UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Inflammatory Conditions – Tremfya Intravenous Utilization Management Medical Policy
- Tremfya® (guselkumab intravenous infusion – Janssen Biotech/Johnson & Johnson)

REVIEW DATE: 09/16/2026

OVERVIEW

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

- **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 IV infusion.[1] 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] and the American Gastroenterological Association (AGA) [2025] have guidelines for the management of CD in adults.[4,5] Both guidelines recommend upfront use of advanced therapies, rather than step-up therapy after failure of corticosteroids and/or immunomodulators. Advanced therapies recommended include tumor necrosis factor (TNF) inhibitors, Entyvio® (vedolizumab IV infusion, SC injection), IL-23 inhibitors, IL-12/23 inhibitors, and Rinvoq® (upadacitinib extended-release tablets).
- **Ulcerative Colitis:** The AGA (2024) and ACG (2025) have clinical practice guidelines on the management of moderate to severe UC in adults.[2,3] 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 that corticosteroids may be avoided entirely when other effective induction strategies are planned.[3] Both guidelines also recommend that any drug that effectively treats induction should be continued for maintenance.[2,3]

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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 in those who meet one of the following criteria:

FDA-Approved Indications

1. **Crohn's Disease**. Approve three doses for induction if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 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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2. **Ulcerative Colitis.** Approve three doses for induction if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 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.

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.

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

REFERENCES

1. Tremfya® intravenous infusion, subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson; May 2026.
2. 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.
3. Rubin D, Ananthakrishnan A, Siegel C. ACG Clinical Guideline Update: Ulcerative Colitis in Adults. *Am J of Gastroenterol.* 2025 June;120(6):1187-1224
4. 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.
5. Scott FI, Ananthakrishnan AN, Click B, et al. AGA Living Clinical Practice Guideline on the Pharmacologic Management of Moderate-to-Severe Crohn's Disease. *Gastroenterology*. 2025 Dec;169(7):1397-1448.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	-	10/02/2024
Selected Revision	**Crohn's Disease:** This new condition of approval was added to the policy.	04/02/2025
Selected Revision	**Ulcerative Colitis:** 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
Annual Revision	No criteria changes.	09/24/2025
Selected Revision	**Crohn's Disease:** For initial therapy, the following options of approval were removed: The patient has tried or is currently taking systemic corticosteroids, or corticosteroids are contraindicated; patient has tried one conventional systemic therapy for Crohn's disease along with the associated Note; patient has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; patient had ileocolonic resection (to reduce the chance of Crohn's disease recurrence). **Appendix:** Otezla XR (apremilast extended-release tablets) was added.	02/11/2026
Annual Revision	**No criteria changes.** **Appendix:** Icotyde (icotrokinra tablets) was added.	09/16/2026

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APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, HS, PJIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, PJIA, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, PJIA, PsO, PsA, RA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Zymfentra® (infliximab-dyyb SC injection)	Inhibition of TNF	CD, UC
Simponi®, Simponi Aria® (golimumab SC injection, IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	RA
Tocilizumab Products (Actemra® IV, biosimilars; Actemra SC, biosimilars)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	PJIA, RA
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, HS, nr-axSpA, PsO, PsA
		IV formulation: AS, nr-axSpA, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Bimzelx® (bimekizumab-bkzx SC injection)	Inhibition of IL-17A/17F	AS, HS, nr-axSpA, PsO, PsA
Ustekinumab Products (Stelara® IV, biosimilars; Stelara SC, biosimilars)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Skyrizi® (risankizumab-rzaa SC injection, IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, IV infusion)	Inhibition of IL-23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, SC injection)	Integrin receptor antagonist	CD, UC
Orencia® (abatacept IV infusion, SC injection)	T-cell costimulation modulator	SC formulation: PJIA, PsA, RA
		IV formulation: PJIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed antibody	RA
Oral Therapies/ Targeted Synthetic Oral Small Molecule Drugs		
Icotyde® (icotrokinra tablets)	Inhibition of IL-23 receptor	PsO
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Otezla® XR (apremilast extended-release tablets)	Inhibition of PDE4	PsO, PsA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	AA, RA
Litfulo® (ritlecitinib capsules)	Inhibition of JAK pathways	AA
Leqselvi® (deuruxolitinib tablets)	Inhibition of JAK pathways	AA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, CD, nr-axSpA, PJIA, PsA, RA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Tofacitinib tablets/oral solution (Xeljanz®, generics)	Inhibition of JAK pathways	Tablets: AS, PsA, RA, UC
		Oral solution: PJIA, PsA
Tofacitinib XR extended-release tablets (Xeljanz XR, generics)	Inhibition of JAK pathways	AS, PsA, RA, UC
Zeposia® (ozanimod tablets)	S1PRM	UC
Velsipity® (etrasimod tablets)	S1PRM	UC

* Not an all-inclusive list of indications. 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; HS – Hidradenitis Suppurativa; PJIA – Polyarticular juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ERA – Enthesitis-related arthritis; PDE4 – Phosphodiesterase 4; TYK2 – Tyrosine kinase 2; JAK – Janus kinase; AD – Atopic dermatitis; AA – Alopecia areata; S1PRM – Sphingosine-1 phosphate receptor modulator.

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