

Effective: October 1, 2024

Guideline Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
-----------------------	---

Applies to:

- CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956
- CarePartners of Connecticut Medicare Advantage PPO plans, 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	Stelara	Tocilizumab (Tofidence, Tyenne)	Tremfya
AS	-	X	X	-	-	X	-	-	X	-	-	-	-
CD	-	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	-	-

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, and 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
 2. Patient is 2 years of age and older
- AND**

Giant Cell Arteritis

1. Documented diagnosis of giant cell arteritis
 2. Patient is 18 years of age or older
 3. Prescribed by or in consultation with a rheumatologist or neurologist
- AND**

Juvenile Idiopathic Arthritis

1. Documented diagnosis of polyarticular or active systemic juvenile idiopathic arthritis
 2. Patient is 2 years of age and older
 3. Prescribed by or in consultation with a rheumatologist
- AND**

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

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

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

Stelara

The plan may authorize coverage of Stelara 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

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

Tremfya

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

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

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 Avsola, 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

HCPCS Codes	Description
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

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) [package insert]. Indianapolis, IN: Eli Lilly and Company; October 2023.
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.; November 2023.
14. Tyenne (tocilizumab-aazg) [package insert]. Lake Zurich, IL: Fresenius Kabi USA, LLC; March 2024.
15. Zymfentra (infliximab-dyyb) [package insert]. Jersey City, NJ: Celltione 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&areald=all&docType=NCA,CAL,NC D,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, Entyvio 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. removed 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)

- February 13, 2024: Added Cosentyx Intravenous to the Medical Necessity Guideline (eff 3/1/2024).
- 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, 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 Tynne 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).

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.