CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761345Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
ELREXFIO (elranatamab-bcmm) REMS

I. Administrative Information

Risk: Cytokine Release Syndrome, neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome

Application Number: BLA 761345

Application Holder: Pfizer Inc.

Initial REMS Approval: 08/2023

II. REMS Goal

The goal of the ELREXFIO REMS is to mitigate the risks of Cytokine Release Syndrome (CRS), and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by:

- Ensuring prescribers are aware of the importance of monitoring for signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to ELREXFIO

III. REMS Requirements

Pfizer Inc. must ensure that healthcare providers, patients, pharmacies, healthcare settings and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe ELREXFIO must:	
To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the Prescriber Training Program and Adverse Reaction Management Guide. 3. Successfully complete the Knowledge Assessment and submit it to the REMS. 4. Enroll in the REMS by completing and submitting the Prescriber Enrollment Form to the REMS.
Before treatment initiation (first step-up dose)	5. Counsel the patient on: a) how to recognize and respond to signs and symptoms of CRS and neurologic toxicity including ICANS, b) the need to report all symptoms suggestive of CRS and neurologic toxicity including ICANS to their healthcare provider or emergency room provider immediately, c) the need to carry the Patient Wallet Card at all times. 6. Complete the Patient Wallet Card and provide the Patient Wallet Card to the patient.

At all times	7. Report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS.
2. Patients who are prescribed ELREXFIO:	
Before treatment	1. Receive counseling from the prescriber using the Patient Wallet Card.
At all times	2. Have the Patient Wallet Card with you and inform other healthcare providers about treatment with ELREXFIO.
3. Pharmacies and healthcare settings that dispense ELREXFIO must:	
To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy and/or healthcare setting. 2. Have the Authorized Representative review the Pharmacy and Healthcare Setting Training Program. 3. Have the Authorized Representative enroll in the REMS by completing and submitting the Pharmacy and Healthcare Setting Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing ELREXFIO on the REMS requirements using the Pharmacy and Healthcare Setting Training Program.
Before dispensing	5. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
To maintain certification to dispense	6. Have a new Authorized Representative enroll in the REMS by completing and submitting the Pharmacy and Healthcare Setting Enrollment Form to the REMS if the Authorized Representative changes.
At all times	7. Report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS. 8. Not distribute, transfer, loan or sell ELREXFIO except to certified pharmacies and healthcare settings. 9. Maintain records of staff training. 10. Maintain records that processes and procedures are in place and are being followed. 11. Maintain records of all ELREXFIO dispenses and provide data to the REMS and Wholesalers-Distributors, as requested. 12. Comply with audits carried out by Pfizer Inc. or a third party acting on behalf of Pfizer Inc. to ensure that all training, processes, and procedures are in place and are being followed.
4. Wholesalers-distributors that distribute ELREXFIO must:	
To be able to distribute	1. Establish processes and procedures to ensure that ELREXFIO is distributed only to certified pharmacies and healthcare settings. 2. Train all relevant staff involved in distribution on the REMS requirements.
At all times	3. Distribute only to certified pharmacies and healthcare settings.

4. Maintain records that all processes and procedures are in place and are being followed.

5. Maintain and submit records of drug distribution to the REMS at least on a monthly basis.

6. Comply with audits carried out by Pfizer Inc. or a third party acting on behalf of Pfizer Inc. to ensure that all processes and procedures are in place and are being followed.

Pfizer Inc. must provide training to healthcare providers who prescribe ELREXFIO. The training includes the following educational materials: Prescriber Training Program, Adverse Reaction Management Guide, and Knowledge Assessment. The training must be available online.

Pfizer Inc. must provide training to pharmacies and healthcare settings that dispense ELREXFIO. The training includes the following educational material: Pharmacy and Healthcare Setting Training Program. The training must be available online.

To inform healthcare providers about the REMS and the risks and safe use of ELREXFIO, Pfizer Inc. must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plans
Healthcare providers including oncologists, oncology physician assistants, oncology nurse practitioners, hematologists, and oncology nurses who are likely to prescribe and care for patients treated with ELREXFIO	**REMS Letters:** Healthcare Provider REMS Letter, Professional Society REMS Letter with attachment REMS Fact Sheet 1. E-mail within 30 calendar days of the date ELREXFIO is first commercially distributed and again 12 months later. a. Send by mail within 30 calendar days of the date the first e-mail was sent if a healthcare provider's e-mail address is not available, or the e-mail is undeliverable. b. Send a second e-mail within 30 calendar days of the date the first e-mail was sent if the first e-mail is marked unopened. c. Send by mail within 30 calendar days of the date the second e-mail was sent if the second e-mail is marked as unopened. 2. Disseminate through field-based sales and medical representatives for 12 months from the date ELREXFIO is first commercially distributed. 3. Disseminate within 30 calendar days of the date ELREXFIO is first commercially distributed and again 12 months later through the following professional societies and request the letter or content be provided to their members. a. American Society of Clinical Oncology (ASCO); American Society of Hematology (ASH); Advanced Practitioner Society for Hematology and Oncology (APSHO); Oncology Nursing Society (ONS); National Comprehensive Cancer Network (NCCN); Society of Hematologic Oncology (SOHO); Hematology Oncology Pharmacy Association (HOPA); American Pharmacists Association (APhA); American Society of Health-System Pharmacists (ASHP) 4. Disseminate at Professional Meetings where Pfizer Inc. has a presence for 12 months from the date ELREXFIO is first commercially distributed. REMS Fact Sheet 1. Disseminate at Professional Meetings where Pfizer Inc. has a presence for 12 months from the date ELREXFIO is first commercially distributed. 2. Disseminate through field-based sales and medical representatives during the initial and/or follow-up discussion with healthcare providers for 12 months after ELREXFIO is first commercially distributed. Field-based sales and/or medical representatives to orally review the key risk messages contained in the REMS Fact Sheet during the visit with the healthcare provider.

To support REMS operations, Pfizer Inc. must:

1. Authorize dispensing for each prescription based on verifying the prescriber is certified.
2. Establish and maintain the REMS Website, www.ELREXFIOREMS.com. The REMS Website must include the capability to enroll prescribers, pharmacies and healthcare settings, complete training online, maintain records of that training, and an option to print the Prescribing Information (PI), Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS- specific links to the REMS Website.
3. Make the REMS Website fully operational and all REMS materials available through the website and the REMS Coordinating Center at the time ELREXFIO first becomes commercially available.
4. Establish and maintain a REMS Coordinating Center for REMS participants at 1-844-923-7845.
5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the REMS.
6. Ensure prescribers, pharmacies and healthcare settings can enroll in the REMS online, by fax and e-mail.
7. Ensure pharmacies and healthcare settings are able to obtain authorization to dispense by phone and online.
8. Notify prescribers, pharmacies and healthcare settings within 1 calendar day after they become certified in the REMS.
9. Provide certified prescribers access to the database of certified pharmacies and healthcare settings.
10. Provide certified pharmacies and healthcare settings access to the database of certified prescribers.
11. Provide authorized wholesalers-distributors access to the list of certified pharmacies and healthcare settings.
12. Report serious CRS and neurologic toxicity including ICANS as soon as possible to the FDA but no later than 15 calendar days from the initial receipt of the information by the applicant. This requirement does not affect the applicant's other reporting and follow-up requirements under applicable FDA regulations.

To ensure REMS participants' compliance with the REMS, Pfizer Inc. must:

13. Verify annually that the designated authorized representative for certified pharmacies and healthcare settings remains the same. If different, the pharmacy/healthcare setting must re-certify with a new authorized representative.
14. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: ELREXFIO distribution and dispensing; certification of pharmacies and healthcare settings; authorized wholesalers-distributors; and audits of REMS participants. These records must be readily available for FDA inspections.
15. Monitor pharmacies, healthcare settings, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including decertification or deauthorization.
16. Establish and maintain a plan for addressing noncompliance with REMS requirements.
17. Audit all certified pharmacies and healthcare settings within 180 calendar days after the pharmacy or healthcare setting receives their first shipment of ELREXFIO and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.
18. Audit wholesalers-distributors that have distributed ELREXFIO within 180 calendar days of being authorized to distribute ELREXFIO and annually thereafter to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements. Take corrective action if noncompliance is identified.
19. Take reasonable steps to improve operations of and compliance with the requirements in the ELREXFIO REMS based on monitoring and evaluation of the ELREXFIO REMS.

