for at least 12 months

AND

2. Documented diagnosis of moderately to severely active ulcerative colitis

AND

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

AND

4. Prescribed by a gastroenterologist

AND

5. Documentation of clinically significant improvement or stabilization in clinical signs and symptoms of disease as determined by the prescriber

AND

6. Documentation the patient is not receiving the requested medication in combination with another biologic drug or with a targeted synthetic oral small molecule drug

Limitations

- For the treatment of Cytokine Release Syndrome, tocilizumab intravenous will be approved for a period of 30 days.
- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements for Infliximab, Remicade, Renflexis, and Zymfentra.
- Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements for Imuldosa, Otulfi, Pyzchiva, Selarsdi, Stelara, and Wezlana
- For ankylosing spondylitis, Crohn's disease, giant cell arteritis, prophylaxis for acute graft versus host disease, non-radiographic axial spondyloarthritis, polyarticular juvenile idiopathic arthritis, rheumatoid arthritis, systemic juvenile idiopathic arthritis, and ulcerative colitis, authorizations will be provided in 12-month intervals. A patient who has received less than 12 months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria.
- For plaque psoriasis and psoriatic arthritis, initial approval will be authorized for six (6) months. Reauthorization will be provided in 12-month intervals. A Member who has received less than six (6) months of therapy or who is restarting therapy with the requested drug is reviewed under Initial Authorization Criteria
- Members new to the plan stable on the requested medication should be reviewed against Initial Authorization Criteria.
- Members who have already initiated the requested medication using samples, free goods, similar offerings, or self-paying for the medication directly do not qualify for an established clinical response and should be reviewed against initial approval criteria.

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
J0717	Injection, certolizumab pegol, 1 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1628	Injection, guselkumab, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10mg
J1748	Injection, infliximab-dyyb 10 mg
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg
J3245	Injection, tildrakizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg

HCPCS Codes	Description
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
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
Q5137	INJECTION USTEKINUMAB-AUUB WEZLANA BS SC 1 MG
Q5138	INJECTION USTEKINUMAB-AUUB WEZLANA BS IV 1 MG
Q5156	Injection, tocilizumab-anoh (avtozma) biosimilar, 1 mg
Q9996	INJECTION, USTEKINUMAB-TTWE (PYZCHIVA), SUBCUTANEOUS, 1 MG
Q9997	INJECTION, USTEKINUMAB-TTWE (PYZCHIVA), INTRAVENOUS, 1 MG
Q9998	INJECTION, USTEKINUMAB-AEKN (SELARSDI), 1 MG
Q9999	INJ USTEKINUMAB-AAUZ 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

References

1. Actemra [package insert]. South San Francisco, CA: Genentech, Inc.; March 2021.
2. Cimzia [package insert]. Smyrna, GA: UCB, Inc.; Dec 2022
3. Cosentyx (secukinumab) [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals; 2023 November.
4. Entyvio [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; Aug 2021.
5. Ilumya (tildrakizumab-asmn) [package insert]. Whitehouse Station; NJ: Merck & Co., Inc.; July 2020
6. Omvoh (mirikizumab-mrkz) [packate insert]. Indianapolis, IN: Eli Lily and Company; January 2025.
7. Orencia (abatacept) [package insert]. Princeton, NJ: Bristol-Myers Squibb; 2021 December
8. Remicade (infliximab) [package insert]. Malvern, PA: Centocor Ortho Biotech, Inc.; 2015 January
9. Simponi Aria (golimumab) [package insert]. Horsham, PA: Janssen Biotech Inc.; February 2021.
10. Skyrizi (risankizumab-rzaa). [package insert]. North Chicago, IL; Abbvie, Inc.; September 2022
11. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; August 2022
12. Tofidence (tocilizumab-bavi) [package insert]. Cambridge, MA: Biogen MA Inc; September 2023.
13. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
14. Tyenne (tocilizumab-aazg) [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2024.
15. Zymfentra (infliximab-dyyb) [package insert]. Jersey City, NJ: Celltion USA, Inc.; February 2024
16. Centers for Medicare and Medicaid Services (CMS). LCD - Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). Cms.Gov, 2021, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394&ver=47&keyword=infliximab&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed August 2024.
17. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 July;73(7):924-39.
18. Feuerstein JD, et al. American Gastroenterological Association (AGA) Clinical Practice Guidelines on the Management of Moderate to Severe Ulcerative Colitis. Gastroenterology. 2020;18:1450-61.
19. Lichtenstein GR, et al. ACG Clinical Guideline: Management of Crohn's Disease and Adults. American Journal of Gastroenterology. 2018 April;113(4):481-517
20. Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Giant Cell Arteritis and Takayasu Arteritis. Arthritis Care & Research. 2021 August;73(8):1071-87
21. Menter A, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. Journal of the American Academy of Dermatology. 2019 April;80(4):1029-72.
22. Onel KB, et al. 2021 American College of Rheumatology Guideline for the Treatment of Juvenile Idiopathic Arthritis: Therapeutic Approaches for Oligoarthritis, Temporomandibular Joint Arthritis, and Systemic Juvenile Idiopathic Arthritis. Arthritis & Rheumatology. 2022 April;74(4):553-69.

