## Tremfya with Me



# The journey begins with your TREMFYA withMe Guide

Say hello to your dedicated TREMFYA withMe Guide—a qualified healthcare professional\* ready to help, just a phone call away. Knowing that your Guide is by your side, you can move forward on your TREMFYA® treatment journey with the help you need.

It's free and easy to enroll in TREMFYA withMe.

\*Guides do not provide medical advice. Please ask your doctor any questions you might have about your disease and treatment.

Actor Portrayal

## You'll enjoy dedicated support throughout your TREMFYA® treatment journey.

We're committed to making sure you have what you want, when you want it. Your treatment journey is about more than appointments and injections: it's about you feeling supported.

## TREMFYA withMe can help you with:



#### Setting Expectations

You'll get information about your TREMFYA® treatment and you'll be guided along the way with educational support.



#### Stay on Track

You'll receive support to help you stay on track with your treatment, plus updates on your TREMFYA® treatment journey.



#### **Prescription and Cost Support**

You'll receive support to help you: verify your insurance coverage, understand how to fill your prescriptions, and look for options that could make your treatment more affordable.

#### **Injection Support**

Your doctor will review the injection process with you. Your doctor is the best person to help you understand what to expect. Your Guide is also available, after you have talked with your doctor, if you have questions about injections.

TREMFYA with Me is limited to education about your Janssen medication, its administration, and/or the condition it treats. It is not intended to provide medical advice, replace a treatment plan you receive from your doctor or nurse, or serve as a reason for you to start or stay on treatment.



Scan this QR CODE with your phone's camera

Learn more now about <u>TREMFYA withMe</u>, the support program built around you If you haven't signed up yet, **Scan or Call:** 

1-833-WITHME1 (948-4631), Monday through Friday from 8:00 AM to 11:00 PM ET

Please read the full <u>Prescribing Information</u> and <u>Medication Guide</u> for TREMFYA® and discuss any questions you have with your doctor.



#### TREMFYA® (trem fye' ah) (guselkumab) 100 mg injection, for subcutaneous use

#### What is TREMFYA®?

TREMFYA® is a prescription medicine used to treat adults:

- with moderate to severe plaque psoriasis who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet or UV light)
- with active psoriatic arthritis (PsA).

It is not known if TREMFYA® is safe and effective in children under 18 years of age.

#### What is the most important information I should know about TREMFYA®?

#### TREMFYA® may cause serious side effects, including:

Serious allergic reactions. Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:

- fainting, dizziness, feeling lightheaded (low blood pressure)
- chest tiahtness
- skin rash, hives
- swelling of your face, eyelids, lips, mouth, tongue or throat
- itching
- trouble breathing or throat tightness

Infections. TREMFYA® is a medicine that may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

- Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:
  - fever, sweats, or chills
  - muscle aches
  - weight loss
  - cough
  - warm, red, or painful skin or sores on your body different from your psoriasis
  - diarrhea or stomach pain
  - shortness of breath
  - blood in your phlegm (mucus)
  - burning when you urinate or urinating more often than normal

See "What are the possible side effects of TREMFYA®?" for more information about side effects.

#### Who should not take TREMFYA®?

Do not take TREMFYA<sup>®</sup> if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

#### What should I tell my healthcare provider before starting treatment with TREMFYA®?

#### Tell your healthcare provider about all of your medical conditions, including if you:

- have any of the conditions or symptoms listed in the section "What is the most important information I should know about TREMFYA®?"
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

#### Tell your healthcare provider about all the medicines you take,

including prescription and over-the-counter medicines, vitamins, and herbal supplements.

#### What are the possible side effects of TREMFYA®?

TREMFYA® may cause serious side effects. See "What is the most important information I should know about TREMFYA®?"

#### The most common side effects of TREMFYA® include:

- upper respiratory infections
- headache
- injection site reactions
- joint pain (arthralgia)
- diarrhea

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

#### What Else Should I Know About This Brief Summary?

- This information is not complete. To get more information:
  - Talk to your healthcare provider
  - Visit www.tremfya.com to obtain the FDA-approved Product Labeling, Medication Guide, and Instructions for Use.
  - Call the FDA at 1-800-FDA-1088 to report side effects.

- stomach flu (gastroenteritis)
- · fungal skin infections
- herpes simplex infections
- bronchitis

## Janssen Patient Support Program Patient Authorization Form

Patients should read the Patient Authorization, check the desired permission boxes, and return both pages of the Form to Janssen Patient Support Program.

