## 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

#### **OVERVIEW**

Tremfya intravenous (IV), a monoclonal antibody against the p19 subunit of the interleukin (IL)-23 cytokine, is indicated for **induction treatment of ulcerative colitis** (UC), in adults with moderate to severe active disease.<sup>1</sup>

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

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 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 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.

Automation: None.

#### RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tremfya IV is recommended in those who meet the following criteria:

## **FDA-Approved Indication**

- **1. 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 <u>Note</u>: Examples include 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone. A trial of a mesalamine product does <u>not</u> 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.
      - 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 <u>Appendix</u> 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 <a href="Appendix">Appendix</a> 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.
  - <u>Note</u>: 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; September 2024.
- 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.

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## HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	-	10/02/2024

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### **APPENDIX**

APPENDIX				
D. I. I	Mechanism of Action	Examples of Indications*		
Biologics Company of the Company of				
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	Inhibition of TNF	SC formulation: AS, PsA, RA, UC		
injection, golimumab IV infusion)	7.17.1	IV formulation: AS, PJIA, PsA, RA		
Tocilizumab Products (Actemra® IV, biosimilar;	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA		
Actemra SC, biosimilar)		IV formulation: PJIA, RA, SJIA		
Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA		
Orencia® (abatacept IV infusion, abatacept SC	T-cell costimulation	SC formulation: JIA, PSA, RA		
injection)	modulator	IV formulation: JIA, PsA, RA		
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic	RA		
W. (a) (a) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c	antibody	H.A. D.A		
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA		
Omvoh® (mirikizumab IV infusion, SC injection)	Inhibition of IL-23	UC		
Stelara® (ustekinumab SC injection, ustekinumab	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC		
IV infusion)	7 1 7 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	IV formulation: CD, UC		
Siliq® (brodalumab SC injection)	Inhibition of IL-17	PsO SG C L C C FR A		
Cosentyx® (secukinumab SC injection;	Inhibition of IL-17A	SC formulation: AS, ERA, nr-		
secukinumab IV infusion)		axSpA, PsO, PsA		
m k ® (; 1; 1 oc; ; ; )	T 1 1 1 1 1 CTT 1 7 1	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 CD PSA P O HG		
Skyrizi® (risankizumab-rzaa SC injection,	Inhibition of IL-23	SC formulation: CD, PSA, PsO, UC		
risankizumab-rzaa IV infusion)	1 1 1 1 1 1 CH 22	IV formulation: CD, UC		
Tremfya® (guselkumab SC injection, guselkumab	Inhibition of IL-23	SC formulation: PsA, PsO, UC		
IV infusion)		IV formulation: UC		
Entyvio® (vedolizumab IV infusion, vedolizimab	Integrin receptor antagonist	CD, UC		
SC injection)  Oral Therapies/Targeted Synthetic Oral Small Molecule Drugs				
		D O D A		
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	AD AS OF STAR DA DA LIC		
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, nr-axSpA, RA, PsA, UC		
Rinvog® 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	UC		
*7.1. · · · · · · · · · · · · · · · · · ·	receptor modulator	II.C		
Velsipity® (etrasimod tablets)	Sphingosine 1 phosphate	UC		
	receptor modulator			

<sup>\*</sup> 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; ^ Offlabel 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.