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
Inpatient Site of Care

Please see Important Safety Information and Indication on pages 10-11 and full Prescribing Information for ELREXFIO, including BOXED WARNINGS, and Medication Guide.

Introduction

Pfizer Inc. has developed this reference guide to assist inpatient 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 their patients. The information provided should not be considered a guarantee of coverage or reimbursement for ELREXFIO.

Please see Important Safety Information and Indication on pages 10-11 and full Prescribing Information for ELREXFIO, including BOXED WARNINGS, and Medication Guide.

*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

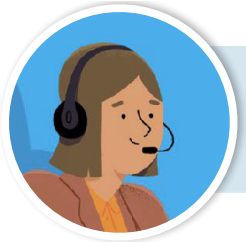
We can review the reasons for a denied claim and provide information on payer requirements. After an appeal is submitted, we can follow up with the payer until a final outcome is determined.

Billing and Coding Assistance for Injectable Products

For your patient claim submissions, we provide easy access to sample forms and template 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.

Please see Important Safety Information and Indication on pages 10-11 and full Prescribing Information for ELREXFIO, including BOXED WARNINGS, and Medication Guide.

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 therapy with ELREXFIO™ (elranatamab-bcmm) when performed in the hospital inpatient site of care to Medicare Administrative Contractors (MACs), private commercial payers, and Medicaid.

The code sets required in all hospital inpatient sites of care include International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) and Procedure Coding System (ICD-10-PCS), and revenue codes. Use and reporting requirements of other code sets may vary by payer and facility.

Coding for ELREXFIO

In the hospital inpatient site of care, Medicare, Medicaid, and private commercial payers may recognize the following codes for reporting ELREXFIO and its administration on claim forms.

Please confirm correct coding using payer guidance.

HCPCS Code[1]	Descriptor
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]	Descriptor
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.

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

Please see Important Safety Information and Indication on pages 10-11 and full Prescribing Information for ELREXFIO, including BOXED WARNINGS, and Medication Guide.

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]

NDC Conversion Example

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, 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]		*Prefilled Syringe Size*	*10-Digit NDC Prescribing Information*	*11-Digit NDC Claims*
	**76 mg/1.9 mL**	Single-dose vial in a carton	0069-4494-01	**0**0069-4494-01
	**44 mg/1.1 mL**	Single-dose vial in a carton	0069-2522-01	**0**0069-2522-01

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 codes 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

Reporting Revenue Codes for ELREXFIO Services

Hospital inpatient departments use revenue codes to report specific accommodations and/or ancillary charges.[5] They are a required code set 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]	**0250:** Pharmacy, general classification *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.

Procedure Coding for ELREXFIO™ (elranatamab-bcmm)

The ICD-10-PCS is a required code set in the inpatient site of care that should be used, as appropriate, to report the patient-specific procedure documented in the medical record. ICD-10-PCS codes may include, but are not limited to, the codes listed below:

ICD-10-PCS Code[8]	*Descriptor*
XW013F5	Introduction of Other New Technology Therapeutic Substance into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 5
For patients discharged on or after October 1, 2023, the following ICD-10-PCS code is relevant for ELREXFIO:	
XW013L9[9]	Introduction of Elranatamab Antineoplastic into Subcutaneous Tissue, Percutaneous Approach, New Technology Group 9

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. https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R167CP.pdf.
6. Research Data Assistance Center (ResDAC). Revenue center code. February 2008. Accessed March 2023. https://resdac.org/sites/datadocumentation.resdac.org/files/Revenue%20Center%20Code%20Code%20Table%20FFS.txt
7. CMS. ICD-10-CM/PCS MS-DRG v40.1 Definitions Manual. Accessed April 4, 2023. https://www.cms.gov/icd10m/FY2023-version40.1-fullcode-cms/fullcode_cms/P0001.html
8. CMS. 2023 ICD-10-PCS. Accessed March 31, 2023. Accessed March 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-pcs
9. CMS. 2024. ICD-10-PCS. Accessed Jun 23, 2023. https://www.cms.gov/files/zip/2024-icd-10-pcs-order-file-long-and-abbreviated-titles.zip

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.

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.

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

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

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

Pfizer Oncology together™