IV. REMS Assessment Timetable

Pfizer Inc. must submit REMS Assessments to the FDA annually from the date of the initial approval of the REMS (08/14/2023). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Pfizer Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the ELREXFIO REMS:

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Pharmacy and Healthcare Setting:

2. Pharmacy and Healthcare Setting Enrollment Form

Training and Educational Materials

Prescriber:

3. Prescriber Training Program
4. Adverse Reaction Management Guide
5. Knowledge Assessment

Patient:

6. Patient Wallet Card

Pharmacy and Healthcare Setting:

7. Pharmacy and Healthcare Setting Training Program

Communication Materials

8. Healthcare Provider REMS Letter
9. Professional Society REMS Letter
10. REMS Fact Sheet

Other Materials

11. REMS Website

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Communication Plan
2. Elements to Assure Safe Use
    - Health care providers who prescribe ELREXFIO are specially certified under 505-1(f)(3)(A)
    - Pharmacies and health care settings that dispense ELREXFIO are specially certified under 505-1(f)(3)(B)
3. Implementation System
4. Timetable for Submission of Assessments

ELREXFIO™ REMS
Prescriber Enrollment Form

Instructions

To become a certified prescriber in the ELREXFIO REMS and prescribe ELREXFIO:

- Review the Prescribing Information, the **Prescriber Training Program** and **Adverse Reaction Management Guide**.
- Successfully complete and submit the **Knowledge Assessment** and this form online at www.ELREXFIOREMS.com
- If not enrolling online,
  - Complete all required fields below and submit this form to the REMS Coordinating Center by e-mail at ELREXFIOREMS@ubc.com, or via fax to 1-800-349-5131.
  - Complete the **Knowledge Assessment** and submit it to the REMS Coordinating Center by e-mail at ELREXFIOREMS@ubc.com, or via fax to 1-800-349-5131.
  - The ELREXFIO REMS will verify both the **Knowledge Assessment** and **Prescriber Enrollment Form** are complete and provide confirmation of certification via e-mail after processing.

If ELREXFIO will be dispensed and administered in the same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Certified ELREXFIO Prescribers cannot be designated as the Authorized Representative for a Pharmacy or Healthcare Setting.

PRESCRIBER INFORMATION (Fields marked with an * are REQUIRED)

First Name*:	Last Name*:	
Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify) _____		
Specialty* (Select one): ☐ Oncology ☐ Hematology ☐ Internal Medicine/Family Medicine ☐ Other (please specify) _____		
National Provider Identifier (NPI)#*:	State License #*:	State of Practice*:
Practice/Facility Name*:		
Address Line 1*:		
Address Line 2:		
City*:	State*:	Zip Code*:
E-mail*:	Phone*:	Fax:

I am a prescriber becoming certified in the ELREXFIO REMS. By signing this form, I agree to comply with all REMS requirements.

To become certified to prescribe, I must:

- Review the ELREXFIO Prescribing Information.
- Review the **Prescriber Training Program** and the **Adverse Reaction Management Guide**.
- Successfully complete the **Knowledge Assessment** and submit it to the REMS.
- Enroll in the REMS by completing and submitting the **Prescriber Enrollment Form** to the REMS.

Before treatment initiation (first step-up dose) of ELREXFIO, I must:

- Counsel the patient on:
  - how to recognize and respond to symptoms of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)
  - the need to report all symptoms suggestive of CRS and neurologic toxicity including ICANS to their healthcare provider or emergency room healthcare provider immediately,
  - the need to carry the **Patient Wallet Card** at all times.
- Complete the **Patient Wallet Card** and provide the **Patient Wallet Card** to the patient.

At all times, I must:

- Report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS.

Signature*:	Date (MM/DD/YYYY)*:

www.ELREXFIOREMS.com | PHONE: 1-844-923-7845
FAX 1-800-349-5131 | e-mail: ELREXFIOREMS@ubc.com

ELREXFIO™ REMS Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the ELREXFIO REMS and dispense ELREXFIO, a pharmacy/healthcare setting must designate an *Authorized Representative to:

- Review the **Pharmacy and Healthcare Setting Training Program**
- Complete this **Pharmacy and Healthcare Setting Enrollment Form**:
  - online at www.ELREXFIOREMS.com for immediate enrollment
  - by e-mail at ELREXFIOREMS@ubc.com or
  - via fax to 1-800-349-5131.
- The ELREXFIO REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and provide confirmation of certification via e-mail after processing.
- ELREXFIO cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

***Certified ELREXFIO Prescribers cannot be designated as the Authorized Representatives for a Pharmacy or Healthcare Setting.**

PHARMACY AND HEALTHCARE SETTING INFORMATION (Fields marked with an * are REQUIRED)

Enrollment Type (Please Check One*) ☐ **New Certification** ☐ **Change in Authorized Representative**

Pharmacy/Healthcare Setting Name*:	
Pharmacy/Healthcare Setting National Provider Identifier (NPI)#*: (If you do not have an NPI, please reach out to the ELREXFIO REMS)	DEA# (On file with distributor account):

Pharmacy/Healthcare Setting Type (select one)*: ☐ Inpatient Hospital Pharmacy ☐ Outpatient Hospital Pharmacy ☐ Oncology Infusion Center ☐ Community Oncology Physician Office ☐ Specialty Pharmacy ☐ Other (please specify) _____

Address Line 1*:		Address Line 2:
City*:	State*:	Zip Code*:
Phone*:	Fax*:	

SHIP TO INFORMATION (Fields marked with an * are REQUIRED)

Ship To Address ☐ **Same as Above** **Ship To Contact Name*:**

Address Line 1*:		Address Line 2:
City*:	State*:	Zip Code*:
Phone*:	Fax*:	

www.ELREXFIOREMS.com | PHONE: 1-844-923-7845
FAX 1-800-349-5131 | e-mail: ELREXFIOREMS@ubc.com

ELREXFIO™ REMS Pharmacy and Healthcare Setting Enrollment Form

AUTHORIZED REPRESENTATIVE INFORMATION (Fields marked with an * are REQUIRED)

E-mail*:

First Name*: | Last Name*:

Credentials* (select one): ☐ PharmD ☐ R.Ph ☐ RN ☐ Other (please specify): (e.g., MD, DO, Office Administrator, Practice Manager):

Phone*: | Fax*:

Your pharmacy or healthcare setting's information will be shared with Pfizer Inc.'s wholesaler-distributor partners, to allow your pharmacy or healthcare setting to purchase product.

AUTHORIZED REPRESENTATIVE RESPONSIBILITIES

As the Authorized Representative, I must:

- Review the **Pharmacy and Healthcare Setting Training Program**.
- Enroll in the REMS by completing and submitting this **Pharmacy and Healthcare Setting Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing ELREXFIO on the REMS requirements using the **Pharmacy and Healthcare Setting Training Program**.
- Oversee implementation and compliance with the REMS requirements on behalf of the pharmacy and/or healthcare setting.

Before dispensing, staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

At all times, staff must:

- Report serious adverse events of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) to the REMS.
- Not distribute, transfer, loan or sell ELREXFIO except to certified pharmacies and healthcare settings.
- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Maintain records of all ELREXFIO dispenses and provide data to the REMS and Wholesalers-Distributors, as requested.
- Comply with audits carried out by Pfizer Inc. or a third party acting on behalf of Pfizer Inc. to ensure that all training, processes, and procedures are in place and are being followed.
- Have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS if the Authorized Representative changes.

Authorized Representative Signature*: | Date (MM/DD/YYYY)*:

ELREXFIO™
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

PRESCRIBER TRAINING PROGRAM

Risk Evaluation and Mitigation Strategy (REMS)

Pfizer Oncology

Reference ID: 5226170

ELREXFIO Prescriber Training Module

- This educational module contains information on adverse reactions associated with ELREXFIO including Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The adverse reactions listed within this module are not all inclusive of adverse reactions associated with ELREXFIO.
- Please refer to the Prescribing Information for additional information.

This training module provides details related to prescriber requirements of the ELREXFIO REMS.

