Pemgarda Infusion Order

Fax 888 511-7654

Patient Name: _____ **DOB:** _____

Patient Phone: _____ **SEX:** M ◯ F ◯

Please Attach All Insurance Information, front and back

MEDICAL INFORMATION

Diagnosis: ◯ _____ (please see list of DX codes provided by Pemgarda)

Patients weight: _____

Lab Date: _____

Allergies: _____

Usage: ◯ Pemgarda is used under EUA for the pre-exposure prophlaxis of coronavirus disease 2019 (COVID-19)

Criteria: ☐ Not currently infected with SARS-CoV-2 and who have not had known recent exposure.

AND

☐ Moderate to severe immune compromised due to a medical condition or receiving immunosuppresive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination.

ALSO INCLUDE...

- ◯ Clinical/ Progress Notes
- ◯ Demographics Sheet
- ◯ Current Medications
- ◯ Labs

PEMGARDA ORDER

Pemgarda Dose:

◯ **4500mg IV once over a minimum of 60 minutes**

◯ **4500mg IV over a minimum of 60 minutes every 3 months for _____ doses**

Date of last infusion

Additional Comments:

In individuals who have recently received a COVID-19 vaccine, Pemgarda should be administered **at least 2 weeks after vaccination.**

PHYSICIAN INFORMATION

Referring Physician: _____ **Phone:** _____

Practice Address: _____

Office Contact: _____ **Fax:** _____

NPI/ TIN: _____

Referring Physician's Signature_____ **Date:** _____

ICD-10-CM CODES[3]

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 (to one or two 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 PATIENT CONDITION			
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#

CODES REPRESENTING ENCOUNTER	
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

*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/mm^3, 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).

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

‡Specific for patients under active treatment.

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

¶When used for solid tumor or hematologic malignancy treatment.

#Solid-organ transplant or islet transplant patients must be taking immunosuppressive therapies. For HSCT patients, must be within 2 years of transplantation or taking immunosuppressive therapy.

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

IMPORTANT SAFETY INFORMATION (cont'd)

See full **Fact Sheet for Healthcare Providers, including Boxed Warning** 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 #).

Please see additional Important Safety Information throughout and see the full Fact Sheet for Healthcare Providers, including Boxed Warning for more information on the EUA of PEMGARDA.