

# Site-of-Care Considerations

**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.

- 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); and
- 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.

## 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.

## REFER TO THE NEXT SECTIONS FOR KEY CONSIDERATIONS WHEN DETERMINING WHERE YOUR PATIENT WILL RECEIVE PEMGARDA

Please see Important Safety Information, including Boxed Warning, throughout and the full **Fact Sheet for Healthcare Providers and the Letter of Authorization**, provided by an Invivyd representative, for more information on the EUA of PEMGARDA.

### DETERMINING WHERE YOUR PATIENT WILL RECEIVE PEMGARDA™

Once the clinical decision is made to prescribe PEMGARDA, there are some details to consider before scheduling an infusion.

It is important to understand your payor and hospital contracts when considering whether your office will be administering the infusion or if you will be referring to an external site of care.

### CONSIDER THE FOLLOWING WHEN DETERMINING HOW PATIENTS IN YOUR HEALTH SYSTEM OR PRACTICE WILL RECEIVE PEMGARDA:

Is your health system or office infusion suite equipped to provide PEMGARDA infusions?

#### HEALTH SYSTEM

- Is PEMGARDA available in your electronic medical record (EMR)? Is it available with pharmacy approval?
- If so, there may be dedicated locations for PEMGARDA infusion currently identified in your system
- If you routinely send your infusion patients to a health system operated center, is there capacity to receive PEMGARDA referrals there?
- Is PEMGARDA currently being infused in another health system department that may be open to receiving referrals from your practice?

#### PRACTICE

Does your practice have:

- Ability to prepare and administer PEMGARDA by a qualified healthcare provider using aseptic technique?
- Immediate access to medications to treat anaphylaxis and the ability to activate the emergency medical system (EMS), as necessary?
- Capabilities to clinically monitor individuals during the infusion and for at least 2 hours after completion of the infusion?
- Appropriate healthcare providers to both administer and supervise the infusions?



### IF YOU CANNOT ADMINISTER PEMGARDA ON SITE, YOU MAY BE ABLE TO REFER YOUR PATIENT TO AN ALTERNATE SITE OF CARE

An Invivyd™ Care Case Manager can help you investigate site-of-care options.

## 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  $\geq 2\%$ ) 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 pediatric patients less than 12 years of age or weighing less than 40 kg. The safety and effectiveness of PEMGARDA has not been established in pediatrics.

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### ALTERNATE SITES OF CARE ARE AVAILABLE FOR YOUR PATIENTS

There may be other types of sites that are equipped to administer PEMGARDA™ infusions in your area. The PEMGARDA Infusion Center Locator can help providers and patients locate an appropriate site of care: <https://www.pemgarda.com/hcp/infusion-center-locator/>



**HOSPITAL OUTPATIENT  
INFUSION CENTERS**



**SPECIALTY OFFICE-BASED  
INFUSION CENTERS  
(e.g., office-based labs)**



**AMBULATORY INFUSION  
CENTERS/SUITES**

#### CONSIDER THE FOLLOWING WHEN DECIDING TO REFER PATIENTS TO EXTERNAL SITES OF CARE TO RECEIVE PEMGARDA:

- Is there an alternate site of care to which you have referred other infusion patients from your practice? If so, this facility may be able to properly administer PEMGARDA
- Does your EMR system have practice-specific permissions that may impact how you refer patients to alternate sites of care?
- Are there requirements related to payor contracts, hospital contracts, and fee schedules that you may need to be mindful of when referring patients outside of your practice or health system?
- Is the infusion center in-network for your patient and are there any site-of-care restrictions from your patient's insurance? Are you recognized as a provider within that network? Patients may incur additional out-of-pocket costs if they are referred to an infusion center that is considered out-of-network by their health plan

**It is recommended to review your payor and hospital contracts when deciding how patients in your practice will receive PEMGARDA**

#### QUESTIONS?

Invivyd™ Care is here to help answer your questions around access and reimbursement for PEMGARDA for your patients. Visit [InvivydCare.com](https://InvivydCare.com) or contact us.



**Phone:** 844-VYD-2220 (844-893-2220)  
**Hours:** Monday-Friday 8 AM to 8 PM ET  
**Email:** [invivydcare@pro-spectus.com](mailto:invivydcare@pro-spectus.com)

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**Invivyd™ Care is here to answer your questions around access and reimbursement for PEMGARDA™.**  
**Visit [InvivydCare.com](https://InvivydCare.com) to learn more.**

### **IMPORTANT SAFETY INFORMATION (cont'd)**

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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 #).

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](https://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).*

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