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Training Outline

- **Prescriber REMS Requirements** (Slides 6-7)
- **Risk of Cytokine Release Syndrome (CRS)** (Slides 9-14)
- **Risk of Neurologic Toxicity including Effector Cell-Associated Neurotoxicity Syndrome (ICANS)** (Slides 16-18)

ELREXFIO™ (elranatamab-bcmm)
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Reference ID: 5226170

What is a REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the FDA to manage known or potential serious risks associated with a drug product. The FDA has determined that a REMS is necessary to ensure that the benefits of ELXREXFIO outweigh its risks.
- The goal of the ELREXFIO REMS is to mitigate the risks of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by ensuring prescribers are aware of the importance of monitoring for signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to ELREXFIO.

Reference ID: 5226170

ELREXFIO Indication

- ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

/01

Prescriber REMS Requirements

ELREXFIO™
(elranatamab-bcmm)

Prescriber REMS Certification Requirements

Requirements to become certified to prescribe ELREXFIO are as follows:

- Review the Prescribing Information, this **Prescriber Training Program**, and the **Adverse Reaction Management Guide**
- Successfully complete the **Knowledge Assessment** and submit it to the REMS
- Enroll in the REMS by completing and submitting the **Prescriber Enrollment Form** to the REMS
- Before treatment initiation (first step-up dose), complete the **Patient Wallet Card** and provide the **Patient Wallet Card** to the patient

At all times

- Report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS

ELREXFIO Prescribers cannot be designated as the Authorized Representative for a certified Pharmacy or Healthcare Setting*

*If ELREXFIO will be dispensed and administered in the same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Prescriber Counseling

- Counsel the patient or caregiver on how to recognize and respond to signs and symptoms of CRS and neurologic toxicity including ICANS using the **Patient Wallet Card**, and instruct the patient to carry it with them at all times.
- Instruct the patient that they should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.
- Instruct the patient of the need to report all symptoms suggestive of CRS and/or neurologic toxicity including ICANS to their healthcare provider or emergency room provider immediately.
- Advise patients not to drive or operate heavy or potentially dangerous machinery for 48 hours after completing each of the 2 step-up doses and the first treatment dose within the ELREXFIO step-up dosing schedule and in the event of new onset of any neurological toxicity symptoms until symptoms resolve.

ELREXFIO™ (elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

/02

Cytokine Release Syndrome (CRS)

ELREXFIO Boxed Warning

Cytokine Release Syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO. Initiate treatment with ELREXFIO step-up dosing schedule to reduce risk of CRS. Withhold ELREXFIO until CRS resolves or permanently discontinue based on severity.

Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and serious and life-threatening reactions, can occur in patients receiving ELREXFIO. Monitor patients for signs and symptoms of neurologic toxicity, including ICANS, during treatment. Withhold ELREXFIO until the neurologic toxicity resolves or permanently discontinue based on severity.

ELREXFIO is available only through a restricted program called the ELREXFIO Risk Evaluation and Mitigation Strategy (REMS).

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Cytokine Release Syndrome

- CRS, including life-threatening or fatal reactions, can occur following treatment with ELREXFIO
- CRS was reported in 58% of patients who received the recommended dosage in the clinical trial (n=183)
- Most patients experienced CRS after the first step-up dose (43%) or the second step-up dose (19%), with 7% of patients having CRS after the-first treatment dose and 1.6% of patients after a later dose
- Recurrent CRS occurred in 13% of patients
- Patients developed mostly Grade 1 (44%) and Grade 2 (14%) CRS.
- 1 (0.5%) patient developed Grade 3 CRS
- The median time to onset of CRS was 2 (range: 1 to 9) days after the most recent dose of ELREXFIO
- The median duration of CRS was 2 (range: 1 to 19) days

Reference ID: 5226170

Clinical Signs and Symptoms of CRS

- Patients should be closely monitored for signs or symptoms of CRS
- Potentially life-threatening complications of CRS may include:
  - Cardiac dysfunction
  - Adult respiratory distress syndrome
  - Neurologic toxicity
  - Renal and/or hepatic failure
  - Disseminated intravascular coagulation (DIC)

Signs and Symptoms

- Fever
- Chills
- Hypoxia
- Hypotension
- Sinus Tachycardia
- Headache
- Elevated Liver Enzymes

Lee DW, Gardner R, Porter DL, et al. Current concepts in the diagnosis and management of cytokine release syndrome. Blood 2014; 124(2): 188-95. Errata in Blood: 2015;126(8):1048. And 2016;128(11):1533

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

ELREXFIO Dosing Schedule

Dosing Schedule	Day	ELREXFIO Dose	
Step-up Dosing Schedule	Day 1[a,]	Step-up dose 1	12 mg
	Day 4[a,b]	Step-up dose 2	32 mg
	Day 8[a,c]	First treatment dose	76 mg
Weekly Dosing Schedule	One week after first treatment dose and weekly thereafter[d] through week 24	Subsequent treatment doses	76 mg
Biweekly (Every 2 Weeks) Dosing Schedule ***Responders only week 25 onward**	Week 25 and every 2 weeks thereafter[d]	Subsequent treatment doses	76 mg

[a] Administer pre-treatment medications prior to each dose in the ELREXFIO step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose
[b] A minimum of 2 days should be maintained between step-up dose 1 (12 mg) and step–up dose 2 (32 mg).
[c] A minimum of 3 days should be maintained between step-up dose 2 (32 mg) and the first treatment (76 mg) dose.
[d] A minimum of 6 days should be maintained between treatment doses.
Note: See Table 2 in Prescribing Information for recommendations on restarting ELREXFIO after dose delays.

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Important Dosing Information

- Administer the following pretreatment medications approximately 1 hour before the first three doses of ELREXFIO in the step-up dosing schedule, which includes step-up dose 1, step-up dose 2, and the first treatment dose to reduce the risk of CRS:
  - Acetaminophen (or equivalent) 650 mg orally
  - Dexamethasone (or equivalent) 20 mg orally or intravenously
  - Diphenhydramine (or equivalent) 25 mg orally
- Due to the risk of CRS, patients should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.

Reference ID: 5226170

CRS Management

- Counsel patients to seek medical attention should signs or symptoms of CRS occur.
- At the first sign of CRS, immediately evaluate patients for hospitalization.
- Withhold or permanently discontinue ELREXFIO based on severity and manage CRS according to the recommendations in the Prescribing Information and in the **Adverse Reaction Management Guide**. Consider further management per current practice guidelines.
- Administer supportive therapy for CRS based on severity, which may include intensive care for severe or life-threatening CRS.
- Consider laboratory testing to monitor for disseminated intravascular coagulation (DIC), hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function.

Reference ID: 5226170

/03

Neurologic Toxicity Including ICANS

ELREXFIO™
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE

Neurologic Toxicity Including ICANS

- Neurologic toxicity, including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), and serious and life-threatening reactions, can occur in patients receiving ELREXFIO.
- In the clinical trial, neurologic toxicity was reported in 59% of patients receiving ELREXFIO.
- Grade 3 or 4 neurologic toxicity occurred in 7% of patients. Neurologic toxicities included headache (18%), encephalopathy (14%), motor dysfunction (14%), sensory neuropathy (13%), and Guillain-Barre Syndrome (0.5%)
- In the clinical trial, ICANS was reported in 3.3% of patients receiving ELREXFIO.
- The most frequent clinical manifestations of ICANS included a depressed level of consciousness and Grade 1 or Grade 2 Immune Effector Cell-Associated Encephalopathy (ICE) scores.
- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.
- ICANS occurred in 2.7% of patients after the first step-up dose (2.7%),
- One (1; 0.5%) patient had ICANS after the second step-up dose, and
- One (1; 0.5%) patient had ICANS after subsequent dose(s).
- Recurrent ICANS occurred in 1.1% of patients.
- The median time to onset was 3 (range: 1 to 4) days after the most recent dose, with a median duration of 2 (range: 1 to 18) days.

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Neurologic Toxicity Management

- Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity occur.
- Monitor patients for signs or symptoms of neurologic toxicity during treatment.
- At the first sign of neurologic toxicity including ICANS, evaluate and treat patients immediately based on severity.
- Withhold or permanently discontinue ELREXFIO and manage neurologic toxicity according to the recommendations in the Prescribing Information and in the table below. Consider further management per current practice guidelines.

Recommendations for Management of Neurologic Toxicity, excluding ICANS		
Adverse Reaction	Severity	Actions
Neurologic Toxicity (excluding ICANS)	Grade 1	• Withhold ELREXFIO until neurologic toxicity symptoms resolve or stabilize.
	Grade 2 Grade 3 (First occurrence)	• Withhold ELREXFIO until neurologic toxicity symptoms improve to Grade 1 or less. • Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	• Permanently discontinue ELREXFIO. • Provide supportive therapy, which may include intensive care.

