Tremfya® (guselkumab)

J1628

TREMFYA® single-dose vial for intravenous (IV) infusion will use the established J code.[1]

HCPCS Code	J1628
HCPCS Description	Injection, guselkumab, 1 mg
Modifiers[2,3]	JA – indicates administration by IV infusion JZ – indicates no product discarded
10-Digit NDC for Ordering[4]	57894-650-02
11-Digit NDC for Billing	57894-0650-02
Description[4]	200-mg vial Single-use vial containing 200 mg/20 mL (10 mg/mL) of guselkumab for IV infusion

Recommended Induction Dosing for TREMFYA® in:
Adults with moderately to severely active ulcerative colitis (UC): Recommended induction dosing: 200 mg IV at Weeks 0, 4, and 8
Adults with moderately to severely active Crohn's disease (CD): Recommended induction dosing: 200 mg IV **or** 400 mg SC at Weeks 0, 4, and 8

- NDCs are required for most commercial and Medicare Advantage payers, as well as Medicaid billing, and should be submitted on the billing form unless payer has stated otherwise[5,6]
- The JA modifier is required for Medicare billing and may be required to indicate IV administration of TREMFYA®[2]*
- Medicare requires the JZ modifier to attest no drug was discarded from a single-dose container[3]

When billing J1628, confirm all required information with respective payers.

Physician Office Sample Claim Form (CMS-1500): 200-mg IV Injection

If NDC information is required, it will be entered in the shaded portion of item 24A.[5]

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. #
N457894065002 ML20																	
MM	DD	YY	MM	DD	YY			J1628	JA	JZ				200		NPI	123 456 7890

HOPD Sample Claim Form (CMS-1450/UB-04): 200-mg IV Injection

If NDC information is required, it will be entered in the unshaded portion of Locator Box 43.[7]

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	N457894065002 ML20	J1628JAJZ	MM DD YY	200			

CD, Crohn's disease; CPT, Current Procedural Terminology; HCP, healthcare professional; HCPCS, Healthcare Common Procedure Coding System; HOPD, Hospital Outpatient Department; NDC, National Drug Code; SC, subcutaneous; UC, ulcerative colitis.

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.

*Medicare requires modifiers to identify the route of administration for drugs that have one HCPCS code but multiple routes of administration. The JA modifier indicates TREMFYA® was administered by IV infusion.

Please see additional Important Safety Information on following page.

Tremfya with Me

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®.

IMPORTANT SAFETY INFORMATION (CONT'D)

WARNINGS AND PRECAUTIONS (CONT'D)

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.

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®.

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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 (≥2%): induction: respiratory tract infections; maintenance (≥3%): injection site reactions, arthralgia, and upper respiratory tract infections. Crohn's disease adverse reactions (≥3%): respiratory tract infections, abdominal pain, injection site reactions, headache, fatigue, arthralgia, diarrhea, and gastroenteritis.

The overall safety profile observed in patients with psoriatic arthritis is generally consistent with the safety profile in 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 adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

TREMFYA® is indicated for the treatment of adult patients 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.

References: 1. Centers for Medicare & Medicaid Services. April 2024 AlphaNumeric HCPCS Files. Updated April 17, 2024. Accessed May 24, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update **2.** Centers for Medicare & Medicaid Services. Billing and Coding: Complex Drug Administration Coding (A58527). Revised April 1, 2024. Accessed May 24, 2024. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58527&ver=37&= **3.** Centers for Medicare & Medicaid Services. Medicare Program Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy Frequently Asked Questions. Accessed May 24, 2024. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf **4.** TREMFYA® [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **5.** 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 June 28, 2024. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf **6.** 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 **7.** Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual. Chapter 25: Completing and Processing the Form CMS-1450 Data Set. Revised December 20, 2023. Accessed April 20, 2024. https://www.cms.gov/regulations-and-guidance/ guidance/manuals/downloads/clm104c25.pdf

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