Tremfya with Me

TREMFYA withMe

A dedicated support program
for patients prescribed TREMFYA®

A guide for bio-coordinators

About this guide

Once a decision has been made to prescribe TREMFYA®, TREMFYA withMe provides dedicated support to help patients start and stay on track with TREMFYA®.

Contents

INDICATION

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

Pre-Treatment Evaluation for Tuberculosis (TB)
Evaluate patients for TB infection prior to initiating treatment with TREMFYA®. Initiate treatment of latent TB prior to administering TREMFYA®. Monitor patients for signs and symptoms of active TB during and after TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection.

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: induction (≥2%): respiratory tract infections; maintenance (≥3%): injection site reactions, arthralgia, and upper respiratory tract infections.

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 in a 100 mg/mL prefilled syringe and One-Press patient-controlled injector for subcutaneous injection, a 200 mg/2 mL prefilled syringe and prefilled pen (TREMFYA® PEN) for subcutaneous injection, and a 200 mg/20 mL (10 mg/mL) single-dose vial for intravenous infusion.

cp-82625v6

TREMFYA® (guselkumab) is for adults with moderately to severely active ulcerative colitis (UC)

Storing, handling, and ordering

Storing and handling TREMFYA®

TREMFYA® is supplied as a sterile, preservative-free, clear and colorless to light yellow solution that may contain small translucent particles.

Store in a refrigerator at 36˚ F to 46˚ F (2˚ C to 8˚ C)

Do not freeze

Do not shake

Protect from light until use

Keep out of reach of children

Ordering TREMFYA®

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[4]	**57894-0650-02**
Description[4]	**200-mg vial** Single-dose vial containing 200 mg/20 mL (10 mg/mL) of guselkumab for IV infusion

HCPCS=Healthcare Common Procedure Coding System; IV=intravenous; NDC=National Drug Code.

SELECTED IMPORTANT SAFETY INFORMATION

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Please click to see the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

TREMFYA® (guselkumab) is for adults with moderately to severely active ulcerative colitis (UC)

TREMFYA® (guselkumab) dosing for UC

Choose the most appropriate dose for your patients

Induction dosing

Not actual size.

3 IV Infusions (200 mg)[4]*

The recommended induction dosage of TREMFYA® is 200 mg administered by intravenous infusion over a period of at least 1 hour at Week 0, Week 4, and Week 8.

Week 0 — Week 4 — Week 8

Maintenance dosing

Not actual size.

TREMFYA® PEN (200 mg)† or Prefilled Syringe (200 mg)[4‡]

200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter.

Week 12 — Week 16 — Week 20 — Week 24

OR

Not actual size.

One-Press Injector (100 mg)§ or Prefilled Syringe (100 mg)[4‡]

100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter.

Week 16 — Week 24 — Week 32 — Week 40

Use the lowest effective recommended dosage to maintain therapeutic response.

Pretreatment Evaluations: Prior to initiating treatment with TREMFYA®, evaluate patients for tuberculosis infection and complete all age-appropriate vaccinations according to current immunization guidelines.

TREMFYA® is intended for use under the guidance and supervision of a physician. TREMFYA® may be administered by a healthcare professional, or a patient may self-inject after proper training in subcutaneous injection technique.[4]

*200 mg/20 mL (10 mg/mL) solution in a single-dose vial.
†200 mg/2 mL in a single-dose prefilled pen.
‡200 mg/2 mL or 100 mg/mL in a single-dose prefilled syringe.
§100 mg/mL in a single-dose One-Press patient-controlled injector.

IV=intravenous; UC=ulcerative colitis.

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Please click to see the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

Once a decision has been made to prescribe TREMFYA®,
TREMFYA withMe can help your patients start and stay on TREMFYA®.

TREMFYA withMe

Program overview

TREMFYA withMe provides free, personalized support for patients throughout their TREMFYA® treatment journey.

Support to help your patients start and stay on treatment

Improved access & affordability support

Eligible patients using commercial insurance:

Pay as little as $0 per dose, including administration and eligible lab costs*

Patients with a delay or denial in coverage can receive TREMFYA® in **as fast as 3 days for up to 3 years**†

Enhanced fulfillment process

Streamlined **BI verification** & evaluation of patient support program eligibility

Single-point enrollment across all TREMFYA withMe patient support offerings

Patient-centered approach

Comprehensive, impactful, and customized program offerings designed to provide support throughout the patient journey

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®.

