

# Billing and Coding Information

**PEMGARDA**  
(pemivibart) injection  
for intravenous use

## EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA™

PEMGARDA has not been approved, but has been authorized for emergency use by FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (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 immune response to COVID-19 vaccination.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

## 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.
- 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.

## 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, have been observed during infusion and up to 24 hours after administration of PEMGARDA. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals during the 60-minute infusion and for at least two hours after completion of the infusion.

### Risk of Cross-Hypersensitivity With COVID-19 Vaccines

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

## 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)<sup>1</sup>

| NDC   | PRODUCT                       | DESCRIPTION                                      |
|---|-------------------------------|--|
| 10-digit: 81960-031-03<br>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)<sup>2</sup>

| 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](http://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](http://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 Not Neutralized by PEMGARDA

Certain SARS-CoV-2 viral variants may emerge that are not neutralized by monoclonal antibodies such as 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 emergent SARS-CoV-2 viral variants not neutralized by PEMGARDA. If signs or 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  $\geq 2\%$ ) 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.

**ICD-10-CM CODES<sup>3</sup>**

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.

| <b>CODES REPRESENTING PATIENT CONDITION</b> |  |         |   |
|---|--|---------|---|
| Z79.52                                      | Long term (current) use of systemic steroids <sup>†</sup>  | Z92.21  | Personal history of antineoplastic chemotherapy <sup>§</sup>              |
| Z79.6+                                      | Long term (current) use of immunomodulators and immunosuppressants; including chemotherapeutic agents      | Z92.241 | Personal history of systemic steroid therapy <sup>§</sup>                 |
| Z85.6                                       | Personal history of leukemia   | Z92.25  | Personal history of immunosuppression therapy <sup>§</sup>                |
| Z85.71                                      | Personal history of Hodgkin lymphomas  | Z92.3   | Personal history of irradiation <sup>§¶</sup>                             |
| Z85.72                                      | Personal history of non-Hodgkin lymphomas  | Z92.850 | Personal history of Chimeric Antigen Receptor T-cell therapy <sup>§</sup> |
| Z86.79                                      | Personal history of other malignant neoplasms of lymphoid, hematopoietic, and related tissues <sup>‡</sup> | Z94+    | Transplanted organ and tissue status <sup>#</sup>                         |
| <b>CODES REPRESENTING ENCOUNTER</b>         |  |         |   |
| 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<sup>3</sup>, 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).

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

<sup>‡</sup>Specific for patients under active treatment.

<sup>§</sup>Personal history codes should be selected only if they are relevant to the patient’s current immunocompromised health status.

<sup>¶</sup>When used for solid tumor or hematologic malignancy treatment.

<sup>#</sup>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, including Boxed Warning](#) 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 #).

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.

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

\*People with HIV and CD4 cell counts <200/mm<sup>3</sup>, 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](http://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](mailto: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](mailto: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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