Pfizer Oncology together™

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

ELREXFIO™ (elranatamab-bcmm) Billing and Coding Guide
Outpatient Site of Care

Please see Important Safety Information and Indication on pages 11-12 and full Prescribing Information for ELREXFIO, including BOXED WARNINGS, and Medication Guide.

Introduction

Pfizer Inc. has developed this reference guide to assist outpatient healthcare providers (HCPs) with understanding coding for ELREXFIO™ (elranatamab-bcmm) approved for use in the United States for subcutaneous injection.

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for ELREXFIO. Coding and coverage policies change periodically and often without notice. The HCP is solely responsible for determining coverage and reimbursement parameters and appropriate coding for treatment of his/her patients. The information provided should not be considered a guarantee of coverage or reimbursement for ELREXFIO.

*Pfizer Oncology Together™ Supports Your Patients**

At Pfizer Oncology Together™, patient support is at the core of everything we do. We've gathered resources and developed tools to help patients and their loved ones throughout ELREXFIO™ (elranatamab-bcmm) treatment. From helping to identify financial assistance options to connecting patients to resources for emotional support, your patients' needs are our priority.*

Benefits Verification

We can help determine a patient's coverage and out-of-pocket costs.

Prior Authorization (PA) Assistance

We can coordinate with a patient's insurer to determine the PA requirements. After a PA request is submitted, we can follow up with the payer until a final outcome is determined.

Appeals Assistance

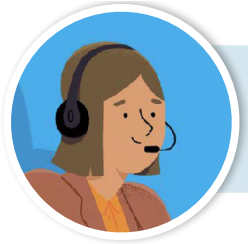
We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

Billing and Coding Assistance for Injectable Products

For your patient claim submissions, we provide easy access to sample forms and letters, along with billing and coding information for physician office and hospital outpatient settings of care.

Patient Financial Assistance

We can help patients understand their benefits and connect them with financial assistance resources.



FOR LIVE, PERSONALIZED SUPPORT
Call **1-877-744-5671** (Monday–Friday 8 AM–8 PM ET)

VISIT
PfizerOncologyTogether.com

*Some services are provided through third-party organizations that operate independently and are not controlled by Pfizer. Availability of services and eligibility requirements are determined solely by these organizations.

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Coding Overview

It is critical to report billing codes that accurately reflect a patient's condition, treatment, and the services that are rendered on the claim form submitted to a payer. The codes in this section may be appropriate to report services related to treatment with ELREXFIO™ (elranatamab-bcmm) when administered in the physician office and hospital outpatient department sites of care to Medicare Administrative Contractors (MACs), private commercial payers, and Medicaid.

Coding for ELREXFIO

In the physician office and hospital outpatient department sites of care, Medicare, Medicaid, and private commercial payers typically recognize the following miscellaneous codes for reporting ELREXFIO and its administration on claim forms.

Please confirm correct coding using payer guidance.

HCPCS Code[1]	Descriptor
C9399	Unclassified drugs and biologicals
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Not otherwise classified, antineoplastic drugs

HCPCS modifiers may be included on claims to provide additional information.

HCPCS Modifier[1]	
JW[a]	Drug amount discarded/not administered to any patient
JZ[a]	Zero drug amount discarded/not administered to any patient
JG[b]	Drug or biological acquired with the 340B program pricing discount, reported for informational purposes
TB[b]	Drug or biological acquired with the 340B program pricing discount, reported for informational purposes for select entities
RE	Furnished in full compliance with FDA-mandated REMS

Key: FDA – Food and Drug Administration; HCPCS – Healthcare Common Procedure Coding System; REMS – Risk Evaluation and Mitigation Strategy.

[a] Use of the JZ modifier (in situations where it applies) is required on Medicare claims with a date of service on or after 7/1/2023. An applicable claim without modifier JW or JZ will be rejected beginning on 10/1/2023.

[b] Reporting informational modifiers JG and TB is mandatory for Outpatient Prospective Payment System (OPPS) providers in calendar year 2023 and for non-OPPS beginning in calendar year 2024.