23. Singh JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2019 January;71(1):5-32.
24. Ward MM, et al. 2019 Update of the American College of Rheumatology/ Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019 October;71(10):1599-1613.

Approval And Revision History

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

- September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC
- December 12, 2023: Updated title of Medical Necessity Guideline from “Actemra” to “Targeted Immunomodulators Skilled Administration”. Wording updates. Added Avsola, Cimzia, Enytvio IV, Ilumya, Inflectra, Infliximab, Orencia IV, Remicade, Renflexis, Simponi Aria, Skyrizi IV, Stelara IV, and Tremfya to the Medical Necessity Guideline. Added provider specialty requirements throughout Medical Necessity Guideline. Added age requirements to Skyrizi IV. Removed coverage criteria for Actemra for Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) and for Skyrizi for Plaque Psoriasis and Psoriatic Arthritis because approval is only in self-administered pharmacy benefit formulations. emoved the Limitation The health plan may authorize coverage of Orencia (abatacept) for I.V. injection, Simponi, Stelara, and Tremfya for up to 12 months if coverage criteria are met. Removed the Limitation Skyrizi (risankizumab-rzaa) pens and pre-filled syringes for subcutaneous injection are covered under the Member’s Part D Prescription Drug Benefit when Skyrizi is being self-administered. Removed the Limitation The health plan considers [the requested medication] as experimental/investigational and not medically necessary for all other indications throughout the individual drug Medical Necessity Guidelines. Aligned coverage of Infliximab Products with LCD L33394. Added the Limitation Refer to the Medicare Part B Step Therapy Medical Necessity Guideline for additional requirements for Avsola and Renflexis. Administrative Update in support of calendar year 2024 Medicare Advantage and PDP Final Rule (eff 3/1/24).
- 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 4/1/24).
- June 11, 2024: Added Zymfentra to the medical necessity guideline (eff 7/1/2024).
- June 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/2024).
- July 1, T2024: 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. Added coverage criteria for infliximab and biosimilars for the indication of microscopic colitis. Modified the Limitation to address the approval duration of all tocilizumab for intravenous injections for cytokine release syndrome.
- September 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 10/1/2024).
- November 12, 2024: Added coverage criteria for Tremfya’s supplemental indication in ulcerative colitis (eff 1/1/25).
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- 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)
- March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 4/1/25).
- April 8, 2025: Added coverage criteria for Tremfya’s supplemental indication in Crohn’s disease (eff 7/1/25)
- June 10, 2025: Added Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Wezlana, and Yesintek to the Medical Necessity Guideline (eff 7/1/25)
- June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/25).
- September 9, 2025: Updated language in the Limitations to support updated preferred product strategy for Infliximab products with Avsola and Inflectra as preferred products. Infliximab, Remicade, Renflexis, and Zymfentra require additional prior authorization requirements per the Medicare Part B Step Therapy Medical Necessity Guideline (eff 1/1/26).
- September 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/26).
- 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.
- June 2026: Joint Medical Policy and Health Care Services UM Committee review; updated age restriction to 2 years of age or older for Crohn’s Disease for the Ustekinumab products (effective 7/1/26)

- September 2026: Joint Medical Policy and Health Care Services UM Committee review: Added objective documentation confirming diagnosis, prerequisite rerequirements, documentation the patient is not receiving another biologic drug, and reauthorization criteria requiring documentation of clinical improvement in symptoms to all indications; Added limited duration of approvals (eff 1/1/27)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.