Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Targeted Immunomodulators Skilled Administration

Effective: July 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 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, Ustekinumab, Ustekinumab-ttwe Wezlana, Yesintek*)
AS	X	-	-	X	-	-	X	-	-	-	-
CD	-	X	-	X	X	-	-	X	-	X	X
CRS	-	-	-	-	-	-	-	-	X (Actemra)	-	-
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

Clinical Guideline Coverage Criteria

Avsola, Inflectra

The plan may authorize coverage of Avsola or Inflectra 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

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

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

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

Yesintek and Starjemza Intravenous

The plan may authorize coverage of Yesintek and Starjemza 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 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

Actemra, Avtozma, Tofidence, and Tyenne Intravenous

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

Cytokine release syndrome

Initial Authorization Criteria

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

AND

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

Giant Cell Arteritis

Initial Authorization Criteria

1. Documented diagnosis of giant cell arteritis

AND

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

AND

3. Prescribed by 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 of history of failure to Simponi Aria, 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 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 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. Avsola
    b. Inflectra
    c. Simponi Aria

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. 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 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. Avsola
    b. Inflectra
    c. Simponi Aria

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 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 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. Avsola
    b. Inflectra
    c. Simponi Aria

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

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 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. Avsola
    b. Inflectra
    c. Omvoh
    d. Skyrizi
    e. Tremfya
    f. Yesintek
    g. Starjemza

AND

6. 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 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. Avsola
    b. Inflectra
    c. Omvoh
    d. Skyrizi
    e. Tremfya
    f. Yesintek
    g. Starjemza

AND

6. 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 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. Avsola
    b. Inflectra

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

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

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

7. Documented diagnosis of active polyarticular juvenile idiopathic arthritis

AND

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

AND

9. Prescribed by a rheumatologist

AND

10. 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

11. Documentation of history of failure to Simponi Aria, unless contraindicated or clinically significant adverse effects are experienced *(Note: Document drug, date, and duration of trial*)

AND

12. 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 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. Avsola
    b. Inflectra
    c. Simponi Aria

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

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 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. Avsola
    b. Inflectra
    c. Simponi Aria

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. 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

Imuldosa, Otulfi, Pzychiva, Selarsdi, Steqemya, Ustekinumab-ttwe, and Wezlana Intravenous

In addition to the coverage criteria for Yesintek and Starjemza Intravenous, the plan may authorize coverage of Imuldosa, Otulfi, Pzychiva, Selarsdi, Steqemya, Ustekinumab-ttwe, or Wezlana Intravenous for Members when the following criteria are met:

1. Documentation of history of failure to a minimum of three (3) month supply of Yesintek, unless contraindicated (*Note: Document date and duration of trial*)

AND

2. Documentation of history of failure to a minimum of three (3) month supply of Starjema, unless contraindicated (*Note: Document date and duration of trial)*

Stelara, Ustekinumab Intravenous

In addition to the coverage criteria for Yesintek and Starjemza Intravenous and Imuldosa, Otulfi, Pzychiva, Selarsdi, Steqemya, Ustekinumab-ttwe, and Wezlana Intravenous, the plan may authorize coverage of Stelara or Ustekinumab Intravenous for Members when the following criteria are met:

1. Documentation of history of failure to Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab-ttwe, and Wezlana, unless contraindicated *(Note: Document drugs, dates and duration of trials*)

Remicade, Infliximab, Renflexis

In addition to the coverage criteria for Avsola and Inflectra, the plan may authorize coverage of Remicade, Infliximab or Renflexis for Members when the following criteria are met:

1. Documentation of history of failure to a minimum of three (3) month supply of Avsola, unless contraindicated (*Note: Document date and duration of trial)*

AND

2. Documentation of history of failure to a minimum of three (3) month supply of Inflectra, unless contraindicated (*Note: Document date and duration of trial)*

Limitations

- 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.
- Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinical inappropriateness to methotrexate therapy.

- For cytokine release syndrome, approval of Actemra, Avtozma, Tofidence, and Tyenne Intravenous will be limited to one (1) month.
- 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.

Codes

The following HCPCS/CPT code(s) are:

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
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
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
Q5164	Injection, ustekinumab-hmny (starjemza), biosimilar, 1 mg
Q5099	Injection, ustekinumab-stba (steqeyma), 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, Cimzia, Cosentyx, Orencia, Simponi, Skyrizi, Stelara, Tremfya, Avtozma, Tyenne, Imuldosa, Otulfi, Pzychiva, Selsardi, 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 immunosuppressants as a prerequisite for Actemra IV for Giant Cell Arteritis. Removed non-biologic prerequisites from psoriatic arthritis throughout the 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, psoriatic arthritis, and plaque psoriasis 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, and For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy (eff 2/1/24).
- November 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).
- April 9, 2024: Removed biologic prerequisites from Skyrizi intravenous (eff 5/1/24).
- 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).
- November 12, 2024: For Entyvio for Crohn’s disease, added Stelara and Skyrizi as prerequisite options. For Entyvio for ulcerative colitis, added Stelara, Skyrizi and Tremfya as perquisite options. For Omvoh added Stelara, Skyrizi, and Tremfya as prerequisite options (eff 12/1/24).
- December 2024: Updated coverage criteria for Omvoh IV to be a first-line treatment (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).
- 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, Imuldosa, Otulfi, Pyzchiva, Selsardi, Steqeyma, Wezlana and Yesintek Intravenous to the Medical Necessity Guideline (eff 9/1/25).
- October 2025: Administrative update to HCPCs Codes: Added Code, Q5156 (Avtozma) to guideline effective 10/1/25.
- October 14, 2025: Moved Remicade and Infliximab to non-preferred status. Moved Avsola and Omvoh IV to preferred status. Provider requirements no longer allow with in consultation with the specialist. Added coverage criteria to prevent duplicative targeted immunomodulator therapy. Updated coverage criteria for Imdulosa, Otulfi, Pzychiva, Selarsdi, Steqemya, Wezlana, Stelara, Renflexis and Remicade. For plaque psoriasis and psoriatic arthritis, initial approvals limited to 6 months with annual reauthorization coverage criteria added, added disease severity requirements, updated prerequisite requirements, and removed previous treatment with a biologic agent indicated for

the requested use and requested agent stability language. 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, approvals limited to 12 months with reauthorization coverage criteria added, updated prerequisite requirements, and removed previous treatment with a biologic agent indicated for the requested use and requested agent stability language (eff 1/1/26).

- April 2026: Administrative update, removed Carelink from 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.
- June 9, 2026: Added Starjemza, Ustekinumab, and Ustekinumab-ttwe to the Medical Necessity Guideline. To support the updated ustekinumab strategy (Yesintek and Starjemza are the preferred ustekinumab products), added a minimum of a three month supply of Starjemza prior to approval of Imuldosa, Otulfi, Pyzchiva, Selarsdi, Steqeyma, Ustekinumab-ttwe, and Wezlana. Updated age requirements for Yesintek and Starjemza in Crohn's disease to at least 2 years of age. For Entyvio intravenous, added Starjemza as a prerequisite option for Crohn's disease and ulcerative colitis. Administrative update to the limitation statement to include members initiated on the requested medication by self-paying for the medication directly do not qualify for established clinical response and should be reviewed against initial approval criteria. Administrative updates: Template updated to remove CareLink from the Medical Necessity Guideline template. Template updated from "Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans" to "Tufts Health Together- MassHealth Accountable Care Partnership Plans." Added HCPCs code Q5164 (Starjemza) to medical necessity guideline, code is effective 7/1/26. (eff 7/1/26).

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.