

**POLICY:** Inflammatory Conditions – Tremfya Intravenous Utilization Management Medical Policy

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

**EFFECTIVE DATE:** 2/1/2025

**LAST REVISION DATE:** 11/20/2025

**COVERAGE CRITERIA FOR:** UCare Exchange Plans Only (All Individual and Family Plans)

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## OVERVIEW

Tremfya intravenous (IV), a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for **induction treatment of:**<sup>1</sup>

- **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 and Ulcerative Colitis*

In CD and UC, 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.

## Guidelines

- **Crohn's Disease:** The American College of Gastroenterology (ACG) [2025] has guidelines for the management of CD in adults.<sup>4</sup> In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab), IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib). If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. 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:** The AGA (2024) and ACG (2025) have clinical practice guidelines on the management of moderate to severe UC in adults.<sup>2,3</sup> In moderate to severe disease, systemic corticosteroids or advanced therapies may be utilized for induction of remission. Advanced therapies recommended include TNF inhibitors, Entyvio, IL-23 inhibitors, IL-12/23 inhibitors, sphingosine-1-phosphate (S1P) receptor modulators, and Janus kinase (JAK) inhibitors. If steroids are utilized for induction, efforts should be made to introduce steroid-sparing agents for maintenance therapy. Of note, guidelines state corticosteroids may be avoided entirely when other effective induction strategies are planned.<sup>3</sup> Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.<sup>2,3</sup>

### **POLICY STATEMENT**

Prior Authorization is recommended for medical benefit coverage of Tremfya IV. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. 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.

**Automation:** None.

### **RECOMMENDED AUTHORIZATION CRITERIA**

Coverage of Tremfya IV is recommended for requests meeting both the preferred product step therapy requirements and indication requirement:

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**Preferred Product(s):** Yesintek and Steqeyma

**Non-Preferred Products(s):** Tremfya IV

### **Step Therapy Requirements:**

**Authorization for a non-preferred biologic product or biosimilar will be granted if the patient has had any one of the listed issues below (A, B, C, or D) with all preferred product(s). Chart notes documenting the issue must be provided at time of request:**

- A. Allergic reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR
- B. Adverse reaction to a specific inactive ingredient in all preferred biologic products or biosimilars OR
- C. Therapeutic success while taking a non-preferred biologic product or biosimilar and therapeutic failure during an adequate trial of all preferred biologic products or biosimilars which allowed sufficient time for a positive treatment outcome documented by medical chart notes OR
- D. The patient has a diagnosis not included in the FDA-approved indications of all preferred products, but is included in the FDA-approved indications of the non-preferred product

Please note:

- Factors such as patient or prescriber preference or healthcare facility's or pharmacy's inability or unwillingness to order or stock the preferred product(s) will not be considered

- Common side effects to all products and infusion-related reactions are not considered documented allergic reactions to a preferred product as they would be expected with the innovator and biosimilar products
- Continuation of therapy overrides are not available to bypass required trial(s) of preferred biosimilar or biologic reference product
- Generally, an adequate trial of a drug is considered to be three months or longer in order to allow time for efficacy to be established

### **FDA-Approved Indications**

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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.

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2. **Ulcerative Colitis.** Approve three doses for induction if the patient meets ALL of the following (A, B, and C):
    - A) Patient is  $\geq 18$  years of age; AND
    - B) The medication will be used as induction therapy; AND
    - C) 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.

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### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Tremfya IV is not recommended in the following situations:

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.

- Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

- Tremfya® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson; March 2025.
- Singh S, Loftus EV Jr, Limketkai BN, et al. AGA Living Clinical Practice Guideline on Pharmacological Management of Moderate-to-Severe Ulcerative Colitis. *Gastroenterology*. 2024 Dec;167(7):1307-1343.
- Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol*. 2025 June;120(6):1187-1224
- Lichtenstein, G, Loftus E, Afzali A, et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol*. 2025 June;120(6):1225-1264.
- Feuerstein JD, Ho EY, Shmidt E, et al. AGA clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease. *Gastroenterology*. 2021;160(7):2496-2508.

## HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	-	10/02/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	12/16/2024
Selected Revision	<b>Crohn's Disease:</b> This new condition of approval was added to the policy.	04/02/2025
Selected Revision	<b>Ulcerative Colitis:</b> Removed the following options of approval: (1) the patient has tried one systemic therapy; (2) the patient has pouchitis and tried an antibiotic, probiotic, corticosteroid enema, or mesalamine enema.	07/23/2025
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/15/2025
Annual Revision	No criteria changes.	09/24/2025
UCare Update	Added step therapy requirement to policy requiring trial of preferred ustekinumab intravenous products (Yesintek and Steqeyma) prior to trial of Tremfya effective 2/1/2026.	11/20/2025

**APPENDIX**

	<b>Mechanism of Action</b>	<b>Examples of Indications*</b>
<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>Omvoh®</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®</b> (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
<b>Velsipity®</b> (etrasimod tablets)	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; <sup>^</sup> 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