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

ICANS Management

- Counsel patients to seek medical attention should signs or symptoms of ICANS occur.
- Monitor patients for signs or symptoms of ICANS during treatment.
- At the first sign of ICANS, evaluate and treat patients immediately based on severity.
- Withhold or permanently discontinue ELREXFIO and manage ICANS according to the recommendations in the Prescribing Information and **Adverse Reaction Management Guide**. Consider further management per current practice guidelines.

Reference ID: 5226170

Adverse Event Reporting

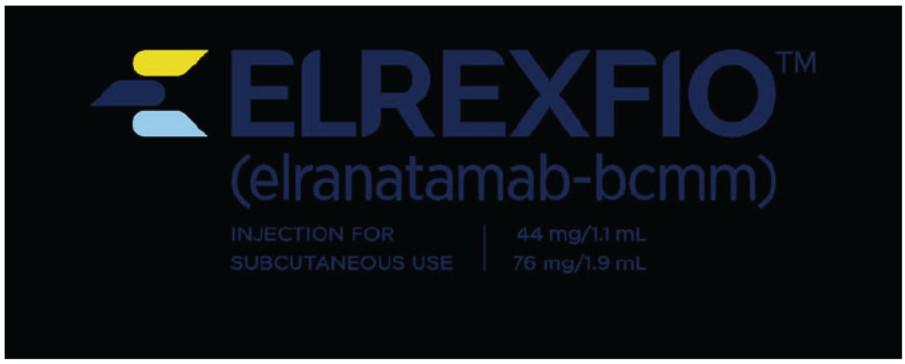
- Reporting of suspected adverse events following administration of therapy is vital for the continued monitoring of the risk/benefit balance of therapy.
- Healthcare providers must report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS Coordinating Center at 1-844-923-7845. Report all other suspected adverse events associated with ELREXFIO to Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Reference ID: 5226170

ELREXFIO™
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

For further information, please visit www.ELREXFIOREMS.com or call 1-844-923-7845

Pfizer Oncology



ELREXFIO Adverse Reaction Management Guide

This is supplemental to the ELREXFIO US Prescribing Information (USPI).

Pfizer

Reference ID: 5226170

Management of Cytokine Release Syndrome (CRS)

Identify CRS based on clinical presentation. Evaluate and treat other causes of fever, hypoxia, and hypotension.

If CRS is suspected, withhold ELREXFIO until CRS resolves. Clinical signs and symptoms of CRS may include, but are not limited to, fever, hypoxia, chills, hypotension, tachycardia, headache, and elevated liver enzymes. At first sign of CRS, evaluate patients immediately for hospitalization. Manage according to the recommendations in Table 1 below and consider further management per current practice guidelines. Withhold or permanently discontinue ELREXFIO based on severity. Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS. Consider laboratory testing to monitor for disseminated intravascular coagulation (DIC), hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function.

Table 1: Recommendations for Management of CRS

Grade[a]	Presenting Symptoms	Actions
Grade 1	Temperature ≥100.4°F (38°C)[b]	• Withhold ELREXFIO until CRS resolves.[c] • Administer pretreatment medications prior to next dose of ELREXFIO.
Grade 2	• Temperature ≥100.4°F (38°C) with either: • Hypotension responsive to fluid and not requiring vasopressors, and/or • Oxygen requirement of low-flow nasal cannula[d] or blow-by	• Withhold ELREXFIO until CRS resolves.[c] • Monitor patients daily for 48 hours following the next dose of ELREXFIO. Instruct patients to remain within proximity of a healthcare facility and consider hospitalization. • Administer pretreatment medications prior to next dose of ELREXFIO.
Grade 3 (First occurrence)	• Temperature ≥100.4°F (38 °C) with either: • Hypotension requiring one vasopressor with or without vasopressin, and/or • Oxygen requirement of high-flow nasal cannula[d], facemask, non-rebreather mask, or Venturi mask	• Withhold ELREXFIO until CRS resolves.[c] • Provide supportive therapy, which may include intensive care. • Patients should be hospitalized for 48 hours following the next dose of ELREXFIO. • Administer pretreatment medications prior to next dose of ELREXFIO.
Grade 3 (Recurrent)	• Temperature ≥100.4°F (38 °C) with either: • Hypotension requiring one vasopressor with or without vasopressin, and/or • Oxygen requirement of high-flow nasal cannula[d], facemask, non-rebreather mask, or Venturi mask.	• Permanently discontinue therapy with ELREXFIO. • Provide supportive therapy, which may include intensive care.
Grade 4	• Temperature ≥100.4°F (38°C) with either: • Hypotension requiring multiple vasopressors (excluding vasopressin), and/or • Oxygen requirement of positive pressure (e.g., continuous positive airway pressure [CPAP], bilevel positive airway pressure [BiPAP], intubation, and mechanical ventilation)	• Permanently discontinue therapy with ELREXFIO. • Provide supportive therapy, which may include intensive care.

a. Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for CRS.
b. Attributed to CRS. Fever may not always be present concurrently with hypotension or hypoxia as it may be masked by interventions such as antipyretics or anti-cytokine therapy.
c. See Table 2 in USPI for recommendations on restarting ELREXFIO after dose delays.
d. Low-flow nasal cannula is ≤6 L/min, and high-flow nasal cannula is >6 L/min.

Management of Neurologic Toxicity and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS)

Manage neurologic toxicity and ICANS according to the recommendations in Tables 2 and 3 below and consider further management per current practice guidelines.

At the first sign of neurologic toxicity, including ICANS, withhold ELREXFIO and consider neurology evaluation. Rule out other causes of neurologic symptoms. Provide supportive therapy, which may include intensive care, for severe or life-threatening neurologic toxicities including ICANS.

Table 2: Recommendations for Management of Neurologic Toxicity, excluding ICANS

Adverse Reaction	Severity	Actions
Neurologic Toxicity (excluding ICANS)	Grade 1	• Withhold ELREXFIO until neurologic toxicity symptoms resolve or stabilize.
	Grade 2 Grade 3 (First occurrence)	• Withhold ELREXFIO until neurologic toxicity symptoms improve to Grade 1 or less. • Provide supportive therapy.
	Grade 3 (Recurrent) Grade 4	• Permanently discontinue ELREXFIO. • Provide supportive therapy, which may include intensive care.

Table 3: Recommendations for Management of ICANS

Grade[a]	Presenting Symptoms[b]	Actions
Grade 1	ICE score 7-9[c] Or depressed level of consciousness[d]: awakens spontaneously.	• Withhold ELREXFIO until ICANS resolves.[e] • Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis.
Grade 2	ICE score 3-6[c] or depressed level of consciousness[d]: awakens to voice.	• Withhold ELREXFIO until ICANS resolves. • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. • Monitor patients daily for 48 hours following the next dose of ELREXFIO. Instruct patients to remain within proximity of a healthcare facility, and consider hospitalization.

Grade[a]	Presenting Symptoms	Actions
Grade 3 (First occurrence)	ICE score 0-2[c] or depressed level of consciousness[d]: awakens only to tactile stimulus, or seizures[d], either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local edema on neuroimaging[d]	• Withhold ELREXFIO until ICANS resolves.[e] • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care. • Patients should be hospitalized for 48 hours following the next dose of ELREXFIO.
Grade 3 (recurrent)	ICE score 0-2[c] or depressed level of consciousness[d]: awakens only to tactile stimulus, or seizures[d], either: • any clinical seizure, focal or generalized, that resolves rapidly, or • non-convulsive seizures on electroencephalogram (EEG) that resolve with intervention, or raised intracranial pressure: focal/local edema on neuroimaging[d]	• Permanently discontinue ELREXFIO. • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Monitor neurologic symptoms and consider neurology consultation and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

