PEMGARDA®
(pemivibart) injection
for intravenous use | 125 mg/mL

Product Ordering, Billing, and Coding Information

PEMGARDA has been authorized by FDA for the emergency use described below. It is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

PEMGARDA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PEMGARDA under Section 564(b)(1) of the FD&C Act, 21 U.S.C. § 360bbb 3(b)(1), unless the authorization is terminated or revoked sooner.

WARNING: ANAPHYLAXIS

- **Anaphylaxis has been observed with PEMGARDA in 0.6% (4/623) of participants in a clinical trial.**
- **Anaphylaxis was reported during the first and second infusion of PEMGARDA.**
- **Anaphylaxis can be life-threatening.**
- **Prior to administering PEMGARDA, consider the potential benefit of COVID-19 prevention along with the risk of anaphylaxis.**
- **Administer PEMGARDA only in settings in which healthcare providers have immediate access to medications to treat anaphylaxis and the ability to activate the emergency medical system (EMS), as necessary.**
- **Clinically monitor individuals during the infusion and for at least two hours after completion of the infusion.**
- **Discontinue PEMGARDA use permanently if signs or symptoms of anaphylaxis or any severe systemic reaction are observed and initiate appropriate medications and/or supportive therapy.**

EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA®

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product PEMGARDA for the pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
- Who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** are unlikely to mount an adequate response to COVID-19 vaccination.

LIMITATIONS OF AUTHORIZED USE

- PEMGARDA is not authorized for use for treatment of COVID-19, or for post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90% based on available information including variant susceptibility to PEMGARDA and national variant frequencies.
- Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

PEMGARDA may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.

Please see full Important Safety Information, including limitations and Boxed Warning, on page 6.

PRODUCT ORDERING, BILLING, AND CODING INFORMATION

PEMGARDA® (pemivibart) injection for intravenous use

PRODUCT INFORMATION

PEMGARDA® INFORMATION

Product Concentration[1]	500 mg/4 mL vial (125 mg/mL)
Billing Unit[1]	1 for 4500 mg
Package Size[1]	9 vials per carton
Carton Contents[1]	Each PEMGARDA carton contains a total dose (4500 mg) of nine (9) single-dose 500 mg vials
NDC[1]	10-digit: 81960-031-03 | 11-digit: 81960-0031-03
WAC[2]	$6,680 per carton
Minimum Quantity per Order	1 carton

STORAGE AND HANDLING[1]

Refrigerate unopened vials at 2-8 °C (36-46 °F) in the original carton to protect from light.

Do not freeze or shake. Do not use if seal is broken or missing.

The diluted solution may be stored at room temperature under ambient light for up to 4 hours. Do not shake the diluted solution.

HOW TO ORDER PEMGARDA

	PHONE	EMAIL	ACCOUNT SETUP
CARDINAL HEALTH	855.855.0708	gmb-spd-csorderentry@cardinalhealth.com	866.677.4844
CENCORA	800.746.6273	service@asdhealthcare.com	asdaccountsetup@amerisourcebergen.com
CURASCRIPT SD	877.599.7748	Customer.Service@curascript.com	Customer.Service@curascript.com
FFF Enterprises	800.843.7477	fffcustomercare@fffenterprises.com	https://Biosupply.fffenterprises.com
MCKESSON MEDICAL & SURGICAL	855.571.2100	customerservice@mckesson.com	https://apply.mms.mckesson.com/
MCKESSON PLASMA AND BIOLOGICS	877.625.2566	mpborders@mckesson.com	mpbonboarding@mckesson.com
MCKESSON SPECIALTY CARE DISTRIBUTION	800.482.6700	physvcscustcare@mckesson.com	onboarding2@mckesson.com

Standard shipping is Monday–Thursday with UPS Next Day service by 10:30 am for orders received by 2 pm CT. To request Saturday delivery, please call Customer Service.

For information on product orders or tracking information, please call Customer Service at 844-220-5938 or email InvivydCS@ICSconnect.com.

Please **scan the QR code** or visit **https://www.pemgarda.com/expiration-date-extension** for current information about PEMGARDA expiration date extensions before administering or requesting a return of a product.

IMPORTANT SAFETY INFORMATION

PEMGARDA is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of PEMGARDA.

