FOR IV INDUCTION

TREMFYA®
(guselkumab)

Billing and Coding Guide

For Ulcerative Colitis and Crohn's Disease

TREMFYA® is indicated for the treatment of adult patients with

- **moderately to severely active ulcerative colitis**
- **moderately to severely active Crohn's disease**

Selected Important Safety Information

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, may occur. TREMFYA® may increase the risk of infection. Do not initiate treatment in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis (TB) before treating with TREMFYA®. Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. Drug-induced liver injury has been reported. For the treatment of Crohn's disease or ulcerative colitis, evaluate liver enzymes and bilirubin levels at baseline, for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Avoid use of live vaccines in patients treated with TREMFYA®. **Please see related and other Important Safety Information on page 12.**

Johnson&Johnson

Tremfya® (guselkumab)

Table of Contents

Johnson & Johnson is committed to providing information to help guide you through the reimbursement process for TREMFYA® (guselkumab).

For billing and coding or reimbursement questions, or to request support from a Field Reimbursement Manager (FRM), call **1-833-844-8463,** Monday-Friday, 8 AM to 8 PM ET

Disclaimer

Please note this information is provided for your background education and is not intended to serve as guidance for specific coding, billing, and claims submissions. Decisions on which codes best describe the services provided must be made by individual providers based on their clinical judgment, payer-specific guidance, and other requirements.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.

Dosing and Formulations

Dosing Information[1]

Pretreatment Evaluations: Evaluate for tuberculosis (TB) infection, obtain liver enzymes and bilirubin levels, and complete all age-appropriate vaccinations according to current immunization guidelines.

Monitor: For signs and symptoms of active TB during and after treatment with TREMFYA; liver enzymes and bilirubin levels for at least 16 weeks of treatment, and periodically thereafter according to routine patient management.

RECOMMENDED UC AND CD INDUCTION DOSING

400 mg SC injection*
Administered by subcutaneous (SC) injection at Week 0, Week 4, and Week 8

Week 0 — Week 4 — Week 8

OR

200 mg IV infusion
Administered by intravenous (IV) infusion over at least 1 hour at Week 0, Week 4,and Week 8

Week 0 — Week 4 — Week 8

*400-mg SC induction injection is given as two consecutive injections of 200 mg each.

RECOMMENDED UC AND CD MAINTENANCE DOSING

100 mg SC injection
Administered by subcutaneous (SC) injection at Week 16 and every 8 weeks thereafter

Week 16 — Week 24 — Week 32 — Week 40

OR

200 mg SC injection
Administered by subcutaneous injection at Week 12 and every 4 weeks thereafter

Week 12 — Week 16 — Week 20 — Week 24

Use the lowest effective recommended dosage to maintain therapeutic response.

TREMFYA® is intended for use under the guidance and supervision of a healthcare professional.

TREMFYA® may be administered by a healthcare professional, or a patient/caregiver may inject after proper training on the correct subcutaneous injection technique.

Please refer to the Dosage and Administration section of the Prescribing Information and to the Instructions for Use for complete information on how to prepare and administer TREMFYA®.

Formulations

Induction

SC Injection

TREMFYA® PEN Induction Pack
Two 200 mg/2 mL Pens
NDC: 57894-651-04

IV Infusion

Single-Dose Vial†
200 mg/20 mL (10 mg/mL) solution
NDC: 57894-650-02

Maintenance

SC Injection

TREMFYA® PEN (100 mg/mL)
NDC: 57894-640-06

One-Press Injector (100 mg/mL)
NDC: 57894-640-11

Prefilled Syringe (100 mg/mL)
NDC: 57894-640-01

TREMFYA® PEN† (200 mg/2 mL)
NDC: 57894-651-02

Prefilled Syringe† (200 mg/2 mL)
NDC: 57894-651-22

†Available for UC and CD only.
Images not to scale; for illustrative purposes only.
CD, Crohn's disease; NDC, National Drug Code; UC, ulcerative colitis.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.