Grade[a]	Presenting Symptoms	Actions
Grade 4	ICE score 0[c] or, depressed level of consciousness[d] either: • patient is unarousable or requires vigorous or repetitive tactile stimuli to arouse, or • stupor or coma, or seizures[d], either: • life-threatening prolonged seizure (>5 minutes), or • repetitive clinical or electrical seizures without return to baseline in between, or motor findings[d]: • deep focal motor weakness such as hemiparesis or paraparesis, or raised intracranial pressure / cerebral edema[d], with signs/symptoms such as: • diffuse cerebral edema on neuroimaging, or • decerebrate or decorticate posturing, or • cranial nerve VI palsy, or • papilledema, or • Cushing's triad	• Permanently discontinue ELREXFIO. • Administer dexamethasone[f] 10 mg intravenously every 6 hours. Continue dexamethasone use until resolution to Grade 1 or less, then taper. • Alternatively, consider administration of methylprednisolone 1,000 mg per day intravenously for 3 days. • Monitor neurologic symptoms and consider consultation with a neurologist and other specialists for further evaluation and management. • Consider non-sedating, anti-seizure medications (e.g., levetiracetam) for seizure prophylaxis. • Provide supportive therapy, which may include intensive care.

a. Based on American Society for Transplantation and Cellular Therapy (ASTCT) 2019 grading for ICANS.
b. Management is determined by the most severe event, not attributable to any other cause.
c. If patient is arousable and able to perform Immune Effector Cell-Associated Encephalopathy (ICE) Assessment, assess: Orientation (oriented to year, month, city, hospital = 4 points); Naming (name 3 objects, e.g., point to clock, pen, button = 3 points); Following Commands (e.g., "show me 2 fingers" or "close your eyes and stick out your tongue" = 1 point); Writing (ability to write a standard sentence = 1 point; and Attention (count backwards from 100 by ten = 1 point). If patient is unarousable and unable to perform ICE Assessment (Grade 4 ICANS) = 0 points.
d. Not attributable to any other cause.
e. See Table 2 in USPI for recommendations on restarting ELREXFIO after dose delays.
f. All references to dexamethasone administration are dexamethasone or equivalent medications.

Please visit www.ELXREXFIOREMS.com for further information and resources.

www.ELREXFIOREMS.com | PHONE: 1-844-923-7845
FAX 1-800-349-5131 | e-mail: ELREXFIOREMS@ubc.com

Reference ID: 5226170

ELREXFIO™ REMS Knowledge Assessment

PRESCRIBER INFORMATION (All Fields Required)		
Prescriber First Name:	Prescriber Last Name:	
NPI #:	State of Practice:	
	State License #:	
Address:		
City:	State:	Zip Code:
Credentials: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify) _____		
Phone:	Fax:	E-mail:
Signature:		Date (MM/DD/YYYY):

As a condition of certification, the prescriber must complete the **Knowledge Assessment**. All 10 questions must be answered correctly.

The **Knowledge Assessment** can be completed online at www.ELREXFIOREMS.com or a completed hard copy can be submitted via fax to 1-800-349-5131or e-mail at ELREXFIOREMS@ubc.com. You must also complete the **Prescriber Enrollment Form** at www.ELREXFIOREMS.com for your certification to be complete.

The ELREXFIO REMS will verify that both the **Knowledge Assessment** and **Prescriber Enrollment Form** are complete, and will provide confirmation of certification via e-mail after processing.

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FAX 1-800-349-5131 | e-mail: ELREXFIOREMS@ubc.com

ELREXFIO™ REMS Knowledge Assessment

1- ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody:

A- True

B- False

2- What is not typically a symptom of CRS:

A- Fever

B- Hypotension

C- Tinnitus

D- Hypoxia

E- Tachycardia

3- Which one of the following is true regarding the median time to onset of CRS for ELREXFIO? It typically occurs:

A- 2 (range: 1 to 9) days after the most recent dose

B- 6 (range: 3-21) days after the most recent dose

C- 10 (range 6-15) days after the most recent dose

D- Rarely starts during the first week following ELREXFIO dosing

4- Which of the following regarding Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) are correct:

A- The onset of ICANS can be concurrent with CRS, following resolution of CRS, or in the absence of CRS.

B- At the first sign of neurologic toxicity including ICANS immediately evaluate patient and institute treatment based on severity

C- ELREXFIO should be withheld from patients experiencing Grade 1 or Grade 2 and Grade 3 (first occurrence) ICANS until resolution of the event

D- The most common signs or symptoms of ICANS included depressed level of consciousness and Grade 1 or 2 changes in the Immune Effector Cell-Associated Encephalopathy (ICE) score

E- All of the above

5- As a part of patient counseling, which of the following are correct regarding ELREXFIO:

A- Before treatment initiation (first step-up dose), the **Patient Wallet Card** must be provided through the processes and procedures established as a requirement of the REMS Program

B- Patients should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose

C- Patients should seek immediate medical attention if they experience symptoms of CRS and/or neurologic toxicity including ICANS

D- All of the above

6- Which one of the following is true regarding the median time to onset of Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) for ELREXFIO? It typically occurs:

A- 3 (range: 1 to 4) days after the most recent dose

B- 5 (range: 3-15) days after the most recent dose

C- 8 (range 6-12) days after the most recent dose

D- Rarely starts during the first week following ELREXFIO dosing

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Reference ID: 5226170

7- Administer acetaminophen, dexamethasone, diphenhydramine (or their equivalent) approximately 1 hour before the first 3 doses of the ELREXFIO in the dosing schedule to reduce the risk of CRS:

A- True
B- False

8- Potentially life-threatening complications of CRS may include:

A- Cardiac dysfunction
B- Adult respiratory distress
C- Neurologic toxicity including ICANS
D- Renal and/or hepatic failure
E- Disseminated intravascular coagulation (DIC)
F- All of the above

9- Which neurologic toxicity has been reported at any time during treatment with ELREXFIO:

A- Headache
B- Confusion
C- Muscular weakness
D- Sensory neuropathy
E- Guillain-Barre Syndrome
F- All of the above

10- If CRS is suspected during treatment with ELREXFIO, which of the following supportive measures should be considered:

A- Withhold ELREXFIO until Grade 1 or Grade 2 and Grade 3 (first occurrence) CRS resolves
B- Administer supportive therapy for CRS, which may include intensive care for severe or life-threatening CRS
C- Laboratory testing to monitor for disseminated intravascular coagulation, hematology parameters, as well as pulmonary, cardiac, renal, and hepatic function
D- All of the above

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FAX 1-800-349-5131 | e-mail: ELREXFIOREMS@ubc.com

Fold

ELREXFIO™ REMS
Patient Wallet Card

1-844-923-7845 www.ELREXFIOREMS.com

Carry this card with you at all times.

SHOW THIS CARD to any healthcare provider involved in your care and if you go to the emergency room.

IMPORTANT SAFETY INFORMATION FOR PATIENTS RECEIVING TREATMENT WITH ELREXFIO

FOR THE PATIENT

Call your healthcare provider or get emergency help right away if you have any of these symptoms:

- Fever 100.4°F (38°C) or higher
- Trouble breathing
- Chills
- Dizziness or light-headedness
- Fast heartbeat
- Headache
- Agitation, trouble staying awake, confusion or disorientation, seeing or hearing things that are not real
- Trouble speaking, thinking, remembering things, paying attention, or understanding things
- Problems walking or muscle weakness
- Shaking (tremors), loss of balance, or muscle spasms
- Numbness and tingling (feeling like "pins and needles")
- Burning, throbbing, or stabbing pain
- Changes in your handwriting

IMPORTANT TO REMEMBER:

If you have **any** of these symptoms call your doctor or seek emergency medical attention right away! These are not all of the possible symptoms of ELREXFIO. Tell your doctor if you have any symptom that bothers you or does not go away.

You should be hospitalized after administration of each of the first 2 step-up doses within the step-up dosing schedule.

You should always ask your doctor about taking other medications while taking ELREXFIO.

Fold

Fold

Fold

+ IMPORTANT SAFETY INFORMATION YOU SHOULD KNOW:
ELREXFIO therapy can cause cytokine release syndrome (CRS) or neurologic toxicity including immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) which may be fatal or life threatening. CRS may involve multiple organ systems.

This Patient has received ELREXFIO.

Name of ELREXFIO treating Oncologist: _____

Office Phone Number: _____

After Hours Phone Number: _____

Healthcare Setting Name: _____

Dates of ELREXFIO Injections :

- **Step-up Dose 1** _____
- **Step-up Dose 2** _____
- **First Treatment Dose** _____

FOR HEALTHCARE PROVIDERS

Print out, cut along the dotted lines and fold in half and half again.