- Download a copy, print, check the desired boxes, and sign. Your healthcare provider may scan the completed Form and upload on Provider Portal, or completed Form may be faxed to 844-322-9402 or mailed to TREMFYA withMe, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560
- You may be able to eSign a digital Form in your healthcare provider's office or on the Janssen CarePath Patient Account at <u>MyJanssenCarePath.com</u>

#### Patient Name: \_

#### Email Address:

I give permission for each of my "Healthcare Providers" (eg, my physicians, pharmacists, specialty pharmacies, other healthcare providers, and their staff) and "Insurers" (eg, my health insurance plans) to share my Protected Health Information as described on this Form.

My "Protected Health Information" includes any and all information related to my medical condition, treatment, prescriptions, and health insurance coverage.

The following person(s) or class of person(s) are given permission to receive and use my Protected Health Information (collectively "Janssen"):

- Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents, and representatives
- Providers of other sources of funding, including foundations and co-pay assistance providers
- Service providers for the patient support programs, including subcontractors or healthcare providers helping Janssen run the programs
- Service providers maintaining, transmitting, de-identifying, aggregating, or analyzing data from Janssen patient support programs

Also, I give permission to Janssen to receive, use, and share my Protected Health Information in order to:

- see if I qualify for, sign me up for, contact me about, and provide services relating to Janssen patient support programs, including in-home services
- manage the Janssen patient support programs
- give me educational and adherence materials, information, and resources related to my Janssen medication in connection with Janssen patient support programs
- communicate with my Healthcare Providers regarding access to, reimbursement for, and fulfillment of my Janssen medication, and to tell my Healthcare Provider that I am participating in Janssen patient support programs
- verify, assist with, and coordinate my coverage for my Janssen medication with my Insurers and Healthcare Providers
- coordinate prescription or treatment location and associated scheduling
- conduct analysis to help Janssen evaluate, create, and improve its products, services, and customer support for patients prescribed Janssen medications
- share and give access to information created by the Janssen patient support programs that may be useful for my care

I understand that my Protected Health Information may be shared by Janssen for the uses written in this Form to:

- My Insurers
- My Healthcare Providers
- Any of the persons given permission to receive and use my Protected Health Information as mentioned above
- Any individual I give permission as an additional contact

## Janssen Patient Support Program Patient Authorization Form

Janssen and the other data recipients listed on this Form may share information about me as permitted on this Form or if any information that specifically identifies me is removed. I understand that Janssen will use reasonable efforts to keep my information private but once my Protected Health Information is disclosed as allowed on this Form, it may no longer be protected by federal privacy laws.

I understand that I am not required to sign this Form. My choice about whether to sign will not change how my Healthcare Providers or Insurers treat me. If I do not sign this Form, or cancel or remove my permission later, I understand I will not be able to participate or receive assistance from Janssen's patient support programs. I understand that my Healthcare Providers may be paid by Janssen for sharing my Protected Health Information

with Janssen as allowed on this Form.

This Form will remain in effect 10 years from the date of signature, except where state law requires a shorter time, or until I am no longer participating in any Janssen patient support programs. Information collected before that date may continue to be used for the purposes set forth in this Form.

I understand that I may cancel the permissions given by this Form at any time by letting Janssen know in writing at: TREMFYA withMe, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

I can also cancel my permission by letting my Healthcare Providers and Insurers know in writing that I do not want them to share any information with Janssen.

I further understand that if I cancel my permission it will not affect how Janssen uses and shares my Protected Health Information received by Janssen prior to my cancellation.

I understand I may request a copy of this Form.

#### Permission for communications outside of Janssen patient support programs:

 $\Box$  Yes, I would like to receive communications relating to my Janssen medication.

□ Yes, I would like to receive communications relating to other Janssen products and services.

For privacy rights and choices specific to California residents, please see Janssen's California privacy notice available at <a href="https://www.janssen.com/us/privacy-policy#california">https://www.janssen.com/us/privacy-policy#california</a>

#### Permission for text communications:

Yes, I would like to receive text messages. By selecting this option, I agree to receive text messages as allowed by this Form to the cell phone number provided below. Message and data rates may apply. Message frequency varies. I understand I am not required to provide my permission to receive text messages to participate in the Janssen patient support programs or to receive any other communications I have selected.

