After You Prescribe:

Site-of-Care Activation Guide

PEMGARDA®
(pemivibart) injection
for intravenous use

GETTING STARTED WITH PEMGARDA® AT YOUR PRACTICE SITE IS EASY

- Hundreds of infusion centers across the United States have ordered PEMGARDA or are prepared to administer PEMGARDA
- Many patients have coverage for PEMGARDA, and co-pay assistance is available for eligible patients with commercial insurance
- Invivyd Care representatives are available to help with access and reimbursement for PEMGARDA

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.

Please see full Important Safety Information, including limitations and Boxed Warning, on page 5.

PEMGARDA® Clinical Considerations

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PEMGARDA EUA DETAILS

Medical conditions or treatments that may result in moderate-to-severe immune compromise and an inadequate immune response to COVID-19 vaccination include[1]:

- Active treatment for solid tumors 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 CAR-T 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 reconstruction, 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)

PEMGARDA DOSING[1]

- Initial dose: 4500 mg administered as a single IV infusion over a minimum of 60 minutes
- Repeat dose: 4500 mg administered as a single IV infusion every 3 months

Examples of treatments that may contribute to immune suppression include[2-8*]:

- B-cell depleting agents: Rituxan® (rituximab), Ocrevus® (ocrelizumab)
- TNF inhibitors: Remicade® (infliximab), Enbrel® (etanercept)
- Antimetabolites: methotrexate
- JAK inhibitors: Xeljanz® (tofacitinib), Rinvoq® (upadacitinib)

*This list is not exhaustive. Other treatments may also contribute to immune suppression.

See the Fact Sheet for Healthcare Providers for more information about PEMGARDA

Consider the recommended dosing frequency for your patient when choosing an appropriate site of care. Patients who require repeat dosing may benefit from a closer treatment site and appointment reminders.

AIDS=acquired immunodeficiency syndrome; CAR-T=chimeric antigen receptor T-cell; COVID-19=coronavirus disease 2019; HIV=human immunodeficiency virus; IV=intravenous; JAK=Janus kinase; TNF=tumor necrosis factor.

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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Getting Started With PEMGARDA®

at Your Practice Site

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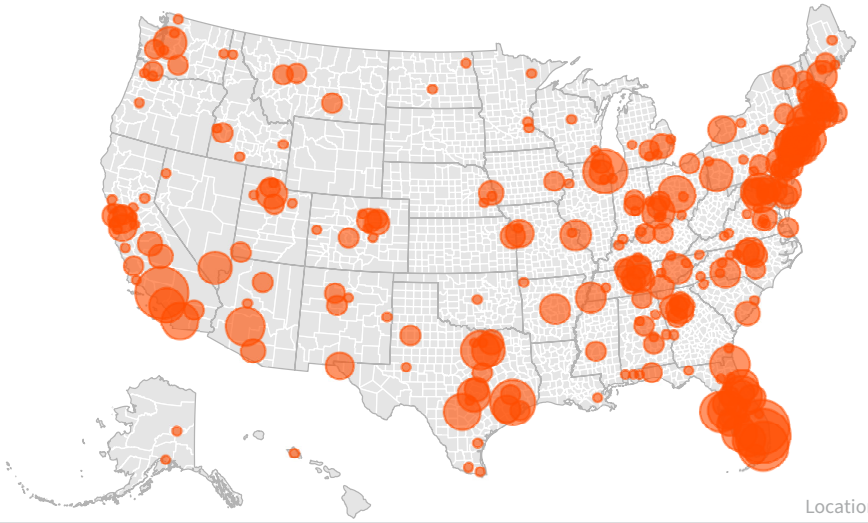
HUNDREDS OF INFUSION CENTERS ACROSS THE UNITED STATES HAVE ORDERED PEMGARDA OR ARE PREPARED TO ADMINISTER PEMGARDA



Locations subject to change.

Visit the PEMGARDA Infusion Center Locator to see other sites of care* near you that are equipped to administer PEMGARDA.

CONSIDER THE FOLLOWING WHEN PLANNING FOR YOUR PATIENT'S VISIT(S) TO RECEIVE PEMGARDA:

- **How does your treatment center order PEMGARDA?** Your electronic medical record (EMR) system may require pharmacy approval to order PEMGARDA
- **Where, in your treatment center, will your patients receive PEMGARDA infusions?** Your patients receiving PEMGARDA may require additional protection from infection due to their immunocompromised status
- **Who are the qualified healthcare providers who can prepare and administer PEMGARDA using aseptic technique?** You will need qualified healthcare providers to prepare, administer, and supervise the infusions (≥1-hour infusion period, ≥2-hour observation period)[1]
- **Where do you store medications to treat anaphylaxis?** The ability to immediately access these medications is necessary[1]
- **How does your treatment center activate the emergency medical system (EMS)?** The qualified healthcare provider administering the PEMGARDA infusion should be prepared to activate the EMS, as necessary[1]
- **What plan does your treatment center have in place to clinically monitor patients?** Patients should be monitored during the infusion and for at least 2 hours after completion of the infusion[1]

*If you cannot administer PEMGARDA on site, you may be able to suggest an alternate site of care to your patient.

