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 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 Intravenous, Tofidence, Tyenne

The plan may authorize coverage of Actemra Intravenous, 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

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

Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular or active systemic juvenile idiopathic arthritis

AND

2. Patient is 2 years of age and older

AND

3. Prescribed by or in consultation with a rheumatologist

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

Cimzia

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

Crohn's Disease

1. Documented diagnosis of Crohn's disease

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Plaque Psoriasis, Psoriatic Arthritis

1. Documented diagnosis of **one (1)** of the following:
    a. Plaque psoriasis
    b. Psoriatic arthritis

AND

2. Patient is 18 years of age or older

AND

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

Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis, Rheumatoid Arthritis

1. Documented diagnosis of **one (1)** of the following:
    a. Ankylosing spondylitis
    b. Non-radiographic axial spondyloarthritis
    c. Rheumatoid arthritis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with rheumatologist

Cosentyx Intravenous

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

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Patient is 18 years of age or older

AND

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

Ankylosing Spondylitis, Non-radiographic Axial Spondyloarthritis

1. Documented diagnosis of **one (1)** of the following:
    a. Ankylosing spondylitis
    b. Non-radiographic axial spondyloarthritis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with rheumatologist

Entyvio Intravenous

The plan may authorize coverage of Entyvio Intravenous when the following criteria are met:

Crohn's Disease, Ulcerative Colitis

1. Documented diagnosis of **one (1)** of the following:
    a. Crohn's disease
    b. Ulcerative colitis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Ilumya

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

Plaque Psoriasis

1. Documented diagnosis of plaque psoriasis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a dermatologist

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

Food and Drug Administration-approved Indications

1. Documented diagnosis of **one (1)** of the following:
    a. Ankylosing spondylitis
    b. Crohn's disease
    c. Plaque psoriasis
    d. Psoriatic arthritis
    e. Rheumatoid arthritis
    f. Ulcerative colitis

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 when **ALL** of the following criteria are met:

Crohn's Disease

1. Documented diagnosis of Crohn's Disease

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Orencia Intravenous

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

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Patient is 18 years of age or older

AND

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

Rheumatoid Arthritis

1. Documented diagnosis of rheumatoid arthritis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of Polyarticular juvenile idiopathic arthritis

AND

2. Patient is 2 years of age or older

AND

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

Prophylaxis of Acute Graft Versus Host Disease

1. Documented diagnosis of acute graft versus host disease

AND

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

AND

3. Patient is 2 years of age or older

Simponi Aria

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

Ankylosing Spondylitis, Rheumatoid Arthritis

1. Documented diagnosis of **one (1)** of the following:
    a. Ankylosing spondylitis
    b. Rheumatoid arthritis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a rheumatologist

Polyarticular Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular juvenile idiopathic arthritis

AND

2. Patient is 2 years of age or older

AND

3. Prescribed by or in consultation with rheumatologist

Psoriatic Arthritis

1. Documented diagnosis of psoriatic arthritis

AND

2. Patient is 2 years of age or older

AND

3. Prescribed by or in consultation with rheumatologist or dermatologist

Skyrizi Intravenous

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

Crohn's Disease, Ulcerative Colitis

1. Documented diagnosis of **one (1)** of the following:
    a. Crohn's disease
    b. Ulcerative colitis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Tremfya

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

Crohn's disease

1. Documented diagnosis of Crohn's disease

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Plaque Psoriasis, Psoriatic Arthritis

1. Documented diagnosis of **one (1)** of the following:
    a. Plaque psoriasis
    b. Psoriatic arthritis

AND

2. Patient is 6 years of age or older

AND

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

Ulcerative Colitis

1. Documented diagnosis of ulcerative colitis

AND

2. Patient is 18 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

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

The plan may authorize coverage of Stelara, Steqeyma, or Yesintek when **ALL** of the following criteria are met:

Crohn's Disease, Ulcerative Colitis

1. Documented diagnosis of **one (1)** of the following:
    a. Crohn's disease
    b. Ulcerative colitis

AND

2. Patient is 2 years of age or older

AND

3. Prescribed by or in consultation with a gastroenterologist

Plaque Psoriasis, Psoriatic Arthritis

1. Documented diagnosis of **one (1)** of the following:
    a. Plaque psoriasis
    b. Psoriatic arthritis

AND

2. Patient is 6 years of age or older

AND

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

In addition to the coverage criteria above for Crohn's disease, ulcerative colitis, plaque psoriasis and psoriatic arthritis, the plan may authorize the coverage of Imuldosa, Otulfi, Pyzchiva, Selarsdi, and Wezlana when ALL the following criteria are met:

1. Documented previous failure, contraindication, or clinical inappropriateness with Stelara, Steqeyma or Yesintek

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.

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
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

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6. Omvoh (mirikizumab-mrkz) [packate insert]. Indianapolis, IN: Eli Lily and Company; January 2025.
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10. Skyrizi (risankizumab-rzaa). [package insert]. North Chicago, IL; Abbvie, Inc.; September 2022
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12. Tofidence (tocilizumab-bavi) [package insert]. Cambridge, MA: Biogen MA Inc; September 2023.
13. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.
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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)

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.