*The TREMFYA withMe Savings Program consists of Medicine Cost Support and Treatment Administration Cost Support (includes eligible laboratory tests). Maximum program benefit per calendar year shall apply. Offer subject to change or end without notice. See **program requirements**.

†See **program requirements** for the TREMFYA withMe Access Program.

BI=benefits investigation.

Please see full Important Safety Information on page 4. Please read the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

How to enroll patients

Fax Patient Enrollment Form (PEF)

A completed PEF includes:

Patient demographics
Name, contact information, medical/pharmacy insurance

Patient consent
Patient consent to treatment and to be contacted about TREMFYA withMe

Prescription
Authority to provide product at no cost to eligible patients or transition to commercial standard prescription with chain of custody of the prescription

Patient Authorization
A signed Patient Authorization Form permits healthcare providers to use and share the patient's medical information with the patient support programs from Johnson & Johnson

Additional ways to initiate enrollment include:

EHR/eRx
Maximize speed to commercial triage and streamlined enrollment

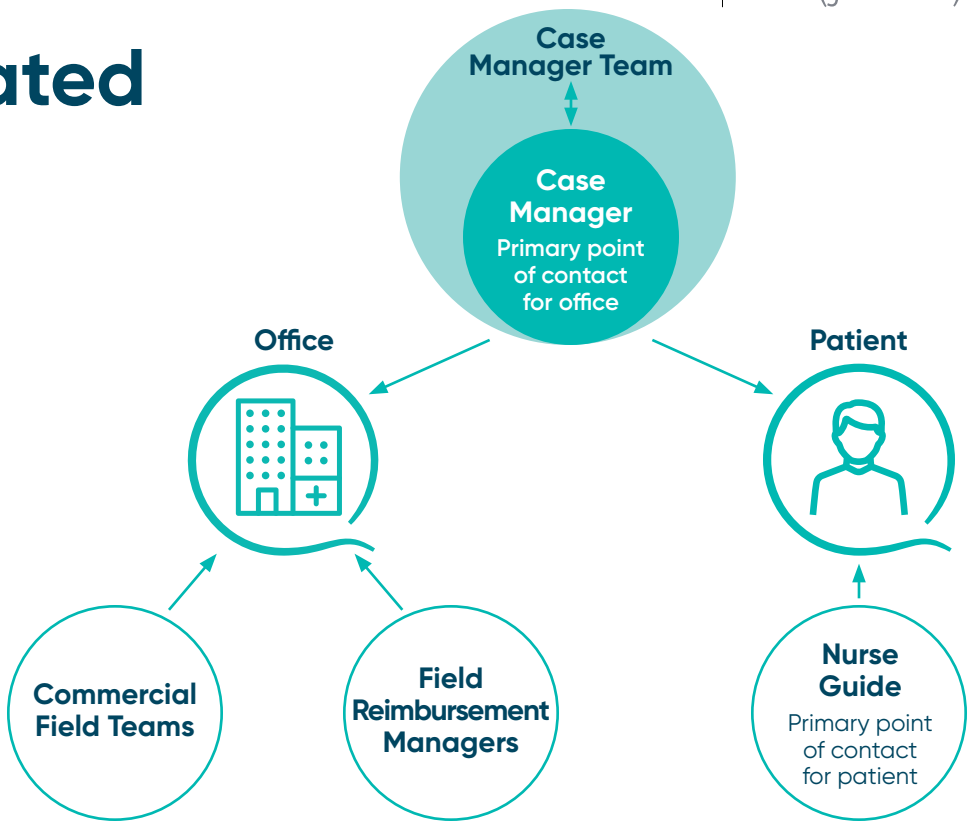
Provider Portal
See status of patient at case level, and access documentation/support

EHR=electronic health record.

Please see full Important Safety Information on page 4. Please read the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

One dedicated team with one goal

The TREMFYA withMe team works together to deliver customized fulfillment support for TREMFYA® patients.



Case Manager Team

Led by your Case Manager, the primary point of contact for HCP office.