Getting ready to order PEMGARDA? Please note: a signed letter of affiliation may be requested if you need to send shipments to a different office address than that of the licensed medical director for your practice. For information on product orders, please call Customer Service at 844-220-5938 or email InvivydCS@icsconnect.com.

For information about PEMGARDA's expiration date extension notice, visit https://www.pemgarda.com/expiration-date-extension

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.

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Billing and Reimbursement for PEMGARDA®

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The wholesale acquisition cost of PEMGARDA is $6,350 per carton.[9]

- 1 carton contains 9 single-dose 500 mg vials, comprising one total dose of 4500 mg

MANY PATIENTS HAVE COVERAGE FOR PEMGARDA

MEDICARE[10]

Patients with Medicare have no cost-sharing for COVID-19 monoclonal antibody products or their administration.

Visit the CMS webpage regarding the Medicare policy.

COMMERCIAL

Many commercial plans provide coverage for PEMGARDA, even if there is not a medical policy posted.*

If you cannot locate a commercial payor's plan for PEMGARDA, contact the plan's provider representative directly to inquire about coverage.

MEDICAID

Medicaid coverage for PEMGARDA varies by state.*

Check with your local Medicaid managed care organization to verify a patient's coverage for PEMGARDA.

*Medical exception and appeals are available with plans that state products with Emergency Use Authorization are investigational.

PEMGARDA BILLING AND CODING

When submitting a claim for PEMGARDA, identify the following:

- CPT codes describing the **procedure (HCPCS codes)** and **supply (NDC codes)**
- **ICD-10-CM diagnosis code(s) that describes the underlying cause** of the moderate-to-severe immunocompromising condition (e.g., the disease or immunosuppressive therapy)
- **ICD-10-CM code(s) that identify the encounter** as a preventative service

See the **PEMGARDA Billing and Coding Information** for detailed billing and coding information.

Contact Invivyd Care for assistance with PEMGARDA billing and coding questions (contact information on page 6).

INVIVYD care

CO-PAY ASSISTANCE

Eligible commercially insured patients† who are prescribed PEMGARDA can access co-pay assistance of up to $500 per dose (subject to an annual limit). Visit Invivydcare.com or contact an Invivyd Care representative to learn more (additional information on page 6).

†Use of the Program is not permitted for prescriptions reimbursed under Medicare, Medicaid, Medigap, VA, DoD, CHAMPUS, TRICARE® or other federal or state health programs (such as medical assistance programs).

CMS=Centers for Medicare & Medicaid Services; CPT=Current Procedural Terminology; DoD=Department of Defense; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NDC=National Drug Code; VA=Veterans Affairs.

IMPORTANT SAFETY INFORMATION (CONT'D)

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.

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Important Safety Information

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- 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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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.

5 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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AS YOU ARE GETTING STARTED WITH PEMGARDA AT YOUR PRACTICE SITE, REMEMBER:

- Many treatment centers across the US have experience administering PEMGARDA for their patients and may be options for sites of care
- Many of your patients may have coverage for PEMGARDA
  - Patients with Medicare have no cost-sharing for PEMGARDA or its administration[10]
  - Many commercial plans provide coverage for PEMGARDA; contact payors regarding a patient's coverage for PEMGARDA if you cannot locate a policy
- Invivyd Care representatives can help you and your patients navigate access and reimbursement for PEMGARDA

INVIVYD care

INVIVYD CARE CAN HELP PROVIDE GUIDANCE ON NAVIGATING ACCESS TO TREATMENT ON BEHALF OF PATIENTS WHO HAVE BEEN PRESCRIBED PEMGARDA

INVIVYD Care is a personalized support program that offers patients, caregivers, and healthcare providers resources and assistance across all aspects of the care pathway:

BENEFITS INVESTIGATION

Assist providers and patients, as applicable, to analyze and understand requirements for each patient's health plan

ACCESS & REIMBURSEMENT

Work with providers and their office staff to assess payor requirements and provide billing and coding support

TREATMENT COORDINATION

Help facilitate patient access to a prescribed INVIVYD treatment (e.g., co-pay assistance, identifying a site of care)

PAYOR ADVOCACY

Support patients with advocating for coverage by providing information around plan specifics and filing appeals

TO CONTACT AN INVIVYD CARE REPRESENTATIVE:

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

VISIT
INVIVYDCARE.COM
TO LEARN MORE!

References: 1. PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc: 2025. **2.** Meneghini M, Bestard O, Grinyo JM. Immunosuppressive drugs modes of action. *Best Pract Res Clin Gastroenterol.* 2021;54-55:101757. **3.** Rituxan. Prescribing information. Genentech, Inc. 2021. **4.** Ocrevus. Prescribing information. Genentech, Inc. 2024. **5.** Remicade. Prescribing information. Janssen Biotech, Inc. 2021. **6.** Enbrel. Prescribing information. Immunex Corporation. 2024. **7.** Xeljanz. Prescribing information. Pfizer Inc. 2025. **8.** Rinvoq. Prescribing information. AbbVie Inc. 2024. **9.** AnalySource®. PEMGARDA WAC report. Accessed March 10, 2025. https://www.analysource.com/ **10.** Centers for Medicare & Medicaid Services (CMS). COVID-19 monoclonal antibodies. Accessed March 11, 2025. https://www.cms.gov/monoclonal

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