Cell phone number: \_

#### Patient name (print):

#### Patient sign here: \_\_\_\_\_

Date:

If the patient cannot sign, patient's legally authorized representative must sign below:

By: \_\_\_\_

Date:

(Signature of person legally authorized to sign for patient)

Describe relationship to patient and authority to make medical decisions for patient:





PATIENT INFORMATION (PEOLIDED



### **Enrollment and Prescription Form**

Complete and fax this form to 844-322-9402 or mail to 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560 For assistance, call 844-4-withMe (844-494-8463), Monday-Friday, 8:00 AM-8:00 PM ET

TREMFYA withMe cannot accept any information without an executed Janssen CarePath Business Associate Agreement or Patient Authorization Form, which can be found on pages 3 and 4 of this document.

The information you provide will be used by Janssen Biotech, Inc., our affiliates, and our service providers for your patient's enrollment and participation in TREMFYA with Me via Janssen CarePath. Our Privacy Policy governs the use of the information you provide. By submitting this form, you indicate that you read, understand, and agree to these terms.

I. PAHENTINI OKMATIOI		2						
PATIENT FIRST NAME	PATIENT LAST NAME		PATIENT LAST NAME	_DO8 (MM/DD/YYYY)				
PATIENT CELL PHONE	ALTERNATE PHONE			PATIENT E-MAIL				
PATIENT ADDRESS	PATIENT CITY			PATIENT STATEPATIENT ZIP CODE				
2. INSURANCE INFORMAT		RED Please fill out this	section in its entirety a	nd provide a copy of	the front and back	of the pharmacy in	osurance card )	
PHARMACY INSURANCE (Rx)						or the pharmacy h		
PHARMACY INSURANCE (Rx)			IN	ISURANCE PROVIDER PHONE				
Rx GROUP #		Rx ID #	R	<pre> BIN #</pre>		Rx PCN #		
Rx CARDHOLDER FIRST NAME Failure to provide this information may result in				Rx RELATIONSHIP TO PATIENT				
MEDICAL INSURANCE (MI)			M	I GROUP #		MI ID #		
MI CARDHOLDER FIRST NAME MI CARDHOLDER LAST N			MI CARDHOLDER LAST NAME	MI RELATIONSHIP TO PATIENT				
3. PRESCRIBER INFORMAT		RED)						
PRESCRIBER FIRST NAME		PRESCRIBER LA	ST NAME		NPI #	TAX	ID#	
					OFFICE CONTACT LAST NAME			
				OFFICE FAX				
OFFICE ADDRESSOFFICE			OFFICE CITY	OFFICE STATEOFFICE ZIP CODE				
4. CLINICAL INFORMATIO	N (REQUIRED	). Information requested	is for benefits investigation	on purposes only.)				
PRIMARY DIAGNOSIS (select on	e):			PRIOR THERAPIES	i:			
PSORIASIS	□ L40.0	Other ICD-10 Code:		Arava®	Corticosteroids	Cosentyx®	Cyclosporine	
ACTIVE PSORIATIC ARTHRITIS	L40.50	Other ICD-10 Code:		Enbrel®	Humira®	Methotrexate	□ Otezla®	
DATE OF DIAGNOSIS OR YEARS WITH DIS	EASE:			Phototherapy	□ Skyrizi®	Soriatane®	□ Stelara®	
SECONDARY DIAGNOSIS (if any):				□ Taltz®	□ Xeljanz®	None	Other	
ICD-10 Code:								
5. PRIOR AUTHORIZATION								
Prior Authorization Form Assistance TREMFYA®. Assistance includes obtai authorization form will be provided to the patient's plan and provides status	ning the healtl o your office fo	h plan-specific prior author or possible completion and	ization form, and providing submission in the office's se	g it based upon the pa ole discretion. TREMFY	tient-specific informat A withMe also actively	ion provided on this	form. The partially comple	eted prior
I do NOT wish to receive Prior Auth medication if delayed >5 days or de		Assistance or Status Moni	toring. This opt-out does n	ot apply when the patie	ent is signed up to rece	ive the product at no	cost until their insurance co	overs the
Prior Authorization is already on f		tient's plan for treatment	with TREMFYA®.					
6. PRESCRIPTION INFORM								

