Tremfya® (guselkumab)

Billing and Coding Considerations for In-Office Administration of TREMFYA® Subcutaneous (SC) Induction for Ulcerative Colitis and Crohn's Disease

Providers may be eligible to receive reimbursement for in-office administration of TREMFYA® SC induction doses.

Once a decision has been made to prescribe TREMFYA®, there are four ways to obtain TREMFYA® SC for in-office use without buy-and-bill:

- Eligible patients can receive their first SC induction dose by enrolling into **TREMFYA withMe**
- **White bagging:** Specialty pharmacy ships it to the HCP office
- **Clear bagging:** Internal specialty pharmacy ships it to the HCP office
- **Brown bagging:** Patient receives the product from specialty pharmacy and brings it to the HCP office

TREMFYA® PEN Induction Pack[1] (200 mg/2 mL) Pen x 2
NDC: 57894-0651-04

Also available in **Prefilled Syringe[1] (200 mg/2 mL) NDC:** 57894-651-22 and **TREMFYA® PEN (200 mg/2 mL) NDC:** 57894-651-02

Images not to scale; for illustrative purposes only.

Relevant Codes for Reimbursement of SC Injection Administration

The following codes may be applicable for reimbursement when administering the SC injection in the office setting. Payer requirements for coding may vary. For the most accurate list of codes and billing requirements, please confirm with the payer.

TREMFYA® National Drug Code (NDC)[1]

The NDC is required for Medicaid rebates[2,3] and on claims for many private payers.[4] 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*
Subcutaneous Injection for Induction				
400 mg	**57894-0651-04**	Carton of two 200 mg/2 mL single-dose prefilled pens	ML	4

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

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®.

INDICATIONS

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

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

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 4.

Coding for TREMFYA®

HCPCS J Code[5]

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. This information may still be required when submitting a claim for drug administration only.

Subcutaneous Injection for Induction

2 Number of Prefilled 200 mg Pens of TREMFYA®

400 Total mg | **400** HCPCS Units*

*Based on J1628 (1 mg TREMFYA® per unit).

HCPCS, Healthcare Common Procedure Coding System.

ICD-10-CM Diagnosis Codes for Consideration[6]

Ulcerative Colitis

K51.00	Ulcerative (chronic) pancolitis without complications
K51.01	Ulcerative (chronic) pancolitis withcomplications
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.

ICD-10-CM, International Classification of Diseases, 10th Revision, Clinical Modification.

CPT® Codes for Drug Administration[7]

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 Subcutaneous Injection	
96372	Therapeutic, prophylactic, or diagnostic injection; subcutaneous or intramuscular

CPT®, Current Procedural Terminology. CPT is a registered trademark of the American Medical Association, 2023.

Coding for TREMFYA®

Place of Service Codes[2]

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
0510	Clinic, general
0636	Pharmacy, drugs requiring detailed coding
0940	Other therapeutic services, general

HCPCS Modifiers[9, 10]

Modifier	Description
JB	Administered via subcutaneous injection
JZ	No discarded drug amounts

Physician Office Sample Claim Form (CMS-1500): Administration Charge for 400-mg SC Injection

If NDC information is required, it will be entered in the shaded portion of item 24A.[2]

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. #
N457894065104 ML4																	
MM	DD	YY	MM	DD	YY			J1628	JB	JZ			$0.01	400		NPI	123 456 7890
MM	DD	YY	MM	DD	YY	11		96372				A		1		NPI	123 456 7890

BOX 19: Billing for administration of TREMFYA® only. Acquired through specialty pharmacy.

CPT, Current Procedural Technology; HCPCS, Healthcare Common Procedure Coding System; NDC, National Drug Code; SC, subcutaneous.

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. 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.

Click here to access the most up-to-date specialty pharmacy network for TREMFYA®.

Tremfya withMe

Personalized support for your patients and education for your office

Visit Tremfya.com to learn more

Call 1-833-WITHME1 (948-4631)

Data rates may apply.

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®.

Please see Important Safety Information on page 4, and read the full Prescribing Information and Medication Guide for TREMFYA®.

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.

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.

cp-82625v9

References: 1. TREMFYA® (guselkumab) [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 26: Completing and Processing the Form CMS-1500 Data Set. Revised December 14, 2023. Accessed October 24, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **3.** Novitas Solutions. Reporting the National Drug Code. Accessed July 9, 2024. https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00251502 **4.** United Healthcare. National Drug Code (NDC) Requirement Policy, Professional and Facility. Revised April 14, 2024. Accessed April 20, 2024. https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-reimbursement/COMM-National-Drug-Code-Requirement-Policy.pdf **5.** Centers for Medicare & Medicaid Services. April 2024 AlphaNumeric HCPCS Files. Updated April 17, 2024. Accessed October 24, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **6.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. April 1, 2024 Update. Accessed October 24, 2024. https://www.cms.gov/medicare/coding-billing/icd-10-codes **7.** American Medical Association. Current Procedural Terminology: CPT® 2024: Professional Edition. Chicago, IL: American Medical Association; 2023 **8.** Noridian Healthcare Solutions. Revenue Codes. Last updated March 18, 2024. Accessed October 24, 2024. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **9.** Centers for Medicare & Medicaid Services. Article – Billing and Coding: Complex Drug Administration Coding (A58527). Revised April 1, 2024. October 24, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527&ver=37&; **10.** Centers for Medicare & Medicaid Services. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed October 24, 2024. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf **11.** Centers for Medicare & Medicaid Services. Billing and Coding: Patients Supplied Donated or Free-of-Charge Drug. Revised November 22, 2023. Accessed August 27, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55045

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