Billing and Coding Information

PEMGARDA
(pemivibart) injection
for intravenous use

EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA™

The U.S. Food and Drug Administration (FDA) has issued an 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.

PEMGARDA has been authorized by FDA for the emergency use described above.

PEMGARDA 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 Federal Food Drug, and Cosmetic Act, 21 U.S.C. § 360bbb 3(b)(1), unless the authorization is terminated or revoked sooner.

IMPORTANT SAFETY INFORMATION

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 immediately if signs or symptoms of anaphylaxis or any severe systemic reaction are observed and initiate appropriate medications and/or supportive therapy.**

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, and infusion-related reactions occurring during the infusion and up to 24 hours after the infusion have been observed with 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. Clinically monitor individuals during infusion for at least two hours after infusion is complete.

Risk of Cross-Hypersensitivity With COVID-19 Vaccine

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.

Please see additional Important Safety Information throughout and see the full Fact Sheet for Healthcare Providers, including Boxed Warning for more information on the EUA of PEMGARDA.

REFER TO THE NEXT SECTIONS FOR BILLING AND CODING INFORMATION

BILLING AND CODING INFORMATION

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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.

PRODUCT-SPECIFIC CODES

NATIONAL DRUG CODE (NDC)[1]		
NDC	**PRODUCT**	**DESCRIPTION**
10-digit: 81960-031-03 11-digit: 81960-0031-03	1 carton (9 vials per carton)	PEMGARDA™ 4500 mg injection, for intravenous use

ADMINISTRATION-SPECIFIC CODES

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS)[2]	
TYPE	**DESCRIPTION**
Q0224*	Code for drug
M0224*	Code for infusion of drug

*Centers for Medicare and Medicaid Services (CMS) payment information available at www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/vaccine-pricing

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, please visit: www.cms.gov/monoclonal

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Risk for COVID-19 Due to SARS-CoV-2 Viral Variants with Substantially Reduced Susceptibility to PEMGARDA

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.

ADVERSE REACTIONS

The most common adverse events (all grades, incidence ≥2%) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. PEMGARDA should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Lactation

There are no available data on the presence of PEMGARDA in human or animal milk, the effects on the breastfed infant, or the effects on milk production. 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.

Pediatric Use

PEMGARDA is not authorized for use in pediatrics less than 12 years of age or weighing less than 40 kg. The safety and effectiveness of PEMGARDA has not been established in pediatrics.

Please see additional Important Safety Information throughout and see the full Fact Sheet for Healthcare Providers, including Boxed Warning for more information on the EUA of PEMGARDA.

BILLING AND CODING INFORMATION

PEMGARDA (pemivibart) injection for intravenous use

ICD-10-CM CODES[3]

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 (to one or two 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 PATIENT CONDITION			
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 lymphomas	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[§]
Z86.79	Personal history of other malignant neoplasms of lymphoid, hematopoietic, and related tissues[‡]	Z94+	Transplanted organ and tissue status[#]
CODES REPRESENTING ENCOUNTER			
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 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).

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

[‡]Specific for patients under active treatment.

[§]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.

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)

See full **Fact Sheet for Healthcare Providers** and **Fact Sheet for Patients, Parents, and Caregivers** for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. The **FDA Letter of Authorization** is also available for reference.

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, using FDA Form 3500 (for information on how to access this form, see below). The FDA requires that such reports, using FDA Form 3500, include the following:

- Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, sex, weight, ethnicity, and race).
- A statement "PEMGARDA use for the pre-exposure prophylaxis of COVID-19 under Emergency Use Authorization (EUA)" under the **"Describe Event, Problem, or Product Use/Medication Error"** heading.
- Information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes).
- Patient's preexisting medical conditions and use of concomitant products.
- Information about the product (e.g., dosage, route of administration, NDC #).

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CODES REPRESENTING PATIENT DIAGNOSIS

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
C85+	Other specified and unspecified types of non-Hodgkin lymphoma	D81.31	Severe combined immunodeficiency due to adenosine deaminase
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.
†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).

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)

Submit serious adverse event and medication error reports using FDA Form 3500 to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm.
- Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
  - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
  - Fax to 1-800-FDA (332)-0178, or
- Call 1-800-FDA (332)-1088 to request a reporting form.

In addition, please provide a copy of all FDA MedWatch forms to:

Invivyd, Inc.
Email: pv@invivyd.com

Or call Invivyd, Inc. at 1-800-890-3385 to report serious adverse events.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about serious adverse events and medication errors following receipt of PEMGARDA™.

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- Other important medical events, which may require a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

You may report side effects related to Invivyd, Inc. products by sending an email to medinfo@invivyd.com.

Please see the full Fact Sheet for Healthcare Providers, including Boxed Warning for more information on the EUA of PEMGARDA.

CAR, chimeric antigen receptor; CMS, Centers for Medicare and 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.

References: 1. PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc: 2024. **2.** Centers for Medicare & Medicaid Services (CMS). 2024 Healthcare Common Procedure Coding System (HCPCS). Accessed April 12, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
3. ICD10Data.com. 2024 ICD-10-CM codes. Accessed February 13, 2024. https://www.icd10data.com/ICD10CM/Codes

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