Navigating Payor Policies

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.

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.

Navigating Payor Policies

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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.

Getting Started

PEMGARDA
(pemivibart) injection
for intravenous use

STEPS TO HELP GET YOUR APPROPRIATE PATIENTS STARTED ON PEMGARDA™

Complete the Patient Enrollment Form using DocuSign, or print it, complete it with your patient, and return it to Invivyd™ Care via fax to 855-233-1706

- Patients can initiate enrollment in Invivyd Care only after a decision to prescribe has been made by their provider. Invivyd Care will contact the provider to complete enrollment fields
- Invivyd Care can secure e-consent/signature from your patient when their contact information is provided in the enrollment form
- Please note: the best practice is for your office to notify the patient that you have initiated enrollment with Invivyd Care

Identify a suitable site for PEMGARDA infusion that is ideally covered by the patient's insurance and/or deemed medically appropriate for their needs and can meet the requirements of the Boxed Warning and Dose Preparation and Administration as outlined in Section 2.3 of the Fact Sheet for Healthcare Providers

- The site of care can include physician office infusion suites or ambulatory infusion centers
- Invivyd Care Case Managers can work with healthcare providers to identify the site of infusion if necessary

Verify your patient's coverage for PEMGARDA with their insurance providers and secure payor approval

- Invivyd Care Case Managers can:
  - Provide information or answer questions about this process
  - Verify coverage, initiate authorizations, and assist with both pre- and post-claim review processes on behalf of the providers

Order PEMGARDA through an authorized distributor (please see page 12 for ordering details)

Shipment is received at infusion site

Invivyd Care Case Managers are available to provide information or answer questions about this process and help patients navigate out-of-pocket costs.

Call 844-VYD-2220 or email invivydcare@pro-spectus.com | Monday-Friday 8 AM - 8 PM ET

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

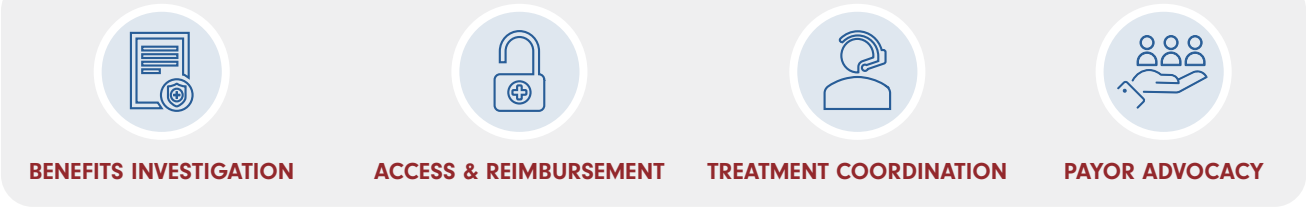
Certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA. PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. Inform individuals of the increased risk, compared to other variants, for COVID-19 due to SARS-CoV-2 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.

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.

Invivyd™ Care

PEMGARDA
(pemivibart) injection
for intravenous use

INVIVYD CARE IS A PERSONALIZED SUPPORT PROGRAM THAT OFFERS PATIENTS, CAREGIVERS, AND HEALTHCARE PROVIDERS RESOURCES AND ASSISTANCE ACROSS ALL ASPECTS OF THE CARE PATHWAY



Invivyd Care Case Managers and Reimbursement Managers are available to offer the support and resources necessary to facilitate access to treatment for patients who have been prescribed PEMGARDA™.

INVIVYD CARE CASE MANAGERS

Case managers can be reached by calling or emailing Invivyd Care and can provide access and reimbursement support for patients prescribed PEMGARDA.

Case managers can:

- Conduct a benefits investigation to help understand a patient's insurance coverage for PEMGARDA
- Offer information and support for prior authorizations and appeals
- Determine a patient's eligibility for Invivyd Care co-pay support programs
- Address logistical questions around treatment coordination for PEMGARDA
  - If requested, can research in-network infusion sites of care

REIMBURSEMENT MANAGERS

Reimbursement Managers serve as on-site contacts and are a primary resource for billing, coding, and product ordering. Reimbursement Managers are well versed in provider case management and provider administration requirements.

