



## Drug Coverage Policy

Effective Date .....05/15/2025  
Coverage Policy Number.....IP0704  
Policy Title.....Tremfya Intravenous  
Prior Authorization Policy

# Inflammatory Conditions – Tremfya Intravenous Prior Authorization Policy

- Tremfya® (guselkumab intravenous infusion – Janssen Biotech/Johnson & Johnson)

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### INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

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## Overview

Tremfya intravenous, a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for **induction treatment of:**

- **Crohn's disease** (CD), in adults with moderate to severe active disease.
- **Ulcerative colitis** (UC), in adults with moderate to severe active disease.

## Dosing

### *Crohn's disease*

In CD, a three-dose induction regimen (200 mg at Weeks 0, 4, and 8) is administered by intravenous (IV) infusion.<sup>1</sup> Following induction therapy with the IV product, the recommended maintenance dose is Tremfya subcutaneous (SC) injection, given as:

- 100 mg SC administered at Week 16, then once every 8 weeks thereafter; OR
- 200 mg SC administered at Week 12, then once every 4 weeks thereafter.

Alternatively, a three-dose induction regimen (400 mg at Weeks 0, 4, and 8) may be administered by SC injection. Following induction with the SC product, the recommended maintenance dose is the same as that following IV induction. The lowest effective maintenance dose is recommended to maintain a therapeutic response.

### *Ulcerative colitis*

In UC, a three-dose induction regimen (200 mg at Weeks 0, 4, and 8) is administered by IV infusion.<sup>1</sup> Following induction therapy with the IV product, the recommended maintenance dose is Tremfya subcutaneous (SC) injection, given as:

- 100 mg SC administered at Week 16, then once every 8 weeks thereafter; OR
- 200 mg SC administered at Week 12, then once every 4 weeks thereafter.

The lowest effective dose is recommended to maintain a therapeutic response.

## Guidelines

- **Crohn's Disease:** Tremfya is not addressed in current guidelines. The American College of Gastroenterology (ACG) has guidelines for Crohn's disease (2018).<sup>4</sup> Biologics are a treatment option in patients who have moderate to severe disease despite treatment with another agent (e.g., corticosteroid, thiopurine, methotrexate, or tumor necrosis factor inhibitors). Guidelines from the American Gastroenterological Association (AGA 2021) include biologics among the therapies for moderate to severe Crohn's disease, for induction and maintenance of remission.<sup>5</sup>
- **Ulcerative Colitis:** Current guidelines do not address the use of Tremfya for UC. The American Gastroenterological Association (2020) and the American College of Gastroenterology (2019) have clinical practice guidelines on the management of moderate to severe UC and make recommendations for the use of biologics for induction and maintenance of remission in adults.<sup>2,3</sup> Generally TNF inhibitors, Entyvio® (vedolizumab intravenous infusion/subcutaneous injection), Stelara® (ustekinumab intravenous infusion/subcutaneous injection), or Xeljanz®/Xeljanz® XR (tofacitinib tablets, tofacitinib extended-release tablets) are recommended for induction treatment of moderate to severe disease (strong recommendations, moderate quality of evidence). The guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.

## Coverage Policy

### POLICY STATEMENT

Prior Authorization is required for benefit coverage of Tremfya IV. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). Because of the specialized skills required for evaluation and diagnosis of patients treated with Tremfya IV as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tremfya IV to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for three months, which is an adequate duration for the patient to receive three doses.

**Tremfya intravenous is considered medically necessary when ONE of the following is met (1 or 2):**

### **FDA-Approved Indications**

**1. Crohn's Disease.** Approve three doses for induction if the patient meets ALL of the following (A, B, C, and D):

**A)** Patient is  $\geq 18$  years of age; AND

**B)** The medication will be used as induction therapy; AND

**C)** Patient meets ONE of the following (i, ii, iii, or iv):

i. Patient has tried or is currently taking a systemic corticosteroid, or a systemic corticosteroid is contraindicated in this patient; OR

ii. Patient has tried one other conventional systemic therapy for Crohn's disease; OR

Note: Examples of conventional systemic therapy for Crohn's disease include azathioprine, 6-mercaptopurine, or methotrexate. An exception to the requirement for a trial of or contraindication to steroids or a trial of one other conventional systemic agent can be made if the patient has already tried at least one biologic other than the requested medication. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for Crohn's disease. A trial of mesalamine does not count as a systemic agent for Crohn's disease.

