PEMGARDA®
(pemivibart) injection
for intravenous use

Sample Appeal Letter

Template Contents:

The template shown on the next page is a guide for offices to use in the development of a letter of appeal. Pink bracketed sections represent information specific to your patient or practice setting that may be populated as relevant. Other content may also be modified as deemed necessary. Letters should be sent according to your facility's standard policy.

Please note: This sample letter and related information are provided for informational purposes only. It is the responsibility of the healthcare provider 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 the coverage or reimbursement for the product and cannot complete or write letters of appeal on your patient's behalf.

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.

SEE PAGE 2 FOR A TEMPLATE SHOWING A SAMPLE LETTER OF APPEAL

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

[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/an] [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 pre-exposure prophylaxis of COVID-19.

In March 2024 , the FDA authorized 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]

Important Safety Information

PEMGARDA®
(pemivibart) injection
for intravenous use

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.

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. 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.

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.

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.

INVIVYD