Reimbursement Managers can:

- Answer questions before and during benefits investigation
- Provide claims support and case coordination
- Answer billing, coding, and reimbursement questions
- Assist with product ordering
- Help enroll in Invivyd Care and Invivyd Care co-pay support programs

Questions? Call 844-VYD-2220 or email invivydcare@pro-spectus.com | Monday-Friday 8 AM - 8 PM ET

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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.

INVIVYD PATIENT SAVINGS PROGRAM

Commercially insured patients can access co-pay assistance for PEMGARDA™

THERE ARE 2 WAYS TO ENROLL:

1. **Call 888-550-4883**
2. **Scan or click the QR code to sign up on the Invivyd Patient Savings Portal**

ONCE THE PATIENT IS ENROLLED, A CLAIM CAN BE SUBMITTED THROUGH THE PORTAL OR MAIL:

1. **To submit a claim via the portal, patients will need:**
   - To create an Invivyd Patient Savings Portal account at https://invivyd.patientsavings.com
   - Their insurance information
   - Information to verify patient's out-of-pocket responsibility (e.g., explanation of benefits from insurance carrier)
2. **To submit a claim via mail,* patients will need:**
   - Explanation of benefits (EOB) or facility invoice
   - If payment to provider, complete Reimbursement Form (available in the Patient Savings Portal)
     - Please note check processing may take 14 to 23 days

Please note: Patients may only submit a claim if they have commercial insurance and are not a participant of Medicare Part B, Medicare Part D, Medicaid, Medigap, Veterans Affairs (VA), Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), TRICARE®, or other federal or state program.

*Mailing address available upon enrollment from the portal or call center (888-550-4883).

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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.

Billing and Coding Overview

PEMGARDA (pemivibart) injection for intravenous use

BILLING AND CODING

- Centers for Medicare & Medicaid Services (CMS) will cover PrEP mAbs under Part B through the end of the calendar year in which the Emergency Use Authorization (EUA) declaration ends[1]
- PEMGARDA™ is a monoclonal antibody payable under the Part B Preventative Vaccine Benefit at 95% of average wholesale price (AWP)[1]
- CMS covers PEMGARDA as a preventative benefit, which means there is no cost to your patients for the drug or administration[1]

When submitting a claim for PEMGARDA, the following will need to be identified:

- CPT codes describing the procedure (HCPCS codes for administration) and supply (NDC codes for product)
- 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 procedure as a preventative service

PRODUCT-SPECIFIC CODES

NDC[2]		
NDC	**PRODUCT**	**DESCRIPTION**
10-digit: 81960-031-03 /11-digit: 81960-0031-03	1 carton (9 vials)	PEMGARDA 4500 mg injection, for intravenous use

ADMINISTRATION-SPECIFIC CODES

HCPCS[3]	
TYPE	**HCPCS SHORT DESCRIPTOR**
Q0224*	Inj, pemivibart, 4500 mg
M0224*	Pemivibart infusion

FACILITIES BILLING ON FORM UB04[4]	
REVENUE CODE	**DESCRIPTION**
0771	Preventative care services
0636	Pharmacy, drugs requiring detailed coding

COVERAGE TIPS:

- Payors may not require authorization for Q0224/M0224
- Requesting voluntary authorization to confirm patient medical necessity with payor is recommended
- Consider securing payor-specific requirements for authorization

PAYMENT TIPS:

- Provider contracts should be reviewed to determine reimbursement for new drugs or Q-codes/inclusion of Q0224/M0224
- Confirm if contracts follow CMS payment methodology and fee schedules

If necessary, request the inclusion of Q0224/M0224 to your contracts or consider a single-case agreement for out-of-network insurers

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; NDC=National Drug Code; PrEP mAbs=pre-exposure prophylaxis using monoclonal antibodies.

*For more information, please visit Centers for Medicare & Medicaid Services (CMS) payment information available at **https://www.cms.gov/medicare/payment/part-b-drugs/vaccine-pricing**

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 payer for all relevant coverage, coding and reimbursement requirements. It is the full responsibility of the provider to select proper codes and ensure 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.

IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

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.

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.