ELREXFIO™
(elranatamab-bcmm)
INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

PHARMACY AND HEALTHCARE SETTING TRAINING PROGRAM

Risk Evaluation and Mitigation Strategy (REMS)

Pfizer Oncology

Reference ID: 5226170

ELREXFIO Pharmacy and Healthcare Setting Training Module

- This training module provides details related to pharmacy and healthcare setting requirements of the ELREXFIO REMS.
- Please refer to the Prescribing Information for additional information.

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Reference ID: 5226170

What is a REMS?

- A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the FDA to manage known or potential serious risks associated with a drug product. The FDA has determined that a REMS is necessary to ensure that the benefits of ELXREXFIO outweigh its risks.
- The goal of the ELREXFIO REMS is to mitigate the risks of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by ensuring prescribers are aware of the importance of monitoring for signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to ELREXFIO.

ELREXFIO Indication

- ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

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Reference ID: 5226170

/01

Pharmacy and Healthcare Setting Certification Requirements

ELREXFIO™
(elranatamab-bcmm)

Pharmacy and Healthcare Setting Certification Requirements

Requirements to become certified to dispense ELREXFIO are as follows:

- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the Pharmacy and/or Healthcare Setting
- Have the Authorized Representative review this **Pharmacy and Healthcare Setting Training Program**
- Have the Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS
- Train all relevant staff involved in dispensing ELREXFIO on the REMS requirements using this **Pharmacy and Healthcare Setting Training Program**
- Before dispensing, obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Pharmacy and Healthcare Setting Responsibilities

At all times:

- Report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS
- Maintain records of staff training
- Maintain records that processes and procedures are in place and are being followed
- Maintain records of all ELREXFIO dispenses and provide data to the REMS and Wholesalers-Distributors, as requested.
- Comply with audits carried out by Pfizer Inc. or a third party acting on behalf of Pfizer Inc., to ensure that all training, processes, and procedures are in place and being followed
- Not distribute, transfer, loan, or sell ELREXFIO except to certified pharmacies and healthcare settings

To maintain certification to dispense:

- Have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS if the Authorized Representative changes

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Who Can Be an Authorized Representative?

An Authorized Representative at the Pharmacy or Healthcare Setting can be a:

- Pharmacist
- Pharmacy Technician
- Registered Nurse
- Any responsible individual assigned by the Pharmacy or Healthcare Setting

Certified ELREXFIO Prescribers cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

One Authorized Representative must enroll for each Pharmacy or Healthcare Setting and uphold the REMS requirements as stated on the Pharmacy and Healthcare Setting Enrollment Form

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Managing Pharmacy and Healthcare Setting Staff

- The Authorized Representative (AR) may grant Pharmacy and Healthcare Setting Staff access via the *Staff Management* tab in the ELREXFIO REMS Portal
- Once the AR has added the Staff member through this page, the Staff member will receive an automated e-mail
- The Staff member will then have the ability to access the Portal to confirm Prescriber Certification prior to dispensing ELREXFIO

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

How to Confirm Prescriber Certification

- When an order for ELREXFIO is received, the Authorized Representative or designated staff will log into the ELREXFIO REMS portal at www.ELREXFIOREMS.com
  - Select **REMS Dispense Authorization (RDA)**
  - After entering either the ordering Prescriber's NPI# or name, one of the following certification statuses will appear:
    - CERTIFIED: OK TO DISPENSE
    - NOT CERTIFIED: DO NOT DISPENSE
      - The RDA code will display for documentation purposes
- ELREXFIO may only be dispensed upon generation of an RDA
- The Authorized Representative or designated staff may also contact the ELREXFIO REMS Coordinating Center via phone at 1-844-923-7845 to obtain an RDA

ELREXFIO™ (elranatamab-bcmm) INJECTION FOR SUBCUTANEOUS USE | 44 mg/1.1 mL 76 mg/1.9 mL

Reference ID: 5226170

Adverse Event Reporting

- Reporting of suspected adverse events following administration of therapy is vital for the continued monitoring of the risk/benefit balance of therapy.
- Pharmacy and healthcare setting staff must report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS Coordinating Center at 1-844-923-7845. Report all other suspected adverse events associated with ELREXFIO to Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

ELREXFIO™
(elranatamab-bcmm)
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For further information, please visit www.ELREXFIOREMS.com or call 1-844-923-7845

Pfizer Oncology

FDA - REQUIRED REMS SAFETY INFORMATION

- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with ELREXFIO
- Required REMS Certification to prescribe ELREXFIO

Dear Healthcare Provider:

The purpose of this letter is to inform you of important safety information for ELREXFIO based on current prescribing information. The FDA has required this safety notice as part of the ELREXFIO REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity including ICANS.

Serious Risks of ELREXFIO

- **Cytokine release syndrome (CRS)**, including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO.
- Initiate treatment with the ELREXFIO step-up dosing schedule to reduce the risk of CRS.
- **Neurologic toxicity including ICANS** and serious and life-threatening reactions, can occur in patients receiving ELREXFIO.
- Monitor patients for signs or symptoms of neurologic toxicity including ICANS during treatment.
- Withhold ELREXFIO until CRS or neurologic toxicity including ICANS resolves or permanently discontinue ELREXFIO based on severity.

Enclosed for your review and awareness of these serious risks is the ELREXFIO **REMS Fact Sheet**, a non-promotional educational document reviewed by the FDA. The ELREXFIO **REMS Fact Sheet** will provide you with more detailed information about these serious risks and the ELREXFIO REMS requirements.

REMS Requirements

- Those who prescribe and/or dispense ELREXFIO must be aware of how to manage the risks of CRS and neurologic toxicity including ICANS.
- ELREXFIO is ONLY prescribed and/or dispensed by certified prescribers, pharmacies, and healthcare settings.
- Prescribers must counsel patients on signs and symptoms of CRS and neurologic toxicity including ICANS.
- Prescribers must complete and provide patients or their caregivers with the **Patient Wallet Card** before treatment initiation (first step-up dose).

Prescriber Knowledge, Attitude, and Behavior (KAB) Survey

The Prescriber KAB Survey is a part of the REMS commitment made by Pfizer Inc., to the FDA to help assess stakeholder knowledge as it pertains to the risks associated with the use of ELREXFIO and in determining if the ELREXFIO REMS is meeting its goal.

We ask that you consider participating in this voluntary KAB survey upon receipt of the survey invitation. The timetable in completing this Prescriber KAB Survey will be **[TIMETABLE TO BE INCLUDED]**.

Indication

ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Adverse Event Reporting

Healthcare Providers must report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS Coordinating Center at 1-844-923-7845.

Healthcare providers should report all other suspected adverse events to Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For a complete safety profile of ELREXFIO, please see the Prescribing Information included.

For additional details about the REMS, please visit www.ELREXFIOREMS.com or contact the ELREXFIO REMS Coordinating Center at 1-844-923-7845.

Sincerely,
Pfizer Inc.

FDA - REQUIRED REMS SAFETY INFORMATION

- Risk of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) with ELREXFIO
- Required REMS Certification to prescribe ELREXFIO

Dear Professional Society,

We request that you share this safety information with your members.

The purpose of this letter is to inform you of important safety information for ELREXFIO based on current prescribing information. The FDA has required this safety notice as part of the ELREXFIO REMS (**R**isk **E**valuation and **M**itigation **S**trategy) to inform you about the serious risks of CRS and neurologic toxicity including ICANS.

Serious Risks of ELREXFIO

- **Cytokine release syndrome (CRS)**, including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO.
- Initiate treatment with the ELREXFIO step-up dosing schedule to reduce the risk of CRS.
- **Neurologic toxicity including ICANS** and serious and life-threatening reactions, can occur in patients receiving ELREXFIO.
- Monitor patients for signs or symptoms of neurologic toxicity including ICANS during treatment.
- Withhold ELREXFIO until CRS or neurologic toxicity including ICANS resolves or permanently discontinue ELREXFIO based on severity.

Enclosed for your review and awareness of these serious risks is the ELREXFIO **REMS Fact Sheet**, a non-promotional educational document reviewed by the FDA. The ELREXFIO **REMS Fact Sheet** will provide you with more detailed information about these serious risks and the ELREXFIO REMS requirements.

REMS Requirements

- Those who prescribe and/or dispense ELREXFIO must be aware of how to manage the risks of CRS and neurologic toxicity including ICANS.
- ELREXFIO is ONLY prescribed and/or dispensed by certified prescribers, pharmacies, or healthcare settings.
- Prescribers must counsel patients on signs and symptoms of CRS and neurologic toxicity including ICANS.
- Prescribers must complete and provide the **Patient Wallet Card** to the patient or caregiver before treatment initiation (first step-up dose).