iii. Patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR

iv. Patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence); AND

**D)** The medication is prescribed by or in consultation with a gastroenterologist.

**Dosing:** Approve 200 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

**2. Ulcerative Colitis.** Approve three doses for induction if the patient meets the following (A, B, C, and D):

**A)** Patient is  $\geq 18$  years of age; AND

**B)** The medication will be used as induction therapy; AND

**C)** Patient meets ONE of the following (i or ii):

i. Patient has tried one systemic therapy; OR

Note: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does not count as a systemic therapy for ulcerative colitis. A trial of one biologic other than the requested medication also counts as a trial of one systemic agent for ulcerative colitis. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for ulcerative colitis.

ii. Patient meets BOTH of the following (a and b):

**a)** Patient has pouchitis; AND

- b) Patient has tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema; AND

Note: Examples of antibiotics include metronidazole and ciprofloxacin.  
Examples of corticosteroid enemas include hydrocortisone enema.

- D) The medication is prescribed by or in consultation with a gastroenterologist.

**Dosing:** Approve 200 mg as an intravenous infusion administered at Weeks 0, 4, and 8.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

**Tremfya intravenous for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):**

1. **Concurrent Use with a Biologic or with a Targeted Synthetic Oral Small Molecule Drug.** This medication should not be administered in combination with another biologic or with a targeted synthetic oral small molecule drug used for an inflammatory condition (see [Appendix](#) for examples). Combination therapy is generally not recommended due to a potentially higher rate of adverse events and lack of controlled clinical data supporting additive efficacy.

Note: This does NOT exclude the use of conventional synthetic disease-modifying antirheumatic drugs (e.g., methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine) in combination with this medication.

## Coding Information

- 1) This list of codes may not be all-inclusive.
- 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HCPCS Codes	Description
J1628	Injection, guselkumab, 1 mg

## References

1. Tremfya® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson; March 2025.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG clinical guideline: ulcerative colitis in adults. *Am J Gastroenterol*. 2019;114(3):384-413.
3. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. *Gastroenterology*. 2020 Apr;158(5):1450-1461.

## Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	11/01/2024
Selected Revision	<b>Crohn's Disease:</b> This new condition of approval was added to the policy.	05/15/2025

The policy effective date is in force until updated or retired.

## APPENDIX

	Mechanism of Action	Examples of Indications*
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia®</b> (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
<b>Etanercept SC Products</b> (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA, RA
<b>Infliximab IV Products</b> (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Zymfentra®</b> (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
<b>Simponi®, Simponi Aria®</b> (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
<b>Tocilizumab Products</b> (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
<b>Kevzara®</b> (sarilumab SC injection)	Inhibition of IL-6	RA
<b>Orencia®</b> (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret®</b> (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Omvo®</b> (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
<b>Ustekinumab Products</b> (Stelara® IV, biosimilar; Stelara SC, biosimilar)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
<b>Siliq®</b> (brodalumab SC injection)	Inhibition of IL-17	PsO
<b>Cosentyx®</b> (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
<b>Taltz®</b> (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Bimzelx®</b> (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	PsO, AS, nr-axSpA, PsA
<b>Ilumya®</b> (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO

<b>Skyrizi®</b> (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
<b>Tremfya®</b> (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
<b>Entyvio®</b> (vedolizumab IV infusion, vedolizumab SC injection)	Integrin receptor antagonist	CD, UC
<b>Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs</b>		
<b>Otezla®</b> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinqo™</b> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant®</b> (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
<b>Litfulo®</b> (ritlecitinib capsules)	Inhibition of JAK pathways	AA
<b>Leqselvi®</b> (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
<b>Rinvoq®</b> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC
<b>Rinvoq® LQ</b> (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
<b>Sotyktu®</b> (deucravacitinib tablets)	Inhibition of TYK2	PsO
<b>Xeljanz®</b> (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
<b>Xeljanz® XR</b> (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
<b>Zeposia® (ozanimod tablets)</b>	Sphingosine 1 phosphate receptor modulator	UC
<b>Velsipity® (etrasimod tablets)</b>	Sphingosine 1 phosphate receptor modulator	UC

\* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn’s disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; TYK2 – Tyrosine kinase 2.

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