Back to Table of Contents

Coding for TREMFYA® for IV Induction

The following codes may be relevant for seeking reimbursement for TREMFYA® **induction therapy** in UC and CD. Payer requirements for coding may vary. For the most accurate list of codes and billing requirements, please confirm with the payer.

HCPCS J Code[2] | **J1628** Injection, guselkumab, 1 mg

Effective January 1, 2019

J CODE BILLING UNIT CONVERSION

When coding **J1628**, report the total number of **1 mg** increments administered.

Intravenous Infusion for Induction

1 Number of 200 mg Vials of TREMFYA®

200 Total mg | **200** HCPCS Units*

ICD-10-CM Diagnosis Codes for Consideration[3]

Ulcerative Colitis

K51.00	Ulcerative (chronic) pancolitis without complications
K51.01	Ulcerative (chronic) pancolitis with complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.21	Ulcerative (chronic) proctitis with complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.31	Ulcerative (chronic) rectosigmoiditis with complications
K51.50	Left sided colitis without complications
K51.51	Left sided colitis with complications
K51.80	Other ulcerative colitis without complications
K51.81	Other ulcerative colitis with complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.91	Ulcerative colitis, unspecified, with complications

Crohn's Disease

K50.00	Crohn's disease of small intestine without complications
K50.01	Crohn's disease of small intestine with complications
K50.10	Crohn's disease of large intestine without complications
K50.11	Crohn's disease of large intestine with complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.81	Crohn's disease of both small and large intestine with complications
K50.90	Crohn's disease unspecified without complications
K50.91	Crohn's disease unspecified with complications

These codes are not intended to be promotional or to encourage or suggest a use of a drug that is inconsistent with FDA-approved use. The codes provided are not exhaustive, additional codes may apply, and listed codes may require a higher level of specificity when reporting for individual patients. Please consult your ICD-10-CM codebook for more information.

*Some payers may require both NDC units and Healthcare Common Procedure Coding System (HCPCS) units for billing.

CD, Crohn's disease; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IV, intravenous; UC, ulcerative colitis.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.
Back to Table of Contents

Coding for TREMFYA® for IV Induction (cont'd)

CPT® Codes for Drug Administration[4]

Payer policies for codes that describe drug administration services may vary. Contact your payer for guidance regarding use of required codes.

CPT® Code	Descriptor
For Intravenous Infusion	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96365	Intravenous infusion for therapy, prophylaxis, or diagnosis; initial, up to 1 hour

TREMFYA® National Drug Codes (NDCs)[1]

The NDC is required for Medicaid rebates[5,6] and on claims for many private payers.[7] Payer requirements for NDC use and format can vary widely. Refer to sample claims forms for additional information.

Dose to be billed	11-Digit NDC (5-4-2 Format)	Packaging	NDC unit of measure	NDC units*
Intravenous Infusion for Induction				
200 mg	57894-0650-02	200 mg/20 mL (10 mg/mL) solution in a single-dose vial	mL	20

*Some payers may require both NDC units and Healthcare Common Procedure Coding System (HCPCS) units for billing.

Place of Service Codes[5]

Code	Place of Service
11	Office
19	Off campus: outpatient hospital
22	On campus: outpatient hospital
49	Independent clinic

Revenue Codes[8]

Revenue Code	Descriptor
0250	Pharmacy, general
0260	IV (intravenous) therapy, general
0510	Clinic, general
0636	Pharmacy, drugs requiring detailed coding
0940	Other therapeutic services, general

HCPCS Modifiers[9,10]

Modifier	Description
JA	Administered via intravenous infusion
JZ	No discarded drug amounts

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.
Back to Table of Contents

Sample Claim Forms for Intravenous Infusion

TREMFYA® IV INFUSION FOR INDUCTION

SAMPLE CMS-1500 FORM:

Use to submit claims for TREMFYA® administered in **your office.**

1

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. K51.50 B. C. D.

