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

Site-of-Care Considerations

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 sending the prescription or infusion order to an external site of care.

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.

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

Please see full Important Safety Information, including limitations and Boxed Warning, on page 3.

Site-of-Care Considerations

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(pemivibart) injection
for intravenous use

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 patients there?
- Is PEMGARDA currently being infused in another health system department that may be open to receiving patients from your practice?
- Does the infusion center fulfill the necessary practice criteria for the administration of PEMGARDA (listed to the right)?

PRACTICE

Does your practice have[1]:

- Ability to prepare and administer PEMGARDA by a qualified healthcare provider using aseptic technique?
- Immediate access to medications to treat severe hypersensitivity reactions, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary?
- Capabilities to clinically monitor patients during the infusion and observe patients 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 SEND A PRESCRIPTION OR INFUSION ORDER TO AN ALTERNATE SITE OF CARE

Invivyd Care is a personalized support program that offers patients, caregivers, and healthcare providers resources and assistance across all aspects of the care pathway. See back page for contact information.

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

Home Infusion:
In settings with immediate access to medications to treat anaphylaxis and the ability to activate EMS, as necessary

CONSIDER THE FOLLOWING WHEN DECIDING TO SEND A PRESCRIPTION OR INFUSION ORDER TO EXTERNAL SITES OF CARE FOR PEMGARDA ADMINISTRATION:

- Is there an alternate site of care to which you routinely send orders for 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 prescribe infusion drugs for administration 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 for the treatment of 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 at infusion centers that are considered out-of-network by their health plan

Consider reviewing your payor and hospital contracts when deciding how patients in your practice will receive PEMGARDA

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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Important Safety Information

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- 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.

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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.

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.

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.

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

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Actor portrayal

Invivyd Care is here to answer your questions around access and reimbursement for PEMGARDA®.

QUESTIONS?

Visit InvivydCare.com or contact us.

INVIVYD care

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

Reference: 1. PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc: 2025.

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