Indication

ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

For a complete safety profile of ELREXFIO, please see the Prescribing Information included. For additional details about the REMS, please visit www.ELREXFIOREMS.com or contact the ELREXFIO REMS Coordinating Center at 1-844-923-7845.

Sincerely,
Pfizer Inc.

ELREXFIO™ REMS Fact Sheet

FDA - REQUIRED REMS SAFETY INFORMATION

ELREXFIO REMS Overview

- The ELREXFIO **R**isk **E**valuation and **M**itigation **S**trategy (REMS) is a safety program that manages the risks of Cytokine Release Syndrome (CRS) and Neurologic Toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS). The ELREXFIO REMS is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.
- Healthcare providers, pharmacies, and healthcare settings that prescribe and/or dispense ELREXFIO must be specially certified and trained on how to manage the risks of CRS and neurologic toxicity including ICANS.
- Patients or their caregivers must receive the **Patient Wallet Card** before the first step-up dose of ELREXFIO.
- Wholesalers-distributors must ONLY distribute ELREXFIO to certified pharmacies and healthcare settings.

What Are the Risks?

- CRS, including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO. Initiate treatment with the ELREXFIO step-up dosing schedule to reduce the risk of CRS.
- Neurologic toxicity, including ICANS, and serious and life-threatening reactions, can occur in patients receiving ELREXFIO. Monitor patients for signs or symptoms of neurologic toxicity including ICANS during treatment.

How Can Healthcare Providers Manage the Risks?

- Follow the ELREXFIO step-up dosing schedule as outlined in the **Prescriber Training Program**.
- Administer pretreatment medications approximately 1 hour before each dose in the step-up dosing schedule (step-up dose 1, step-up dose 2, and the first treatment dose) of ELREXFIO to reduce the risk of CRS as outlined in the **Prescriber Training Program**.
- Complete and provide patients or their caregivers with the **Patient Wallet Card** before treatment initiation (first step-up dose).
- Counsel patients about the risks of CRS and neurologic toxicity including ICANS and to seek medical attention should signs or symptoms of CRS and neurologic toxicity occur.
- Advise patients not to drive or operate heavy or potentially dangerous machinery for 48 hours after completing each of the 2 step-up doses and the first treatment dose within the ELREXFIO step-up dosing schedule and in the event of new onset of any neurological toxicity symptoms until symptoms resolve.
- Instruct patients that they should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.
- Monitor patients for signs or symptoms of CRS and of neurologic toxicity during treatment.
    - At the first sign of CRS, immediately evaluate the patient for hospitalization. Administer supportive therapy based on severity and consider further management per current practice guidelines.
    - At the first sign of neurologic toxicity including ICANS immediately evaluate the patient and provide supportive therapy based on severity.

ELREXFIO™ REMS Fact Sheet

ELREXFIO REMS Overview (continued)

- Withhold ELREXFIO until CRS or neurologic toxicity including ICANS resolves or permanently discontinue ELREXFIO based on severity, as indicated in the Prescribing Information.
- For further details on recommended actions to be taken and treatment guidance for CRS and neurologic toxicity including ICANS refer to the **Prescriber Training Program** and **Adverse Reaction Management Guide.**

Key Requirements of the ELREXFIO REMS

Healthcare providers who prescribe ELREXFIO

Receive training on the REMS requirements at www.ELREXFIOREMS.com by using the **Prescriber Training Program** and the **Adverse Reaction Management Guide**.

Successfully complete the **Knowledge Assessment** and submit it to the REMS online.

Enroll in the REMS by completing and submitting the **Prescriber Enrollment Form** online to the REMS. Fax and e-mail options are also available.

If ELREXFIO will be dispensed and administered in the same location, an Authorized Representative must complete the Pharmacy and Healthcare Setting certification.

Instruct patients that they should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose. Monitor patients for signs and symptoms of CRS and neurologic toxicity including ICANS during treatment with ELREXFIO.

Pharmacies and Healthcare Settings that dispense ELREXFIO

Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS requirements.

NOTE: Certified ELREXFIO Prescribers cannot be designated as an Authorized Representative for a certified Pharmacy or Healthcare Setting.

Authorized Representative must be trained at www.ELREXFIOREMS.com using the **Pharmacy and Healthcare Setting Training Program**.

Authorized Representative must enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** online to the REMS. Fax and e-mail options are also available.

Pharmacies and Healthcare Settings must verify prescriber certification in the ELREXFIO REMS before dispensing ELREXFIO.

ELREXFIO™ REMS Fact Sheet

Key Requirements of the ELREXFIO REMS (continued)

Patients

Receive the **Patient Wallet Card** before treatment.

Should be hospitalized for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.

Adverse Event Reporting

Healthcare Providers must report serious adverse events of CRS and neurologic toxicity including ICANS to the REMS Coordinating Center at 1-844-923-7845.

Healthcare providers should report all other suspected adverse events to Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, to enroll in the ELREXFIO REMS, and for all REMS materials go to www.ELREXFIOREMS.com.

Reference ID: 5226170

ELREXFIO™ Risk Evaluation and Mitigation Strategy (REMS)

The goal of the ELREXFIO REMS is to mitigate the risks of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) by ensuring prescribers are aware of the importance of monitoring for signs and symptoms of CRS and neurologic toxicity including ICANS in patients exposed to ELREXFIO.

Prescribers

Prescribers must be certified in the ELREXFIO REMS to treat patients with ELREXFIO.

Learn More >

Pharmacies and Healthcare Settings

Pharmacies and Healthcare Settings must be certified in the ELREXFIO REMS to dispense ELREXFIO to patients.

Learn More >

Patients

All patients treated with ELREXFIO should receive a Patient Wallet Card. Patients should carry the Patient Wallet Card to remind them of the signs and symptoms of CRS and neurologic toxicity including ICANS and when to seek immediate medical attention. Patients should share this card with any healthcare provider who provides care to them to inform them of receipt of ELREXFIO treatment and when to contact the patient's oncologist.

Resources for Patients

Patient Wallet Card - English

Patient Wallet Card - Spanish

What is the ELREXFIO REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a safety program to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA).

The FDA has determined that a REMS is necessary to ensure that the benefits of ELREXFIO outweigh the risks of cytokine release syndrome and neurologic toxicity including ICANS.

Indication

ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Reporting Adverse Events

To report serious adverse events of CRS or neurologic toxicity including ICANS, contact the REMS Coordinating Center at 1-844-923-7845.

To report all other suspected adverse events, contact Pfizer Inc. at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Resources for Prescribers

- Prescriber Training Program
- Adverse Reaction Management Guide
- Knowledge Assessment
- Prescriber Enrollment Form
- Patient Wallet Card - English
- Patient Wallet Card - Spanish
- Fact Sheet
- Healthcare Provider Letter
- Professional Society Letter

Download All Prescriber Resources

Resources for Pharmacies and Healthcare Settings

- Pharmacy and Healthcare Setting Training Program
- Pharmacy and Healthcare Setting Enrollment Form

Download All Pharmacy and Healthcare Setting Resources

Have Questions?

Contact the ELREXFIO REMS by calling 1-844-923-7845.

Prescribers

ELREXFIO REMS Requirements

All Healthcare Providers involved in the prescribing of ELREXFIO are trained on the ELREXFIO REMS requirements and must successfully complete the **Knowledge Assessment**.

Prescribers must enroll and become certified in the ELREXFIO REMS to be able to prescribe ELREXFIO .

To become enrolled in the ELREXFIO REMS, Prescribers MUST:

STEP 1	STEP 2	STEP 3	STEP 4
Review the following materials: • Prescribing Information • Prescriber Training Program • Adverse Reaction Management Guide	Successfully complete the Knowledge Assessment and submit it to the REMS	Complete the Prescriber Enrollment Form and submit it to the REMS	Before treatment initiation (first step-up dose), counsel patients and/or their caregivers using the Patient Wallet Card. Complete and provide patients or their caregivers with the Patient Wallet Card.