E. 2 F. 3 G. 4 H. 5

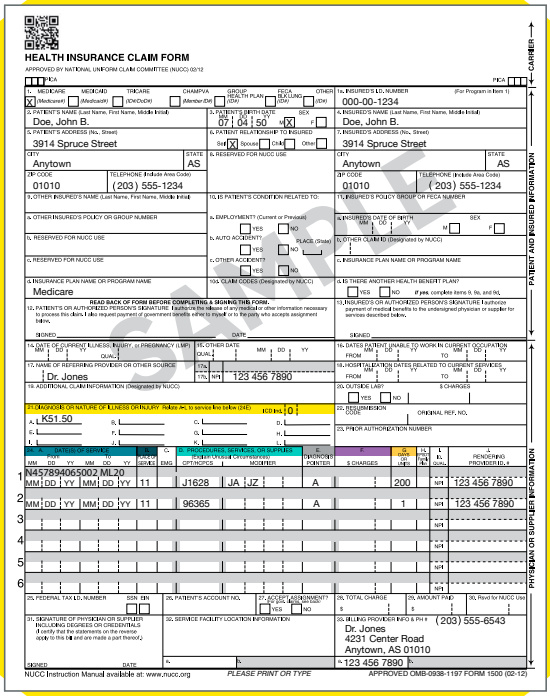
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER 6 7

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N457894065002 ML20															
MM	DD	YY	MM	DD	YY	11		J1628	JA JZ	A		200		NPI	123 456 7890
2															
MM	DD	YY	MM	DD	YY	11		96365		A		1		NPI	123 456 7890

ER INFORMATION



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare) MEDICAID (Medicaid) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER

1a. INSURED'S I.D. NUMBER: 000-00-1234

2. PATIENT'S NAME: Doe, John B.

3. PATIENT'S BIRTH DATE: 07 04 50 SEX: M

4. INSURED'S NAME: Doe, John B.

5. PATIENT'S ADDRESS: 3914 Spruce Street

6. PATIENT RELATIONSHIP TO INSURED: Self Spouse Child Other

7. INSURED'S ADDRESS: 3914 Spruce Street

CITY: Anytown STATE: AS

8. RESERVED FOR NUCC USE

ZIP CODE: 01010 TELEPHONE: (203) 555-1234

9. OTHER INSURED'S NAME

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME: Medicare

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 9a, and 9d.

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.

SIGNED DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. DATE OF CURRENT: ILLNESS, INJURY, or PREGNANCY (LMP) QUAL.

15. OTHER DATE QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY FROM TO

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE: Dr. Jones

17a. 17b. NPI 123 456 7890

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES MM DD YY FROM TO

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind. 0

A. K51.50 B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1 N457894065002 ML20															
MM	DD	YY	MM	DD	YY	11		J1628	JA JZ	A		200		NPI	123 456 7890
2															
MM	DD	YY	MM	DD	YY	11		96365		A		1		NPI	123 456 7890
3															
4															
5															
6															

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT? (For govt. claims, see back) YES NO

28. TOTAL CHARGE $

29. AMOUNT PAID $

30. Rsvd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS I certify that the statements on the reverse apply to this bill and are made a part thereof.

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH # (203) 555-6543

Dr. Jones
4231 Center Road
Anytown, AS 01010

a. 123 456 7890 b.

NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

SAMPLE

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

CMS-1500: 200 mg IV

Check with the individual payer, as specific claim requirements may vary.

For detailed guidance on completing CMS-1500 items, refer to Medicare Claims Processing Manual, Pub. 100-04, Chapter 26, available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26.pdf[5]

These documents are presented for informational purposes only and are not intended to provide reimbursement or legal advice, nor do they promise or guarantee coverage, levels of reimbursement, payment, or charge.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.

Back to Table of Contents

Sample Claim Forms for Intravenous Infusion (cont'd)

1

ITEM 21
Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

2

ITEM 24A
If line item NDC information is required, it will be entered in the shaded portion of Item 24A.[5] This is where NDC units will be added (if applicable) as shown above.

Payer requirements for NDC entries may vary.

3

ITEM 24B
Identify the location where the service was rendered.

4

ITEM 24D
Indicate appropriate CPT® and HCPCS codes and modifiers (if required by payer).