Billing and Coding Overview

PEMGARDA (pemivibart) injection for intravenous use

ICD-10-CM CODES

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 (one to three 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 ENCOUNTER[5]	
Z23	Encounter for immunization
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

CODES REPRESENTING PATIENT CONDITION[5]			
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#

The "+" denotes a group of codes with the most specific, billable code to be found underneath in the ICD-10 code list.

Preventative services are covered by CMS, which means there is no cost to your patients for the drug or administration[1]

*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/mm3, 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).[5]

†Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks).[5]

‡Specific for patients under active treatment.[5]

§Personal history codes should be selected only if they are relevant to the patient's current immunocompromised health status.[5]

¶When used for solid tumor or hematologic malignancy treatment.[5]

#Solid-organ transplant or islet transplant patients must be taking immunosuppressive therapies. For hematopoietic stem cell transplantation patients, must be within 2 years of transplantation or taking immunosuppressive therapy.[5]

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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.

ICD-10-CM CODES (cont'd)

CODES REPRESENTING PATIENT DIAGNOSIS[5]			
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		

The "+" denotes a group of codes with the most specific, billable code to be found underneath in the ICD-10 code list.

*People with HIV and CD4 cell counts <200/mm^3, history of AIDS-defining illness without immune reconstitutions, or clinical manifestations of symptomatic HIV.[5]
†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).[5]

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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.

Coverage Approval Process

PEMGARDA (pemivibart) injection for intravenous use

NAVIGATING THE COVERAGE APPROVAL PROCESS

- On March 22, 2024, FDA issued an EUA authorizing the emergency use of PEMGARDA™ for the pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg)[6]:
  - 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
  - View the EUA here.
- CMS has established coding, coverage, and guidelines for PEMGARDA[1]
- Commercial coverage and payment are subject to payor and contract-specific requirements

General guidance on the approval process:

REQUESTING PAYOR APPROVAL

Confirm clinical eligibility

Review the patient's medical history to ensure there is comprehensive documentation of moderate to severe immunocompromise due to a medical condition or receipt of immunosuppressive medications or treatments as specified in section 1 of the Fact Sheet for Healthcare Providers.

Complete and submit relevant payor forms

Newly approved drugs and EUA drugs frequently will not have payor coverage policies available for review. Requesting voluntary prior authorization (PA) to confirm patient medical necessity with payors is recommended. When submitting a PA or Letter of Medical Necessity (LMN), keep the following in mind:

- Investigate the PA requirements of the patient's health plan
- Provide relevant patient medical history, including diagnosis and appropriate ICD-10-CM codes
- Provide relevant patient information, including patient name, address, date of birth, gender, and insurance policy number
- Provide relevant provider information, including name, specialty, address, NPI, and office/fax numbers

When submitting a PA and an LMN, supplementary materials can be included, such as additional relevant medical documentation, EUA for PEMGARDA and the Fact Sheet for Healthcare Providers.

If the PA request for PEMGARDA has been denied, you may submit an appeal letter. This letter should be submitted along with a copy of the patient's relevant medical records. Payors can have different levels and escalations for the appeal process and can include peer-to-peer and external reviews. Please refer to the plan's specific appeal guidelines when filing.

Please see the following pages for sample LMN and Appeals Letter templates.

DETERMINING SITE OF CARE

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

If you cannot administer PEMGARDA on site, you may be able to refer your patient to an alternate site of care. There may be a number of outpatient infusion centers in your area that have the capabilities to administer PEMGARDA as specified by the Boxed Warning for PEMGARDA in the Fact Sheet for Healthcare Providers:

- 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

Invivyd™ Care and the PEMGARDA Infusion Center Locator are resources that can help providers and patients locate an appropriate site of care:

- PEMGARDA Infusion Center Locator: https://www.pemgarda.com/hcp/infusion-center-locator/

IMPORTANT SAFETY INFORMATION (cont'd)

LIMITATIONS OF AUTHORIZED USE (cont'd)

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.

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.

