Pemgarda™ for Emergency Use Authorization (EUA) ONLY
Provider Order Form Rev. 05/2024
Please fax completed referral form & all required documents to (833) 786-0025

HEALIX INFUSION CARE

PATIENT DEMOGRAPHICS

Patient Name: _____ DOB: _____ Phone: _____

Address: _____ City/ST/Zip: _____

Allergies: _____ ☐ NKDA Weight: _____ ☐ lbs ☐ kg Height: _____ ☐ in ☐ cm

Patient Status: ☐ New to Therapy ☐ Dose or Frequency Change ☐ Order Renewal

INSURANCE INFORMATION: ***Please attach copy of insurance card (front and back).***

DIAGNOSIS*

ICD 10 Code Required

Diagnosis resulting in patient being immunocompromised:

☐ _____, ICD10 _____ ☐ _____, ICD10 _____

INFUSION ORDERS

MEDICATION	DOSE	DIRECTIONS/DURATION
Pemgarda™ (pemivibart)	4500 mg	Infuse IV over 60 minutes once every 3 months x 1 year *Observe patient for 2 hours after completion of infusion

Is patient currently receiving therapy above from another facility?

☐ Yes ☐ No

If yes, Facility Name: _____

Date of last treatment:_____ Date of next treatment:_____

PRE-MEDICATION ORDERS

☐ No premeds ordered at this time

☐ Acetaminophen 650mg PO ☐ Diphenhydramine 25mg PO

☐ Methylprednisolone 40mg IVP -OR- ☐ Hydrocortisone 100mg IVP

☐ Other: _____

LAB ORDERS

Labs to be drawn by: ☐ Infusion Center ☐ Referring Physician

☐ No labs ordered at this time

☐ CBC q _____ ☐ CMP q _____ ☐ CRP q _____

☐ ESR q _____ ☐ LFTs q _____ ☐ Other: _____

REFERRING PHYSICIAN INFORMATION

Physician Signature: _____ Date: _____

Physician Name: _____ NPI:_____ TIN:_____ Specialty:_____

Address: _____ City/ST/Zip: _____

Contact Person: _____ Phone #: _____ Fax #: _____

Email Where Follow Up Documentation Should Be Sent: _____

REQUIRED CLINICAL DOCUMENTATION

Please attach medical records: Initial H&P, current MD progress notes, medication list, and labs/test results to support diagnosis.

Clinical Information, select all that apply:

☐ The patient is not currently infected with SARS-CoV-2 and has no known recent exposure to an individual infected with SARS-CoV-2.

☐ The patient is moderately-to-severely immune compromised due to a medical condition or receipt of immunosuppressive medications/treatments and is unlikely to mount an adequate immune response to COVID-19 vaccination.

Please specify reason(s) for immunosuppression:

- ☐ Active treatment for solid tumor and hematologic malignancies
- ☐ Hematologic malignancies associated with poor responses to COVID-10 vaccines regardless of current treatment status
- ☐ 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
- ☐ Advanced or untreated HIV infection
- ☐ Active treatment with high-dose corticosteroids, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory
- ☐ Other: _____

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.

BILLING AND CODING INFORMATION

PEMGARDA
(pemivibart) injection
for intravenous use

CODES REPRESENTING PATIENT DIAGNOSIS

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		

*People with HIV and CD4 cell counts <200/mm^3, history of AIDS-defining illness without immune reconstitutions, 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).

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)

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 the full Fact Sheet for Healthcare Providers, including Boxed Warning for more information on the EUA of PEMGARDA.

CAR, chimeric antigen receptor; CMS, Centers for Medicare and Medicaid Services; COVID-19, coronavirus disease 2019; EUA, emergency use authorization; FDA, US Food and Drug Administration; HCPCS, Healthcare Common Procedure Coding System; HSCT, hematopoietic stem cell transplant; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; NDC, National Drug Code; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

References: 1. PEMGARDA [Fact Sheet for Healthcare Providers]. Waltham, MA; Invivyd, Inc: 2024. **2.** Centers for Medicare & Medicaid Services (CMS). 2024 Healthcare Common Procedure Coding System (HCPCS). Accessed April 12, 2024. https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system/quarterly-update
3. ICD10Data.com. 2024 ICD-10-CM codes. Accessed February 13, 2024. https://www.icd10data.com/ICD10CM/Codes

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