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ELREXFIO™ (elranatamab-bcmm) National Drug Code

National Drug Codes (NDCs) are unique 10-digit or 11-digit, 3-segment numbers used to identify drugs by manufacturer, product, and package size.[2]

NDCs will be required on claims that include a miscellaneous HCPCS code. For claims-reporting purposes, the Health Insurance Portability and Accountability Act (HIPAA) requires conversion of the 10-digit NDC to an 11-digit NDC by adding a leading "0" (zero), where appropriate, to create a 5-4-2 configuration. For ELREXFIO claims, the zero is added in front of the first segment of numbers in the 10-digit format as listed in the prescribing information. See placement of the red zero in the example below.

Strength[3]		*Size*	*10-Digit NDC Prescribing Information*	*11-Digit NDC Claims*
	**76 mg/1.9 mL**	Single-dose vial in a carton	0069-4494-01	00069-4494-01
	**44 mg/1.1 mL**	Single-dose vial in a carton	0069-2522-01	00069-2522-01

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Coding for ELREXFIO™ (elranatamab-bcmm) Administration Services

Current Procedural Terminology (CPT®)* codes define specific medical procedures performed by physicians or other qualified HCPs.[4] The following code may be used to report the subcutaneous (SC) administration of ELREXFIO:

Type of Code	*Code/Descriptor*
CPT® code[4]	**96401:** Chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic

*Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association.

Reporting Revenue Codes for ELREXFIO Services

Hospital outpatient departments use revenue codes to report specific accommodations and/or ancillary charges.[5] They are used by hospitals to identify the department in which services were provided, the types of services provided, and the supplies used.

Type of Code	*Code/Descriptor[a]*
Revenue code[5,6]	**0636:** Drugs requiring detailed coding *May be used for ELREXFIO*
	0940: Other therapeutic services, general *May be used for the SC injection*

[a] Other revenue codes may be appropriate.

Diagnosis Coding for ELREXFIO™ (elranatamab-bcmm)

The ICD-10-CM is a required code set that should be used by hospitals, as appropriate, to report the patient-specific diagnosis documented in the medical record.

Reporting the medical necessity for ELREXFIO may require a primary and secondary diagnosis, in some cases. HCPs should verify payer-specific diagnosis coding and sequencing requirements before submitting a claim, as they may vary by payer.

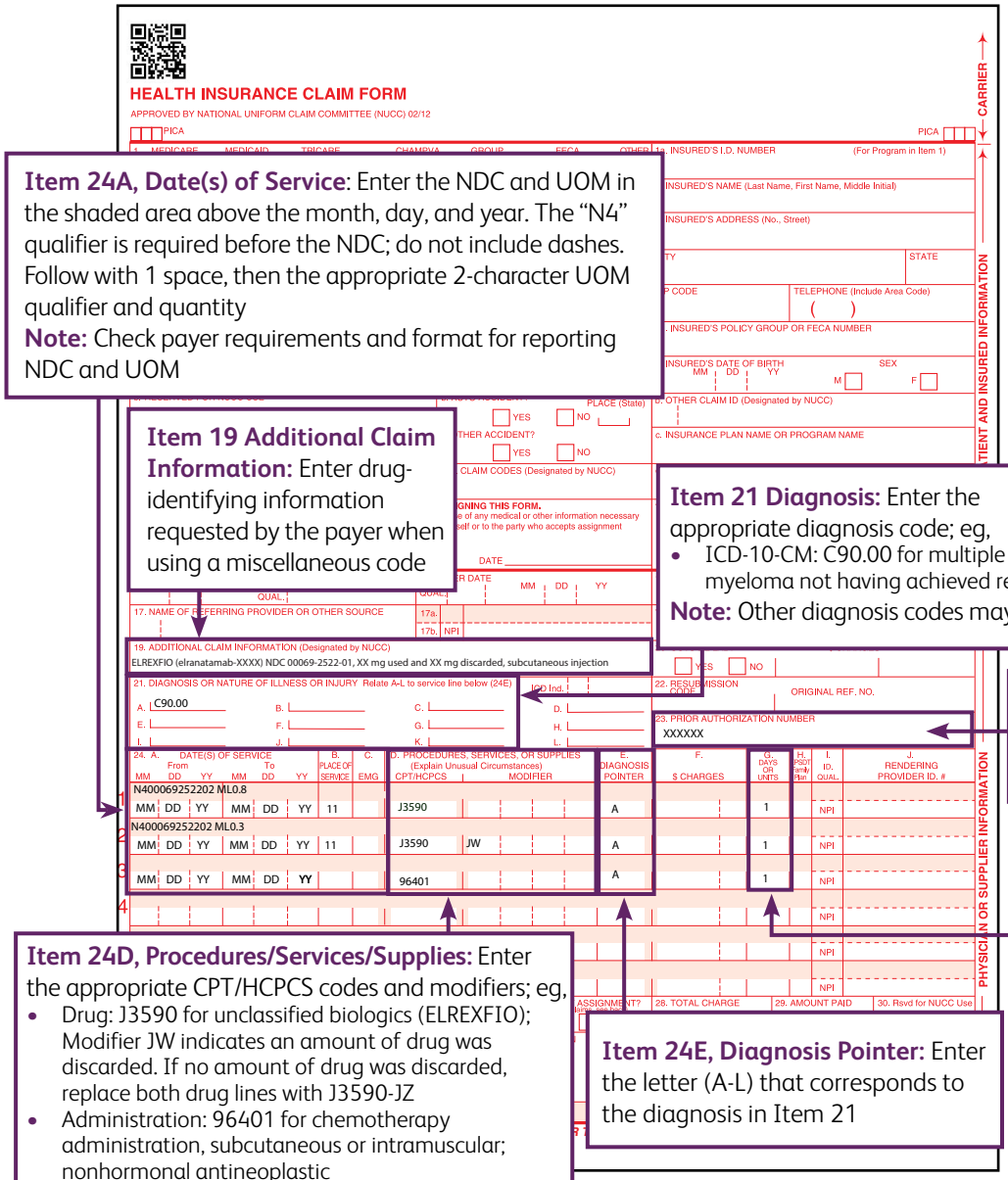
ELREXFIO is a B-cell maturation antigen (BCMA)-directed and CD3-directed bispecific antibody indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