SAMPLE LETTER OF MEDICAL NECESSITY TEMPLATE

[INSERT ON PRESCRIBER LETTERHEAD]
Re: Letter of Medical Necessity for PEMGARDA™ (pemivibart)

[Date]

[Health plan name]
Attn: [Name of prior authorization department]
[Contact name (if available)]
[Health plan address 1]
[Health plan address 2]
[City, State, Zip code]

[Patient name]
[Date of birth]
[Insurance ID number]
[Insurance group number]
[Case ID number]

Dear [Contact Name/Medical director],

This letter is sent on behalf of [patient's name] to [request a medical exception for/request a prior authorization of/document the medical necessity for] PEMGARDA™ (pemivibart) for my patient. I am writing to document my patient's medical history and diagnosis and summarize my treatment rationale.

Patient Clinical History

[Patent's name] is [a/an] [age]-year-old [male/female] who has moderate-to-severe immune compromise due to [detail medical condition or immunosuppressive medications or treatment] and is unlikely to mount an adequate immune response to COVID-19 vaccination. This patient has been under my care since [date].

[Provide any other information that in your professional medical judgment is relevant, including but not limited to, a brief summary of patient's medical history and what factors led you to recommend the use of PEMGARDA.]

Treatment Plan

In March 2024, the FDA authorized PEMGARDA for the emergency use of the unapproved product PEMGARDA (pemivibart), a SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents.

[Include plan of treatment. Consider including information from Section 14 Clinical Studies of the PEMGARDA Fact Sheet for HCPs, citing experts in the field supporting PEMGARDA, or Society Guidelines.]

Summary

Given the patient's history, condition, and the data supporting use of PEMGARDA, I believe treatment of [patient's name] with PEMGARDA is warranted, appropriate, and medically necessary. Enclosed you will find other relevant supporting documentation. Please contact my office by calling [phone number] for any additional information. I look forward to your timely approval.

Sincerely,
[Prescriber signature]

[Insert name]

[Insert prescriber NPI]

Enclosures

[List all enclosed documents, which may include package insert for PEMGARDA, copy of clinical notes/patient medical records, FDA EUA Letter of Authorization, and other relevant supporting documentation]

This sample letter and related information are provided for informational purposes only. It is the responsibility of the HCP and/or their office staff to determine the correct diagnosis and treatment and content of all such letters and related forms for each individual patient. Invivyd does not guarantee coverage or reimbursement for the product and cannot complete or write letters of medical necessity/appeal on your patient's behalf.

SAMPLE APPEAL LETTER TEMPLATE

[INSERT ON PRESCRIBER LETTERHEAD]
Re: Appeal for denial of PEMGARDA™ (pemivibart)

[Date]

[Health plan name]
Attn: [Name of prior authorization department]
[Contact name (if available)]
[Health plan address 1]
[Health plan address 2]
[City, State, Zip code]

[Patient name]
[Date of birth]
[Insurance ID number]
[Insurance group number]
[Case ID number]

Dear [Contact Name/Medical director],

This letter is sent on behalf of [patient's name] to request an appeal of a denied prior authorization for PEMGARDA™ (pemivibart). [Patent's name] is a [age]-year-old [male/female] who has been in my care since [date]. According to the enclosed denial letter, [name of health plan] denied this prior authorization because [reason from denial letter]. I am asking that you reconsider your denial of coverage for PEMGARDA for [patient's name] for the for pre-exposure prophylaxis of COVID-19.

In March 2024 , the FDA authorized PEMGARDA for the emergency use of the unapproved product PEMGARDA (pemivibart), a SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents. In the FDA Letter of Authorization, PEMGARDA met the criteria for issuance of an authorization for the following reasons:

1. SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that PEMGARDA may be effective for use as pre-exposure prophylaxis of COVID-19 in certain adults and adolescents, as described in the Scope of Authorization (Section II), and that, when used under the conditions described in this authorization, the known and potential benefits of PEMGARDA outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of PEMGARDA for pre-exposure prophylaxis of COVID-19 as further described in the Scope of Authorization (section II)

Additionally, Medicare is providing coverage for COVID-19 monoclonal antibody products, when furnished consistent with their approvals or EUAs, under the Part B preventive vaccine benefit until the end of the calendar year in which the EUA declaration for COVID-19 drugs and biologicals ends.

[Provide a summary of rationale for treatment with PEMGARDA. This includes a brief description of patient's medical history and what factors led you to recommend the use of PEMGARDA.]