TREMFYA®
J1628: Injection, guselkumab, 1 mg

Modifiers Required by Medicare
- **JA to indicate intravenous infusion**
- **JZ to indicate there was no discarded amount from a single-dose container**

Infusion Services
CPT® 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour; or
CPT® 96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

5

ITEM 24E
Refer to the diagnosis for this service (see Item 21). Enter only one diagnosis pointer per line.

6

ITEM 24F
Indicate total charges.
Note: When administering drug that is obtained via manufacturer program, enter "0.01" charges. Payer policies may vary.[11]

7

ITEM 24G
Enter the number of units:

- **J1628** | Enter the amount of drug in HCPCS units according to dose. 1 mg = 1 unit, each TREMFYA® 200-mg vial = 200 units
- **96365 or 96413** | Enter 1 unit for the first hour of infusion

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.
Back to Table of Contents

Sample Claim Forms for Intravenous Infusion

TREMFYA® IV INFUSION FOR INDUCTION

SAMPLE CMS-1450 FORM:

Use to submit claims for TREMFYA® administered in a **hospital outpatient setting.**

1	2	3	4	5
42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV DATE	46 SERV. UNITS	47 TOTAL CHARGES
0260	IV therapy	96365	MM-DD-YY	1	
0636	N457894065002 ML20	J1628JAJZ	MM-DD-YY	200	

6

66 DX K51.90

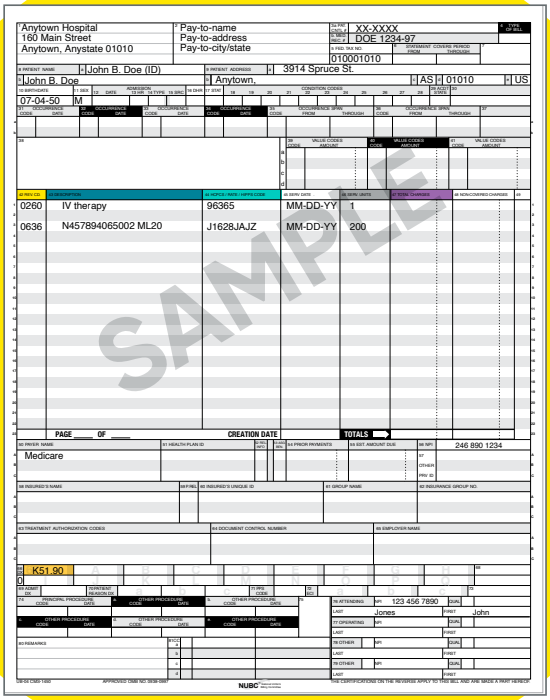
0

69 ADMIT DX

74 PRINCIPAL PROCEDURE CODE DATE

c. OTHER PROCEDURE CODE DATE

80 REMARKS



CMS-1450/UB-04: 200-mg IV

Check with each individual payer, as specific claim requirements may vary.

For detailed guidance on completing the CMS-1450 items, please see the Medicare Claims Processing Manual, Pub. 100-04, Chapter 25, available at: https://www.cms.gov/Regulations-and Guidance/Guidance/Manuals/Downloads/clm104c25.pdf[12]

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.

Back to Table of Contents

Sample Claim Forms for Intravenous Infusion (cont'd)

1

BOX 42
List revenue codes in ascending order.

2

BOX 43
Enter narrative description for corresponding revenue code (eg, IV therapy, drug). Alternatively, if line item NDC information is required, it will be entered in the unshaded portions of Box 43.[12] Payer requirements for NDC entries may vary.

3

BOX 44
Indicate appropriate CPT®, HCPCS codes, and modifiers as required by the payer.