ICD-10-CM codes may include, but are not limited to, the codes listed below:

ICD-10-CM Code[7]	*Descriptor*
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
Z51.12	Encounter for antineoplastic immunotherapy

Report ICD-10-CM codes to the highest level of specificity. Codes that have a fifth digit option must be reported with all 5 digits based on medical record documentation. Use only valid codes.

Sample Claim Form: CMS-1500, Physician Office of Service



Item 24A, Date(s) of Service: Enter the NDC and UOM in the shaded area above the month, day, and year. The "N4" qualifier is required before the NDC; do not include dashes. Follow with 1 space, then the appropriate 2-character UOM qualifier and quantity

Note: Check payer requirements and format for reporting NDC and UOM

Item 19 Additional Claim Information: Enter drug-identifying information requested by the payer when using a miscellaneous code

Item 21 Diagnosis: Enter the appropriate diagnosis code; eg,

- ICD-10-CM: C90.00 for multiple myeloma not having achieved remission

Note: Other diagnosis codes may apply

Item 23, Prior Authorization: Enter the prior authorization number as obtained by the payer

Item 24G, Units: Enter the appropriate number of units of service; eg,

- For J3590, a "1" is typically reported with a miscellaneous code since it does not have a specific unit value
- For 96401, 1 unit represents 1 subcutaneous injection

Note: Payer requirements may vary.

Item 24D, Procedures/Services/Supplies: Enter the appropriate CPT/HCPCS codes and modifiers; eg,

- Drug: J3590 for unclassified biologics (ELREXFIO); Modifier JW indicates an amount of drug was discarded. If no amount of drug was discarded, replace both drug lines with J3590-JZ
- Administration: 96401 for chemotherapy administration, subcutaneous or intramuscular; nonhormonal antineoplastic

Item 24E, Diagnosis Pointer: Enter the letter (A-L) that corresponds to the diagnosis in Item 21

This sample claim form is intended as a reference for the billing and coding of ELREXFIO™ (elranatamab-bcmm). This form is not intended to be directive, and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice, patients, and services rendered.

