CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 10/02/2024; selected revision 04/02/2025

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

In CD, a three-dose induction regimen (200 mg at Weeks 0, 4, and 8) is administered by intravenous (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.

Ulcerative colitis

In 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.

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).[4] 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 [TNF] 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.[5]
- **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.[2,3] Generally TNF inhibitors, Entyvio® (vedolizumab IV infusion/SC injection), Stelara® (ustekinumab IV infusion/SC 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.

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, C, and D):
   - **A)** Patient is ≥ 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, C, and D):
   - **A)** Patient is ≥ 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.

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.

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; 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 Apr158(5):1450-1461.
4. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113(4):481-517.
5. 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
Selected Revision	**Crohn's Disease:** This new condition of approval was added to the policy.	04/02/2025

APPENDIX

	Mechanism of Action	Examples of Indications*
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, 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, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Tocilizumab Products (Actemra® IV, biosimilar; Actemra SC, biosimilar)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PSA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	CD, UC
Ustekinumab Products (Stelara® IV, biosimilar; Stelara SC, biosimilar)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection; secukinumab IV infusion)	Inhibition of IL-17A	SC formulation: AS, ERA, 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	PsO, AS, nr-axSpA, PsA
Ilumya® (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC
		IV formulation: CD, UC
Tremfya® (guselkumab SC injection, guselkumab IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO, UC
		IV formulation: CD, UC
Entyvio® (vedolizumab IV infusion, vedolizimab SC injection)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA, AA
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, nr-axSpA, RA, PsA, UC
Rinvoq® LQ (upadacitinib oral solution)	Inhibition of JAK pathways	PsA, PJIA
Sotyktu® (deucravacitinib tablets)	Inhibition of TYK2	PsO
Xeljanz® (tofacitinib tablets/oral solution)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC
Zeposia® (ozanimod tablets)	Sphingosine 1 phosphate receptor modulator	UC
Velsipity® (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; ^ 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.