Serious hypersensitivity reactions, including anaphylaxis, and infusion-related reactions can occur during the infusion and up to 24 hours after the infusion of PEMGARDA and may be severe or life threatening. If signs and symptoms of a clinically significant hypersensitivity reaction or infusion-related reaction occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Permanently discontinue PEMGARDA in individuals who experience signs or symptoms of anaphylaxis.

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BILLING AND CODING INFORMATION

OVERVIEW

Content provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Please note that codes can change and may differ from those found in this resource. This list of codes is not exhaustive. Providers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the full responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. This resource is not intended to be legal advice or a substitute for a provider's independent professional judgment.

ADMINISTRATION-SPECIFIC CODES

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)[3,*]

TYPE	HCPCS SHORT DESCRIPTOR
Q0224*	Inj, pemivibart, 4500 mg
M0224*	Pemivibart infusion

*For more information, please **scan the QR code** or visit Centers for Medicare and Medicaid Services (CMS) payment information at **https://www.cms.gov/medicare/payment/part-b-drugs/vaccine-pricing**

FACILITIES BILLING ON FORM UB-04[4,5]

REVENUE CODE	DESCRIPTION
0771	Preventive Services: Vaccine administration
0636	Pharmacy, drugs requiring detailed coding

Scan the QR code or visit **https://www.cms.gov/monoclonal** for more information regarding CMS policy on Monoclonal Antibodies for Pre-Exposure Prophylaxis of COVID-19, including coverage, billing, coding, payment, and patient cost-sharing information.

IMPORTANT SAFETY INFORMATION (CONT'D)

PEMGARDA contains polysorbate 80, which is in some COVID-19 vaccines and is structurally similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. For individuals with a history of severe hypersensitivity reaction to a COVID-19 vaccine, consider consultation with an allergist-immunologist prior to PEMGARDA administration.

Certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA. PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. Inform individuals of the increased risk, compared to other variants, for COVID-19 due to SARS-CoV-2 viral variants that exhibit significantly reduced susceptibility to PEMGARDA. If signs and symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate.

The most common adverse events (all grades, incidence ≥2% and greater than placebo, through Month 6) observed in participants who have moderate-to-severe immune compromise in Cohort A PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, viral infection, upper respiratory tract infection, influenza-like illness, urinary tract infection, fatigue, headache, sinusitis, nasopharyngitis, influenza and pneumonia.

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BILLING AND CODING INFORMATION (CONT'D)

ICD-10-CM CODES

Please note that the codes provided below are representative of the conditions and/or statuses of those individuals who are currently identified as moderate to severely immunocompromised due to a medical condition or receipt of immunosuppressive medications or treatments and are unlikely to mount an adequate response to COVID-19 vaccination.* Providers are responsible for selecting the most specific ICD-10 billable codes (one to three decimal places) that are relevant to the patient's current medical condition or status based on their independent professional judgment, which could include codes that are not listed herein.

CODES REPRESENTING ENCOUNTER[6]	
Z23	Encounter for immunization
Z29.89	Encounter for other specified prophylactic measures
Z29.9	Encounter for prophylactic measures, unspecified
Z41.8	Encounter for other procedures for purposes other than remedying health state

CODES REPRESENTING PATIENT CONDITION[6]			
Z79.52	Long term (current) use of systemic steroids†	Z92.21	Personal history of antineoplastic chemotherapy§
Z79.6+	Long term (current) use of immunomodulators and immunosuppressants; including chemotherapeutic agents	Z92.241	Personal history of systemic steroid therapy†§
Z85.6	Personal history of leukemia	Z92.25	Personal history of immunosuppression therapy§
Z85.71	Personal history of Hodgkin lymphoma	Z92.3	Personal history of irradiation§¶
Z85.72	Personal history of non-Hodgkin lymphomas	Z92.850	Personal history of Chimeric Antigen Receptor T-cell therapy§
Z85.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic, and related tissues‡	Z94+	Transplanted organ and tissue status#

*Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include: active treatment for solid tumor and hematologic malignancies; hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia); receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy; receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppressive therapy); moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome); advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV); active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents).[1]

†Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks).[1]

‡Specific for patients under active treatment.[1]

§Personal history codes should be selected only if they are relevant to the patient's current immunocompromised health status.

¶When used for solid tumor or hematologic malignancy treatment.

#Solid-organ transplant or islet transplant patients must be taking immunosuppressive therapies. For HSCT patients, must be within 2 years of transplantation or taking immunosuppressive therapy.[1]

The "+" denotes a group of codes with the most specific, billable code to be found underneath in the ICD-10 code list.