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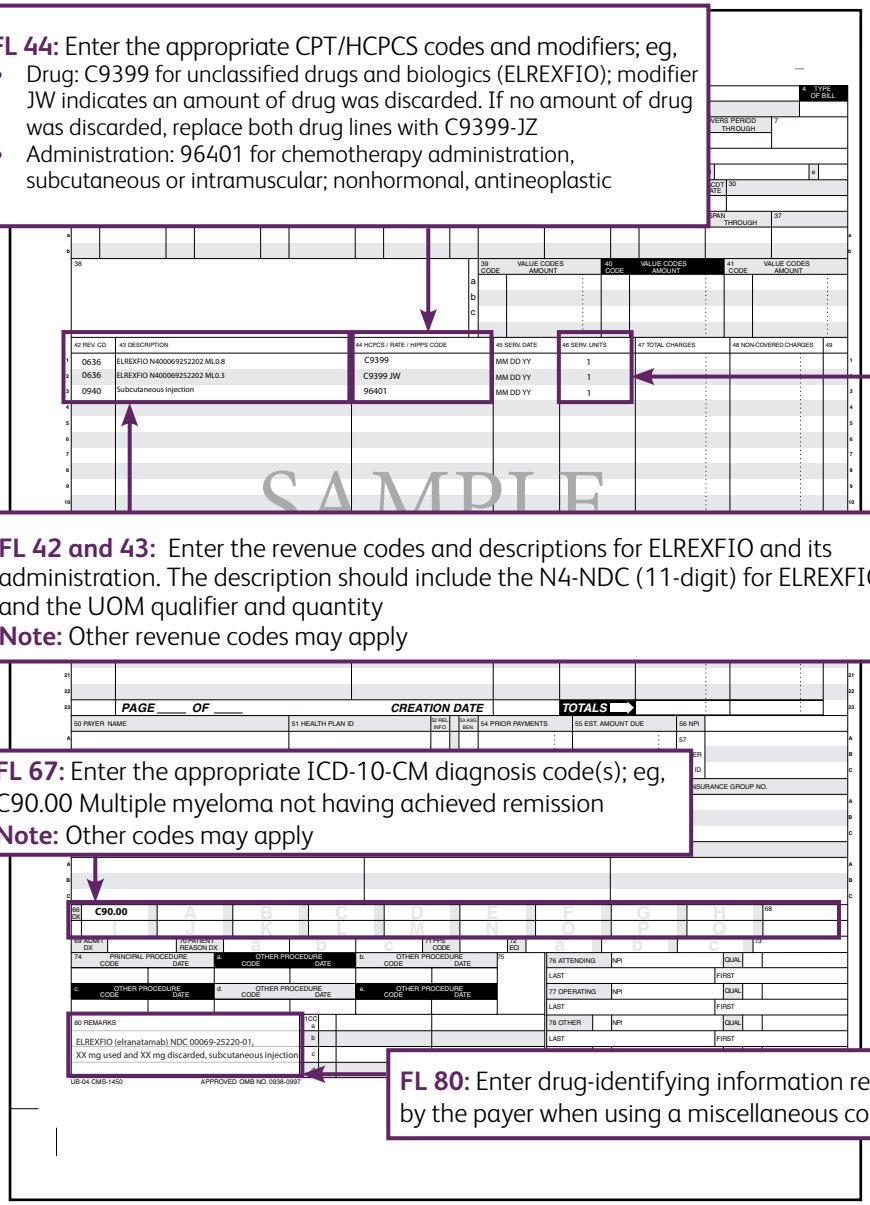
Sample Claim Form: CMS-1450, Hospital Outpatient Site of Service



FL 44: Enter the appropriate CPT/HCPCS codes and modifiers; eg,
- Drug: C9399 for unclassified drugs and biologics (ELREXFIO); modifier JW indicates an amount of drug was discarded. If no amount of drug was discarded, replace both drug lines with C9399-JZ
- Administration: 96401 for chemotherapy administration, subcutaneous or intramuscular; nonhormonal, antineoplastic

FL 42 and 43: Enter the revenue codes and descriptions for ELREXFIO and its administration. The description should include the N4-NDC (11-digit) for ELREXFIO and the UOM qualifier and quantity
Note: Other revenue codes may apply

FL 46: Enter the number of service units eg,
- For C9399, a "1" is is typically reported with a miscellaneous code since it does not have a specific unit value
- For 96401, 1 unit represents 1 subcutaneous injection

Note: Payer requirements may vary

FL 67: Enter the appropriate ICD-10-CM diagnosis code(s); eg, C90.00 Multiple myeloma not having achieved remission
Note: Other codes may apply

FL 80: Enter drug-identifying information requested by the payer when using a miscellaneous code

This sample Medicare claim form is intended as a reference for the billing and coding of ELREXFIO™ (elranatamab-bcmm). This form is not intended to be directive, and the use of the recommended codes does not guarantee reimbursement. HCPs may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal guidelines, payer requirements, practice, patients, and services rendered.