Resources for Prescribers

- Prescriber Training Program
- Adverse Reaction Management Guide
- Knowledge Assessment
- Prescriber Enrollment Form
- Patient Wallet Card - English
- Patient Wallet Card - Spanish
- Fact Sheet
- Healthcare Provider Letter
- Professional Society Letter

Download All Prescriber Resources

Pharmacies and Healthcare Settings

ELREXFIO REMS Requirements

All Pharmacies and Healthcare Settings involved in the dispensing of ELREXFIO must become certified in the ELREXFIO REMS.

How does a Pharmacy and Healthcare Setting become certified in the ELREXFIO REMS?

STEP 1	STEP 2	STEP 3	STEP 4
Designate an Authorized Representative for the Pharmacy and Healthcare Setting	Authorized Representative must review the Pharmacy and Healthcare Setting Training Program	Authorized Representative must complete the Pharmacy and Healthcare Setting Enrollment Form and submit it to the REMS	Train all relevant staff involved in dispensing ELREXFIO on the REMS requirements using the Pharmacy and Healthcare Setting Training Program

Resources for Pharmacies and Healthcare Settings

Pharmacy and Healthcare Setting Training Program

Pharmacy and Healthcare Setting Enrollment Form

Download All Pharmacy and Healthcare Setting Resources

ELREXFIO™ REMS
Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the ELREXFIO REMS and dispense ELREXFIO , a pharmacy/healthcare setting must designate an *Authorized Representative to:

- Review the **Pharmacy and Healthcare Setting Training Program**
- Complete this **Pharmacy and Healthcare Setting Enrollment Form**:
  - below for immediate enrollment
  - by e-mail at ELREXFIOREMS@ubc.com or
  - via fax to 1-800-349-5131.
- The ELREXFIO REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and provide confirmation of certification via e-mail after processing.
- ELREXFIO cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

*Certified ELREXFIO Prescribers cannot be designated as the Authorized Representatives for a Pharmacy or Healthcare Setting.

(Fields marked with an * are REQUIRED)

Pharmacy and Healthcare Information

*Pharmacy/Healthcare Setting National Provider Identifier (NPI)#

CONTINUE

If you do not have an NPI, please reach out to the ELREXFIO REMS by calling 1-844-923-7845

ELREXFIO™ REMS
Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the ELREXFIO REMS and dispense ELREXFIO , a pharmacy/healthcare setting must designate an *Authorized Representative to:

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- Complete this **Pharmacy and Healthcare Setting Enrollment Form**:
  - below for immediate enrollment
  - by e-mail at ELREXFIOREMS@ubc.com or
  - via fax to 1-800-349-1131.
- The ELREXFIO REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and provide confirmation of certification via e-mail after processing.
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(Fields marked with an * are REQUIRED)

Pharmacy and Healthcare Information

*Pharmacy/Healthcare Setting National Provider Identifier (NPI)#

*Enrollment Type (Please Check One)
○ New Certification ○ Change in Authorized Representative

*Pharmacy/Healthcare Setting Name
University Hospital

DEA# (On file with distributor account)

*Pharmacy/Healthcare Setting Type
○ Inpatient Hospital Pharmacy ○ Outpatient Hospital Pharmacy ○ Oncology Infusion Center
○ Community Oncology Physician Office ○ Specialty Pharmacy ○ Other (please specify)

*Address Line 1 | Address Line 2

*City | *State (– Please Select –) | *Zip Code

*Phone | *Fax

Ship To Information

*Ship To Contact Name

☐ Shipping Address - Same as above

*Address Line 1 | Address Line 2

*City | *State (– Please Select –) | *Zip Code

*Phone | *Fax

Authorized Representative Information

*E-Mail | *First Name | *Last Name

*Credentials (select one)
○ PharmD ○ RPh ○ RN
○ Other (please specify: e.g., MD, DO, Office Administrator, Practice Manager)

*Phone | *Fax

Your pharmacy or healthcare setting's information will be shared with Pfizer Inc.'s wholesaler-distributor partners, to allow your pharmacy or healthcare setting to purchase product.

Authorized Representative Responsibilities

As the Authorized Representative, I must:
- Review the **Pharmacy and Healthcare Setting Training Program**.
- Enroll in the REMS by completing and submitting this **Pharmacy and Healthcare Setting Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing ELREXFIO on the REMS requirements using the **Pharmacy and Healthcare Setting Training Program**.
- Oversee implementation and compliance with the REMS requirements on behalf of the pharmacy and/or healthcare setting.

Before dispensing, staff must:
- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

At all times, staff must:
- Report serious adverse events of Cytokine Release Syndrome (CRS) and neurologic toxicity including Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) to the REMS.
- Not distribute, transfer, loan or sell ELREXFIO except to certified pharmacies and healthcare settings.
- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Maintain records of all ELREXFIO dispenses and provide data to the REMS and Wholesalers Distributors, as requested.
- Comply with audits carried out by Pfizer Inc. or a third party acting on behalf of Pfizer Inc. to ensure that all training, processes, and procedures are in place and are being followed.
- Have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS if the Authorized Representative changes.

*Authorized Representative e-signature

☐ *Authorized Representative Attestation

[e-Signature functionality will be available within 30 days of approval of ELREXFIO REMS]

CLEAR | CANCEL | SUBMIT

ELREXFIO™ REMS
Pharmacy and Healthcare Setting Enrollment Form

Instructions

To become certified in the ELREXFIO REMS and dispense ELREXFIO, a pharmacy/healthcare setting must designate an *Authorized Representative to:

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  - by e-mail at ELREXFIOREMS@ubc.com or
  - via fax to 1-800-349-5131.
- The ELREXFIO REMS will verify that the **Pharmacy and Healthcare Setting Enrollment Form** is complete and provide confirmation of certification via e-mail after processing.
- ELREXFIO cannot be dispensed until the Pharmacy and Healthcare Setting certification is complete.

*Certified ELREXFIO Prescribers cannot be designated as the Authorized Representatives for a Pharmacy or Healthcare Setting.

(Fields marked with an * are REQUIRED)

Pharmacy and Healthcare Information

*Pharmacy/Healthcare Setting National Provider Identifier (NPI)#
123456789

*Enrollment Type (Please Check One)
○ New Certification ○ Change in Authorized Representative

*Pharmacy/Healthcare Setting Name
University Hospital

DEA# (On file with distributer account)

*Pharmacy/Healthcare Setting Type
○ Inpatient Hospital Pharmacy ○ Outpatient Hospital Pharmacy ○ Oncology Infusion Center
○ Community Oncology Physician Office ○ Specialty Pharmacy ◉ Other (please specify)

*Other Pharmacy/Healthcare Setting Type
Other

*Address Line 1 | Address Line 2

*City | *State — Please Select — | *Zip Code

*Phone | *Fax

Ship To Information

*Ship To Contact Name

☑ Shipping Address - Same as above

Authorized Representative Information

*E-Mail | *First Name | *Last Name

*Credentials (select one)
○ PharmD ○ R.Ph ○ RN
◉ Other (please specify: e.g., MD, DO, Office Administrator, Practice Manager)

*Other Credentials
Please Specify

*Phone | *Fax

Your pharmacy or healthcare setting's information will be shared with Pfizer Inc.'s wholesaler-distributor partners, to allow your pharmacy or healthcare setting to purchase product.

Authorized Representative Responsibilities

As the Authorized Representative, I must:

- Review the **Pharmacy and Healthcare Setting Training Program**.
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- Maintain records of staff training.
- Maintain records that processes and procedures are in place and are being followed.
- Maintain records of all ELREXFIO dispenses and provide data to the REMS and Wholesalers-Distributors, as requested.
- Comply with audits carried out by Pfizer Inc. or a third party acting on behalf of Pfizer Inc. to ensure that all training, processes, and procedures are in place and are being followed.
- Have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy and Healthcare Setting Enrollment Form** to the REMS if the Authorized Representative changes.

*Authorized Representative e-signature

☐ *Authorized Representative Attestation

[e-Signature functionality will be available within 30 days of approval of ELREXFIO REMS]

CLEAR | CANCEL | SUBMIT

ELREXFIO™ REMS
Pharmacy and Healthcare Setting Enrollment Form

Thank you for submitting your information to enroll in the ELREXFIO REMS.

A confirmation of this submission has been sent to the e-mail address provided.

You can expect to receive an e-mail with a link to create your online account.

Contact Us

Phone	Fax	Hours of Operation
1-844-923-7845	1-800-349-5131	Monday - Friday 08:00 AM – 08:00 PM Eastern

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARC R THEORET
08/14/2023 12:29:03 PM