Rx DIRECTIONS						
STARTER DOSE:	MAINTENANCE THERAPY:					
□ Single-dose One-Press patient-controlled injector 100 mg/mL SC at □ Week 0 □ Week 4	□ Single-dose One-Press patient-controlled injector; 100 mg/mL SC every 8 weeks Refills #					
(NDC: 57894-640-11)	□Single-dose prefilled syringe; 100 mg/mL SC every 8 weeks Refills #					
□ Single-dose prefilled syringe 100 mg/mL SC at □ Week 0 □ Week 4						
(NDC: 57894-640-01)						
PRESCRIBER SIGNATURE REQUIRED (NO STAMPS ALLOWED) TO VALIDATE PRESCRIPTION: I certify that therapy with TREMFYA® is medically necessary for this patient. I will be supervising the patient's						

treatment accordingly, and I have reviewed the current TREMFYA® full Prescribing Information. I authorize TREMFYA withMe to act on my behalf for the limited purposes of transmitting this prescription to the appropriate pharmacy designated by me, the patient, or the patient's plan.

#### **Delay and Denial Support**

When commercial insurance coverage is delayed >5 business days or denied, TREMFYA with Me offers eligible patients TREMFYA® at no cost until their commercial insurance covers the medication. By enrolling the patient for this support, I certify that I agree to the program requirements and will take any necessary action described in the requirements for my patient. See program requirements on the next page.

DATE

PRESCRIBER SIGNATURE (Dispense as written)

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

Information about your patient's insurance coverage, cost support options, and treatment support is given by service providers for TREMFYA withMe via Janssen CarePath. The information you get does not require you or your patient to use any Janssen product. Because the information we give you comes from outside sources, TREMFYA withMe cannot promise the information will be complete. TREMFYA withMe cost support is not for patients in the Johnson & Johnson Patient Assistance Foundation.

#### **Delay and Denial Support**

TREMFYA withMe offers eligible patients TREMFYA® (guselkumab) at no cost until their commercial insurance covers the medication. See program requirements below.

#### **Program Requirements**

#### To be eligible, patient must have:

- 1. a TREMFYA® prescription for an on-label, FDA-approved indication
- 2. commercial insurance with biologics coverage
- 3. a delay of more than 5 business days or a denial of treatment from their insurance.

In addition, for patient to be eligible, Prescriber must submit:

- 4. a program enrollment form\*
- 5. a coverage determination form (ie, prior authorization or prior authorization with exception) to the commercial insurance. If coverage is denied, Prescriber must also submit a Letter of Formulary Exception, Letter of Medical Necessity, or appeal within 90 days of patient becoming eligible for patient to stay in the program.

#### Patient is not eligible if:

- 1. patient uses any state or federal government-funded healthcare program to cover medication costs. Examples of these programs are Medicare, Medicaid, TRICARE, Department of Defense, and Veterans Administration
- 2. prior authorization is denied due to missing information on coverage determination form, use for a non-FDA-approved indication, or invalid clinical rationale.

Patient is eligible until commercial insurance covers the medication. Program requires periodic verification of insurance coverage status to confirm continued eligibility.

Delay and Denial Support covers the cost of therapy only—not associated administration cost. Prescriber cannot bill commercial insurance plan for any part of the prescribed subcutaneous treatment. Patient cannot submit the value of the free product as a claim for payment to any health plan. Program good only in the United States and its territories. Void where prohibited, taxed, or limited by law. Program terms may change.

#### Participating prescribers authorize TREMFYA withMe to:

- 1. conduct a benefits investigation and confirm prior authorization requirements
- 2. provide prior authorization form assistance and status monitoring, including the exceptions and appeals processes
- 3. refer eligible patients to Wegmans Specialty Pharmacy for further program support and shipment of medication
- 4. support the transition of patients to commercial product if the medication is covered
- 5. check insurance coverage status during the program.

\*TREMFYA withMe, via Janssen CarePath, cannot accept any information without an executed Janssen CarePath Business Associate Agreement and/or Patient Authorization on file. The Patient Authorization can be found on this Enrollment and Prescription Form, or patient can create an account on <u>MyJanssenCarePath.com</u> and electronically sign a patient authorization there.

Please see full <u>Prescribing Information</u> and <u>Medication Guide</u> for TREMFYA<sup>®</sup>. Provide the Medication Guide to your patients and encourage discussion.