In conclusion, please reconsider the PEMGARDA denial for [patient's name]. Given the patient's history, condition, and the data supporting use of PEMGARDA, I believe treatment of [patient's name] with PEMGARDA is warranted, appropriate, and medically necessary. A copy of the most recent denial letter is included, along with medical notes and other relevant supporting documentation.

Please contact my office by calling [phone #] for any additional information. I look forward to your timely approval.

Sincerely,

[Prescriber signature]

[Insert name]

[Insert prescriber NPI]

Enclosures:

[List all enclosed documents, which may include package insert for PEMGARDA, copy of clinical notes/ patient medical records, letter of denial (if applicable), FDA EUA Letter of Authorization, relevant print outs from www.cms.gov/monoclonal, or other relevant supporting documentation]

This sample letter and related information are provided for informational purposes only. It is the responsibility of the HCP and/or their office staff to determine the correct diagnosis and treatment and content of all such letters and related forms for each individual patient. Invivyd does not guarantee coverage or reimbursement for the product and cannot complete or write letters of medical necessity/appeal on your patient's behalf.

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.

Product Information

PEMGARDA
(pemivibart) injection
for intravenous use

PRODUCT CONCENTRATION[2]	500 mg/4 mL vial (125 mg/mL)
BILLING UNIT[2]	1 for 4500 mg
PACKAGE SIZE[2]	9 vials per carton (1 dose)
CARTON CONTENTS[2]	Each PEMGARDA™ carton contains a total dose (4500 mg) of nine (9) single-dose 500 mg vials
NDC[2]	10-digit: 81960-031-03 | 11-digit: 81960-0031-03
WAC[7]	$5,775 per carton
MINIMUM QUANTITY PER ORDER	1 carton

PEMGARDA CAN BE ORDERED THROUGH ONE OF THESE PARTICIPATING SPECIALTY DISTRIBUTORS:

	PHONE	EMAIL	ACCOUNT SETUP
CARDINAL HEALTH	855.855.0708	gmb-spd-csorderentry@cardinalhealth.com	866.677.4844
CENCORA	800.746.6273	service@asdhealthcare.com	asdaccountsetup@amerisourcebergen.com
CURASCRIPT SD	877.599.7748	Customer.Service@curascript.com	Customer.Service@curascript.com
MCKESSON PLASMA AND BIOLOGICS	877.625.2566	mpborders@mckesson.com	mpbonboarding@mckesson.com
MCKESSON SPECIALTY CARE DISTRIBUTION	800.482.6700	physvcscustcare@mckesson.com	onboarding2@mckesson.com

Standard shipping is Monday–Thursday with UPS Next Day service by 10:30 AM for orders received by 2 PM CT. To request Saturday delivery, please call Customer Service.

For information on product orders or tracking information, please call Customer Service at 844-220-5938 or email InvivydCS@icsconnect.com.

Please check the FDA's Expiration Dating Extension website for updates before administering or requesting return of a product.

IMPORTANT SAFETY INFORMATION (cont'd)

LIMITATIONS OF AUTHORIZED USE (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.

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.

PEMGARDA
(pemivibart) injection
for intravenous use

IMPORTANT SAFETY INFORMATION (cont'd)

LIMITATIONS OF AUTHORIZED USE (cont'd)

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.
- 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 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.

References: 1. Centers for Medicare & Medicaid Services (CMS). COVID-19 monoclonal antibodies. Accessed November 18, 2024. https://www.cms.gov/monoclonal **2.** PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc: 2024. **3.** Centers for Medicare & Medicaid Services (CMS). 2024 Healthcare Common Procedure Coding System (HCPCS). Accessed April 12, 2024. https://www.cms.gov/medicare/codingbilling/healthcare-common-procedure-system/quarterly-update **4.** Noridian Healthcare Solutions. Revenue Codes. Accessed March 18, 2024. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **5.** ICD10Data.com. 2024 ICD-10-CM codes. Accessed February 13, 2024. https://www.icd10data.com/ICD10CM/Codes **6.** US Food and Drug Administration. PEMGARDA Letter of Authorization. Accessed September 10, 2024. https://invivyd.com/wp-content/uploads/2024/08/Pemgarda-EUA-122-LOA_2024-August-26.pdf **7.** AnalySource®. PEMGARDA WAC report. Accessed November 22, 2024. https://www.analysource.com/

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