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Appeals

If you believe a claim for ELREXFIO™ (elranatamab-bcmm) has been improperly reimbursed or denied, consider submitting an appeal to the payer. The notice of denial should include the reason for that decision, as well as instructions for filing an appeal.

Claims Submission Checklist

The following may be considered to assist with submitting claims for ELREXFIO™ completely and accurately, which is important for timely claims processing, appropriate payment, and preventing denied claims.

- **Provide the patient name, address, and insurance identification number, and review each of these for accuracy**
- **Include the HCP's name, NPI, and payer-specific provider ID (if applicable)**
- **Indicate the appropriate place of service code (2-digit code) for where the treatment was provided**
- **Check to ensure that ICD-10-CM diagnosis codes, CPT procedure codes, and modifiers (if applicable) are valid and consistent with information included in the patient's medical record**
- **Review the ELREXFIO product-specific information (eg, name of drug (brand and generic), HCPCS code, NDC 11-digit format, correct number of units, and administration route)**

When submitting claims with an unclassified HCPCS code, additional documentation, such as the ELREXFIO prescribing information, a letter of medical necessity, and patient clinical notes, may be required by the payer for claims processing.

Key: NPI – National Provider Identifier.

References

1. Centers for Medicare & Medicaid Services (CMS). HCPCS quarterly update. April 2023 Alpha-numeric HCPCS file. Accessed March 31, 2023. https://www.cms.gov/medicare/coding/hcpcsreleasecodesets/hcpcs-quarterly-update
2. FDA. National Drug Code database background information. Accessed March 31, 2023. https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information
3. ELREXFIO prescribing information. Pfizer, Inc.; 2023.
4. American Medical Association. 2023 CPT Professional Edition. Current Procedural Terminology (CPT®) copyright 2022 by the American Medical Association. All rights reserved. Chicago, IL: AMA; 2022.
5. CMS. Transmittal 167. April 30, 2004. Accessed March 31, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R167CP.pdf
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7. CMS. 2023 ICD-10-CM tabular list of disease and injuries. Accessed March 31, 2023. https://www.cms.gov/medicare/icd-10/2021-icd-10-cm

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IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

ELREXFIO™ (elranatamab-bcmm) is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager 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.

This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

WARNING: CYTOKINE RELEASE SYNDROME and NEUROLOGIC TOXICITY including IMMUNE EFFECTOR CELL-ASSOCIATED NEUROTOXICITY SYNDROME

Cytokine release syndrome (CRS), including life-threatening or fatal reactions, can occur in patients receiving ELREXFIO. Initiate treatment with ELREXFIO step-up dosing 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.

Because of the risk of CRS and neurologic toxicity, including ICANS, ELREXFIO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ELREXFIO REMS.

Cytokine Release Syndrome (CRS): ELREXFIO can cause CRS, including life-threatening or fatal reactions. In the clinical trial, CRS occurred in 58% of patients who received ELREXFIO at the recommended dose, with Grade 1 CRS in 44% of patients, Grade 2 CRS in 14% of patients, and Grade 3 CRS in 0.5% of patients. Recurrent CRS occurred in 13% of patients. 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 subsequent dose. The median time to onset of CRS was 2 (range: 1-9) days after the most recent dose, with a median duration of 2 (range: 1-19) days.

Clinical signs and symptoms of CRS may include, but are not limited to, fever, hypoxia, chills, hypotension, tachycardia, headache, and elevated liver enzymes.

Initiate therapy according to the ELREXFIO step-up dosing schedule to reduce risk of CRS and monitor patients following administration of ELREXFIO accordingly. Administer pretreatment medications prior to each dose in the step-up dosing schedule to reduce risk of CRS.

Counsel patients to seek medical attention should signs or symptoms of CRS occur. At the first sign of CRS, evaluate patients immediately for hospitalization. Manage CRS according to the recommendations and consider further management per current practice guidelines. Withhold or permanently discontinue ELREXFIO based on severity.