TREMFYA®
J1628: Injection, guselkumab, 1 mg

Modifiers Required by Medicare
- **JA to indicate intravenous infusion**
- **JZ to indicate there was no discarded amount from a single-dose container**

Infusion Services
CPT® 96365: Intravenous infusion, for therapy, prophylaxis, or diagnosis; initial, up to 1 hour; or
CPT® 96413: Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug

4

BOX 46
Enter the number of units:
- **CPT® 96365 or 96413:** Enter 1 unit for the first hour of infusion
- **J1628:** Enter the amount of drug in HCPCS units according to dose. 1 mg = 1 unit, each TREMFYA® 200-mg vial = 200 units

5

BOX 47
Indicate total charges.
Note: When administering drug that is obtained via manufacturer program, enter "0.01" charges. Payer policies may vary.[12]

6

BOX 67
Indicate diagnosis using appropriate ICD-10-CM codes. Use diagnosis codes to the highest level of specificity for the date of service and enter the diagnoses in priority order.

CPT®, Current Procedural Terminology. CPT is a registered trademark of the American Medical Association, 2023. HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; IV, intravenous; NDC, National Drug Code.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.
Back to Table of Contents

Claim Filing Checklist

Once your patient receives TREMFYA®, you'll need to submit a claim for reimbursement to their health insurance provider. To streamline the process, it's important to be familiar with the payer's specific billing and coding requirements and ensure that your claim is as thorough as possible. Here are some general tips to consider when filing claims for TREMFYA®:

- **If conducting a benefits investigation while payer coverage is pending, an NDC should be included to distinguish use of TREMFYA® for CD or UC.**
- **Use appropriate codes to report the patient's condition, the drugs the patient received, and the services you have provided.**
  - CPT code
  - ICD-10-CM code/patient diagnosis and information
  - NDC (payers typically require the 11-digit format)
  - HCPCS code
  - JZ and JA
    - Commercial, Medicare Advantage, and Medicaid payers generally require the NDC. Medicare Part B will require the modifiers. Please check with each payer for their requirements.
- **Review the claim for accuracy, including patient identification numbers and coding.**
- **File the claim as soon as possible and within health plan filing time limits.**
- **Reconcile claim reports promptly and thoroughly to ensure claims have been appropriately processed and paid.**

Under certain circumstances, qualified patients may acquire donated or no-cost drugs, or drugs may be covered under a pharmacy benefit and delivered to the administering provider. When the drug is supplied by a third party at no cost to the provider, it should NOT be billed to Medicare or any other payer. However, the administration of the drug, regardless of the source, is a service that represents an expense to the physician. Therefore, administration of the drug is payable if the drug would have been covered if the physician purchased it. When reporting drug administration services for free-of-charge drugs, it may be necessary to include drug information on the claim and enter "0.01" charges.[11] Payer policies may vary.

For billing and coding or reimbursement questions, or to request support from a Field Reimbursement Manager (FRM), call **1-833-844-8463,** Monday-Friday, 8 AM to 8 PM ET

CD, Crohn's disease; CPT®, Current Procedural Terminology. CPT is a registered trademark of the American Medical Association, 2023. HCPCS, Healthcare Common Procedure Coding System; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code; UC, ulcerative colitis.

Please see Important Safety Information for TREMFYA® on page 12.
Please click here to see the full Prescribing Information.
Back to Table of Contents

Patient Access and Support

ONCE A DECISION HAS BEEN MADE TO PRESCRIBE TREMFYA®... | Tremfya withMe

TREMFYA withMe provides streamlined support to help your patients get on therapy.

From a dedicated Nurse Guide* to access, affordability, and educational support, TREMFYA withMe has everything your patients may need to start and stay on track.

See what dedicated support can do for your patients.

Access & Affordability Support
Your case manager team can help verify insurance coverage and enroll eligible patients in the right programs and support offerings.

Office Educational Support
Get customized patient fulfillment support from a dedicated team that includes a Case Manager and a Field Reimbursement Manager.

Dedicated Nurse Guide*
Your patient is connected with a dedicated Nurse Guide*—a registered nurse, who can:

- Answer questions about prescription fulfillment and cost support
- Provide information about the treatment process
- Connect patients to supplemental self-injection training and resources
- Help patients stay on track with treatment goals and milestones, as well as updates and reminders at their request

Patient authorization is required for enrollment in Nurse Guide support.