- **Care Liaison**
  Data entry, material fulfillment
- **Specialty Pharmacy Liaison**
  Specialty pharmacy point of contact, network coordination, and reconciliation
- **Reimbursement Specialist**
  Validate/investigate pharmacy and medical benefits

Field Reimbursement Manager

The Field Reimbursement Manager (FRM) works directly with your Case Manager team to help patients get started on therapy as quickly as possible.

- The ability to see detailed fulfillment data* and help minimize delays
- Deliver necessary education to help patients start and stay on therapy*
- Connect with specialty pharmacies regarding specific patient case information as needed*

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*Protected Health Information cannot be exchanged without a Patient Authorization on file.

Please see full Important Safety Information on page 4. Please read the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

Personalized support from a dedicated Nurse Guide*

Help patients with treatment onboarding and prepare for their infusions

- Navigate insurance coverage and affordability options
- Infusion support
- Explain specialty pharmacy process

Offer further support after you have provided the initial injection training

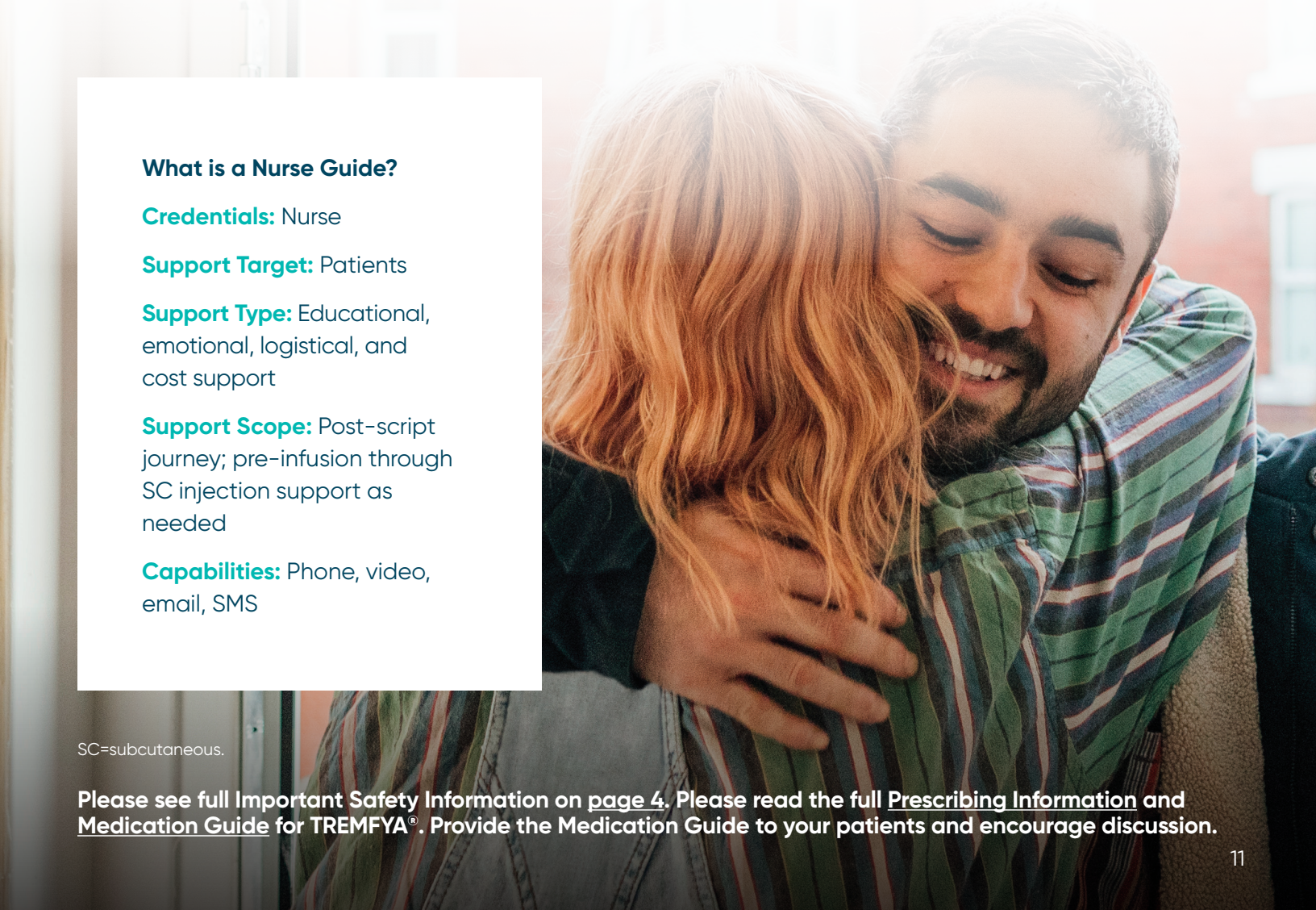
- Answer additional questions
- Coordinate supplemental injection trainings