Neurologic Toxicity Including ICANS: ELREXFIO can cause serious or life-threatening neurologic toxicity, including ICANS.

In the clinical trial, neurologic toxicity occurred in 59% of patients who received ELREXFIO at the recommended dose, with Grade 3 or 4 neurologic toxicity occurring in 7% of patients. Neurologic toxicities included headache (18%), encephalopathy (15%), motor dysfunction (13%), sensory neuropathy (13%), and Guillain-Barré Syndrome (0.5%).

In the clinical trial, ICANS occurred in 3.3% of patients who received ELREXFIO at the recommended dose. Most patients had ICANS after the first step-up dose (2.7%), 1 (0.5%) patient had ICANS after the second step-up dose, and 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: 1-4) days after the most recent dose, with a median duration of 2 (range: 1-18) days. 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.

Continued on the next page

Please see full Prescribing Information for ELREXFIO, including BOXED WARNINGS, and Medication Guide.

IMPORTANT SAFETY INFORMATION (cont.)

Counsel patients to seek medical attention should signs or symptoms of neurologic toxicity occur. Monitor patients for signs and symptoms of neurologic toxicities during treatment with ELREXFIO. At the first sign of neurologic toxicity, including ICANS, evaluate and treat patients immediately based on severity. Withhold or permanently discontinue ELREXFIO based on severity per recommendations and consider further management per current practice guidelines.

Due to the potential for neurologic toxicity, including ICANS, patients receiving ELREXFIO are at risk of depressed level of consciousness. 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 neurologic toxicity symptoms until symptoms resolve.

REMS: ELREXFIO is available only through a restricted program under a REMS called the ELREXFIO REMS because of the risks of CRS and neurologic toxicity, including ICANS.

Hepatotoxicity: ELREXFIO can cause hepatotoxicity. In the clinical trial, elevated ALT occurred in 36% of patients, with Grade 3 or 4 ALT elevation occurring in 3.8%; elevated AST occurred in 40% of patients, with Grade 3 or 4 AST elevation occurring in 6%. Grade 3 or 4 total bilirubin elevations occurred in 0.5% of patients. Liver enzyme elevation can occur with or without concurrent CRS.

Monitor liver enzymes and bilirubin at baseline and during treatment as clinically indicated. Withhold ELREXFIO or consider permanent discontinuation of ELREXFIO based on severity.

Infections: ELREXFIO can cause severe, life-threatening, or fatal infections. In the clinical trial, in patients who received ELREXFIO at the recommended dose, serious infections, including opportunistic infections, occurred in 42% of patients, with Grade 3 or 4 infections in 31% and fatal infections in 7%. The most common serious infections reported (≥5%) were pneumonia and sepsis.

Do not initiate treatment with ELREXFIO in patients with active infections. Monitor patients for signs and symptoms of infection prior to and during treatment with ELREXFIO and treat appropriately. Withhold or permanently discontinue ELREXFIO based on severity. Administer prophylactic antimicrobial and antiviral medications according to current practice guidelines. Consider treatment with subcutaneous or intravenous immunoglobulin (IVIG) as appropriate.

Neutropenia: ELREXFIO can cause neutropenia and febrile neutropenia. In patients who received ELREXFIO at the recommended dose in the clinical trial, decreased neutrophils occurred in 62% of patients, with Grade 3 or 4 decreased neutrophils in 51%. Febrile neutropenia occurred in 2.2% of patients.

Monitor complete blood cell counts at baseline and periodically during treatment. Provide supportive care according to current practice guidelines. Monitor patients with neutropenia for signs of infection. Withhold ELREXFIO based on severity.

Embryo-Fetal Toxicity: Based on its mechanism of action, ELREXFIO may cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment with ELREXFIO and for 4 months after the last dose.

Adverse Reactions: In patients who received ELREXFIO, the most common adverse reactions (incidence ≥20%) were CRS, fatigue, injection-site reaction, diarrhea, upper respiratory tract infection, musculoskeletal pain, pneumonia, decreased appetite, rash, cough, nausea, and pyrexia. The most common Grade 3 or 4 laboratory abnormalities (≥30%) were decreased lymphocytes, decreased neutrophils, decreased hemoglobin, decreased white blood cells, and decreased platelets.

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