IMPORTANT SAFETY INFORMATION (CONT'D)

PEMGARDA should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PEMGARDA and any potential adverse effects on the breastfed infant from PEMGARDA.

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BILLING AND CODING INFORMATION (CONT'D)

CODES REPRESENTING PATIENT DIAGNOSIS[6]

B20	Human immunodeficiency virus (HIV) disease*	C96+	Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue
C81+	Hodgkin lymphoma	D80+	Immunodeficiency with predominantly antibody defects (including hereditary and nonfamilial hypogammaglobulinemia and immunoglobulin deficiencies)
C82+	Follicular lymphoma	D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
C83+	Non-follicular lymphoma	D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
C84+	Mature T/NK-cell lymphomas	D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
C85+	Other specified and unspecified types of non-Hodgkin lymphoma	D81.31	Severe combined immunodeficiency due to adenosine deaminase deficiency
C86+	Other specified types of T/NK-cell lymphoma	D82+	Immunodeficiency associated with other major defects (including Wiskott-Aldrich syndrome, DiGeorge syndrome, immunodeficiency following hereditary defective response to Epstein-Barr virus)
C88+	Malignant immunoproliferative diseases and certain other B-cell lymphomas	D83+	Common variable immunodeficiency (including B- and T-cell disorders)
C90+	Multiple myeloma and malignant plasma cell neoplasms	D84.821	Immunodeficiency due to drugs†
C91+	Lymphoid leukemia		
C92+	Myeloid leukemia		
C93+	Monocytic leukemia		
C94+	Other leukemias of specified cell type		
C95+	Leukemia of unspecified cell type		

*People with HIV and CD4 cell counts <200/mm^3, history of AIDS-defining illness without immune reconstitutions, or clinical manifestations of symptomatic HIV.[1]

†Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents).[1]

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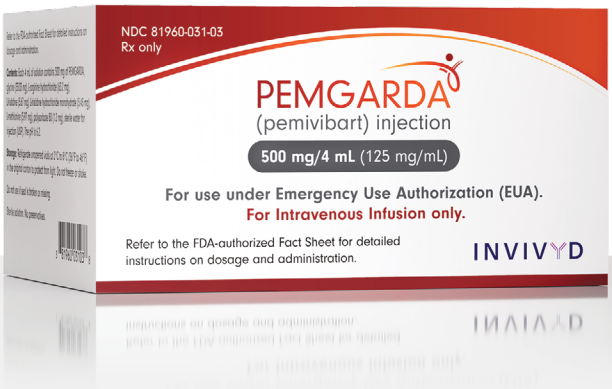

IMPORTANT SAFETY INFORMATION (CONT'D)

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events and medication errors potentially related to PEMGARDA within 7 calendar days from the healthcare provider's awareness of the event. See Section 6.4 of the accompanying Fact Sheet for more information.

Complete and submit the report online: www.fda.gov/medwatch/report.htm. See Section 6.4 of the Fact Sheet for additional mechanisms for reporting.

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Important Safety Information

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See accompanying Fact Sheet for Healthcare Providers and FDA Letter of Authorization.

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Actor portrayal.

For information on product orders or tracking information, please call Customer Service at 844-220-5938 or email InvivydCS@icsconnect.com.

CAR, chimeric antigen receptor; CMS, Centers for Medicare & Medicaid Services; COVID-19, coronavirus disease 2019; EUA, Emergency Use Authorization; FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; HSCT, hematopoietic stem cell transplant; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; WAC, wholesale acquisition cost.

References: 1. PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc. 2026. **2.** AnalySource®. PEMGARDA WAC report. Accessed May 12, 2026. https://www.analysource.com/ **3.** Centers for Medicare & Medicaid Services (CMS). COVID-19 monoclonal antibodies. Accessed May 12, 2026. https://www.cms.gov/monoclonal **4.** Centers for Medicare & Medicaid Services (CMS). Medicare Claims Processing Manual. Accessed June 5, 2026. https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms018912 **5.** Centers for Medicare & Medicaid Services. COVID-19 frequently asked questions (FAQs) on Medicare Fee-for-Service (FFS) billing. Accessed June 16, 2026. https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf **6.** Centers for Medicare & Medicaid Services (CMS). ICD-10-CM Tabular list of diseases and injuries. Accessed May 12, 2026. https://www.cms.gov/medicare/coding-billing/icd-10-codes

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