Give ongoing support customized to each patient's needs

- Send infusion and injection reminders
- Provide education about their condition
- Patients get the same Nurse Guide every time
- Available M-F, 8 AM to 11 PM ET, in up to 100 languages

Patient authorization is required for enrollment in Nurse Guide

*Nurse Guides do not provide medical advice.



What is a Nurse Guide?

Credentials: Nurse

Support Target: Patients

Support Type: Educational, emotional, logistical, and cost support

Support Scope: Post-script journey; pre-infusion through SC injection support as needed

Capabilities: Phone, video, email, SMS

SC=subcutaneous.

Please see full Important Safety Information on page 4. Please read the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

Access and affordability support

Commercial or private insurance

TREMFYA withMe Savings Program

Helps eligible patients save on their out-of-pocket costs for TREMFYA®. Savings may apply toward co-pay, co-insurance, or deductible. Program provides two separate offerings: Medicine Cost Support and Treatment Administration Cost Support.

Eligible commercial patients may pay **as little as $0 per dose**

SINGLE ENROLLMENT

Medicine Cost Support
- TREMFYA® UC IV and SC medicine costs

Treatment Administration Cost Support
- Treatment administration costs for IV infusions
- Tuberculosis test costs (Quantiferon Gold or TB-Spot)

Maximum program benefit per calendar year shall apply. Terms expire at the end of each calendar year. Offer subject to change or end without notice. Restrictions, including monthly maximums, may apply.

See program requirements at **TREMFYAwithMeSavings.com**.

TREMFYA withMe Access Program

Eligible commercial patients with a delay or denial in coverage can receive TREMFYA® in as fast as **3 days** and for **up to 3 years** through the TREMFYA withMe Access Program.

PATIENT MAY BE ELIGIBLE IF

1. Benefits investigation outcome is "not covered"
2. Prior Authorization (PA) is denied
3. Delay >5 days after Prior Authorization/LMN submission

TREMFYA withMe offers eligible patients TREMFYA® at no cost. Offer is valid for up to 3 years or until insurance covers the medication.

See TREMFYA withMe Access Program requirements at **TREMFYAwithMeAccess.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®.

Complete a benefits investigation request in the Provider Portal at **JanssenCarePathPortal.com** or **download** the Patient Enrollment Form, complete the form, and fax to TREMFYA withMe at 800-600-7226.

Please see full Important Safety Information on page 4. Please read the full Prescribing Information and Medication Guide for TREMFYA®. Provide the Medication Guide to your patients and encourage discussion.

Government-funded coverage or underinsured

Affordability programs may be available.

Government programs

The following programs may be available to help patients with government-funded coverage pay for their treatment:

- State-sponsored programs
- Medicare Part D Extra Help/Low-income Subsidy
- Medicare Savings Program
- Medicaid

For a comprehensive list of affordability programs, visit **JanssenCarePath.com/HCP/TREMFYA/Affordability**.

Be sure to let your patients know that they should contact the programs directly to get details on eligibility and application requirements, and to see if funding is available to help them.

Independent foundations

The following foundations are here to help your patients afford the medication they need:

- HealthWell Foundation®: 800-675-8416 | **healthwellfoundation.org**
- PAN Foundation: 866-316-7263 | **panfoundation.org**
- Patient Advocate Foundation: 866-512-3861 | **copays.org**
- The Assistance Fund: 855-845-3663 | **TAFCares.org**

Independent co-pay assistance foundations have their own rules for eligibility, which are subject to change. We have no control over these independent foundations and can only refer your patients to a foundation that supports their disease state. We do not endorse any particular foundation. The foundations on this list are not the only ones that might be able to help your patients.