Infusion Services
A contracted network of Infusion Service Providers (ISPs) "coordinates" continuity of care and "supports" the overall patient experience by leveraging existing infrastructure and clinical expertise.

Specialty Pharmacy Enhanced Services
Our contracted specialty pharmacies provide your patients with streamlined product fulfillment support, prescription transfers to payer-mandated pharmacies, and patient outreach related to starting and staying on treatment. Enhanced services provided by each specialty pharmacy may vary.

*Nurse Guides do not provide medical advice.

Eligible, commercially insured patients pay as little as $0 per dose with the **TREMFYA withMe Savings Program.**

†Your eligible patients using commercial or private insurance pay as little as $0 per dose. The program provides two separate offerings: Medicine Cost Support for the cost of TREMFYA® medicine and Treatment Administration Cost Support for the cost of TREMFYA® administration and eligible laboratory tests. Maximum program benefit per calendar year shall apply. Offer subject to change or end without notice. Patients may participate without sharing their income information. See program requirements at **TREMFYAwithMeSavings.com**.

The patient support and resources provided by TREMFYA withMe are not intended to give medical advice, replace a treatment plan from the patient's healthcare provider, offer services that would normally be performed by the provider's office, or serve as a reason to prescribe TREMFYA®.

For additional assistance and support with billing and coding questions, please contact TREMFYA withMe at **1-833-WITHME1 (948-4631)** or visit **JanssenCarePath.com/hcp/Tremfya**

Please see Important Safety Information for TREMFYA® on page 12
Please click here to see the full Prescribing Information.

Back to Table of Contents

Important Safety Information

INDICATIONS

TREMFYA® (guselkumab) is indicated for the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with moderate to severe plaque psoriasis and who are candidates for systemic therapy or phototherapy.

TREMFYA® is indicated for the treatment of adults and pediatric patients 6 years of age and older who also weigh at least 40 kg with active psoriatic arthritis.

TREMFYA® is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis.

TREMFYA® is indicated for the treatment of adult patients with moderately to severely active Crohn's disease.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection. Initiate treatment of latent TB prior to administering TREMFYA®. Consider anti-TB therapy prior to initiating TREMFYA® in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor all patients for signs and symptoms of active TB during and after TREMFYA® treatment.

Hepatotoxicity

A serious adverse reaction of drug-induced liver injury was reported in a clinical trial subject with Crohn's disease following three doses of a higher than recommended induction regimen.

In patients with Crohn's disease or ulcerative colitis, evaluate liver enzymes and bilirubin at baseline, for at least 16 weeks of treatment, and periodically thereafter according to routine patient management. In patients with plaque psoriasis or psoriatic arthritis, if clinically indicated, evaluate liver enzymes and bilirubin at baseline, and periodically thereafter according to routine patient management.

Consider other treatment options in patients with evidence of acute liver disease or cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Prior to initiating TREMFYA®, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common adverse reactions associated with TREMFYA® include: plaque psoriasis and psoriatic arthritis adverse reactions (≥1%): upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections. Ulcerative colitis adverse reactions (≥3%): injection site reactions, arthralgia, upper respiratory tract infections, headache, gastroenteritis, fatigue, pyrexia, and rash. Crohn's disease adverse reactions (≥3%): respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis.

The safety profile observed in pediatric patients 6 years of age and older treated with TREMFYA® up to 52 weeks was consistent with the safety profile observed in adult patients with moderate to severe plaque psoriasis.

The overall safety profile observed in adult patients with psoriatic arthritis is generally consistent with the safety profile in adult patients with plaque psoriasis, with the addition of bronchitis and neutrophil count decreased.

Please read the full Prescribing Information and Medication Guide for TREMFYA®.

Provide the Medication Guide to your patients and encourage discussion.

Dosage Forms and Strengths: TREMFYA® is available as 100 mg/mL and 200 mg/2 mL for subcutaneous injection and as a 200 mg/20 mL (10 mg/mL) single-dose vial for intravenous infusion.

cp-82625v9

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Back to Table of Contents

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