Additional support

Patient Assistance from Janssen is available if your patient has commercial, employer-sponsored, or government coverage that does not fully meet their needs. Your patient may be eligible to receive their Janssen medication free of charge for up to one year if they meet the eligibility and income requirements for the Janssen Patient Assistance Program. See terms and conditions at **PatientAssistanceInfo.com/IMM**.

IV=intravenous; LMN=Letter of Medical Necessity; SC=subcutaneous; UC=ulcerative colitis.

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Enhanced offerings

Infusion Services

Once a decision has been made to prescribe TREMFYA®, TREMFYA withMe Infusion Services is designed to deliver a streamlined patient fulfillment experience for adult patients with moderately to severely active ulcerative colitis taking TREMFYA®. TREMFYA withMe Infusion Services is intended to help patients start on therapy and successfully transition from the 3 intravenous (IV) induction doses to subcutaneous (SC) maintenance doses.

TREMFYA withMe Infusion Services utilizes Infusion Service Providers (ISPs) to coordinate continuity of care and support the overall patient experience by leveraging existing infrastructure and clinical expertise.

The Role of ISPs

ISPs will provide proactive medication adherence education and will transfer the maintenance injection prescription to a payer-approved specialty pharmacy as needed, confirming the transfer with the patient and the prescribing healthcare professional. ISPs will also work closely with TREMFYA withMe to enroll patients in applicable cost support and treatment support programs. The process is intended to strengthen patient continuity of care and streamline the patient treatment journey. TREMFYA withMe Infusion Services is available through the following ISPs*:

vitalcare INFUSION SERVICES

Phone: 877-488-4825

vitalcare.com/patientstart

option care health

Email: OneOrder@optioncare.com

Phone: 877-974-4844

Fax: 847-589-1118

InfuCare Rx®

Email: contact@infucarerx.com

Phone: 877-828-3940

infucarerx.com

amerita specialty infusion services

Phone: 800-841-4445

Fax: 855-765-8494

CSI PHARMACY

Phone: 833-569-1005

Fax: 430-200-4889

*The listed ISPs are not the only ISPs available, and Janssen Biotech, Inc., does not endorse the use of any infusion service providers in particular. The information provided represents no statement, promise, or guarantee of Janssen Biotech, Inc., concerning levels of reimbursement, payment, or charge. Please consult specific payer organizations with regard to local or actual coverage, reimbursement policies, and determination processes.

SELECTED IMPORTANT SAFETY INFORMATION

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A streamlined patient-focused fulfillment experience

Infusion | Adherence call

TREMFYA® IV induction doses administered.

Baseline Adherence Call to patient emphasizes the importance of adherence and explains the steps of the program.

Triage and transfer

After the induction doses have been administered, the ISP will conduct a pharmacy benefits investigation to identify a payer-approved specialty pharmacy (SP). The ISP will then transfer the maintenance prescription to that SP to dispense the maintenance doses.*

Patient call

Within 2 business days after the TREMFYA® maintenance dose prescription has been transferred to the SP, the ISP will contact the patient to inform them of the name of the SP to which the prescription was transferred.

HCP communication

Within 2 business days after the prescription has been transferred to the SP, the ISP will inform the patient's HCP, via electronic communication, of the name of the SP to which the prescription was transferred and the date of the transfer.

Throughout the process, the ISP will partner with TREMFYA withMe and offer to enroll patients in appropriate programs such as cost support and Nurse Guide† support.

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®.

*ISPs may be able to provide administration of maintenance doses, eliminating need to triage and transfer to SP.
†Nurse Guides do not provide medical advice.

HCP=healthcare professional.

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Support every step of the way

Delivering comprehensive patient support for patients prescribed TREMFYA®

To request any additional materials, please contact your local Johnson & Johnson representative.

Tremfya withMe | Tremfya® (guselkumab)

Once a decision has been made to prescribe TREMFYA®, TREMFYA withMe helps eligible patients start and stay on treatment

Improved access & affordability support

Enhanced fulfillment process

Patient-centered approach

Initiate enrollment of your patients into TREMFYA withMe today via faxed PEF, eRx, or HCP Portal.

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INDICATION

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

SELECTED IMPORTANT SAFETY INFORMATION

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PEF=Patient Enrollment Form.

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.