V.1 UCSF Health Guidance for Adult COVID-19 Pre-Exposure Prophylaxis (passive immunity)
Author: Adult COVID-19 Monoclonal Antibody Use Task Force
5/24/2024, updated 8/14/24

Background: On March 22, 2024, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for pemivibart (Pemgarda™) for use as pre-exposure prophylaxis (prevention) of COVID-19 in eligible immunocompromised patients who are not currently infected nor exposed to COVID-19.

This drug is not a substitute for vaccination, and all patients who can receive vaccination should do so. This document contains information about how the drug will be allocated to adults at UCSF Health.

For other COVID-19 therapeutics, refer to the UCSF Adult **IDMP** (Infectious Disease Management Program) website here. C

Contact S Arora MD with questions.

Updates

Date	Update
8/14/24	Update web links, removed pemivibart from HEIP, added to IDMP, kept old direct link live which directs user to IDMP page, edited direct link above to IDMP.

Important Information: Consider prior to ordering pemivibart and discuss with your patient:

- EUA authorization is based on immunobridging studies
- Clinical Data are limited
- Newer mAb for PrEP are under investigation and may be EUA authorized by July 2024
- High incidence of infusion related and hypersensitivity reactions (up to 9%), along with 0.6% rate of anaphylaxis
- The medication + infusion clinic visit will be billed to insurance. Unlike tixagevimab/cilgavimab, pemivibart is not free.

Data re: pemivibart and rationale for its EUA authorization

Scientific Publications
FDA Pemgarda FAQ
Pemivibart Patient Fact Sheet
Pemivibart Package Insert

Dosing of Pemivibart and Timing with COVID-19 vaccination

- Initial dose 4500mg IV, infused over 1-hour
  - Requires 2-hour monitoring period after infusion in the infusion center
  - Requires premedication for prevention of hypersensitivity/infusion reaction (included in therapy plan)
- Requires repeat dosing every 3 months
- Pemivibart must be separated by 2 or more weeks after COVID-19 vaccination

Prior Authorization required prior to scheduling

- Referring clinical team must obtain prior authorization for the following codes:
  - M0224 – administration code
  - Q0224 – product/drug code
- Patients should be counseled on potential cost-sharing of medication and infusion clinic visit

Definitions

CDC Description of Moderate and Severe Immunocompromising Conditions and Treatment / Not expected to mount an adequate immune response to complete vaccination

Inclusion Criteria for Pemivibart

Moderate and severe immunocompromising conditions and treatments include but are not limited to:

- 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 therapy or hematopoietic cell transplant (HCT) (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 HIV infection (people with HIV and CD4 cell counts less than 200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

Intended Population for Pemivibart

Due to pemivibart's limited efficacy data, safety profile, and the current COVID-19 climate (low-level community spread, existing immunity, effective treatment options), suggest limiting administration of pemivibart to those at highest risk for severe COVID-19 infection.

Inpatient, Adults

1. Pemivibart will not be offered in the inpatient setting

Outpatient, Adults

1. Hematologic Malignancy Diagnosis
    a) Diagnosis of AML or ALL on active treatment, or have received cytotoxic chemotherapy in the past 3 months
    b) CAR T-cell or alloHCT in the past 3 months
    c) Not on a research study unless approval documented by study PI
2. Receiving B-cell depleting agents actively or with persistent substantial B-cell depletion from recent prior B-cell depleting therapy
3. Primary Immunodeficiency Diagnosis
    a) Combined immunodeficiencies (eg SCID/CVID), B-cell deficiencies, and/or needing immunoglobulin replacement, idiopathic CD4 lymphopenia/severe lymphopenia
        i. But NOT CGD or most DiGeorge's syndrome
4. *May consider in other severe immunocompromising conditions or treatments as noted in description above and per CDC criteria*

Other requirements

1. Received at least 1 dose of CDC-approved monovalent or ineligible for COVID19 vaccination
2. 2-weeks or more after receipt of last COVID19 vaccine
3. EUA and risk, benefit, alternatives reviewed with patient
4. No evidence of active COVID19 infection

Exclusion Criteria for Pemivibart

1. COVID19 vaccination in the past 2-weeks
2. Active COVID19 infection
3. Previous reaction to pemivibart or COVID-19 vaccine

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Outpatient PrEP/Pemivibart Workflow:

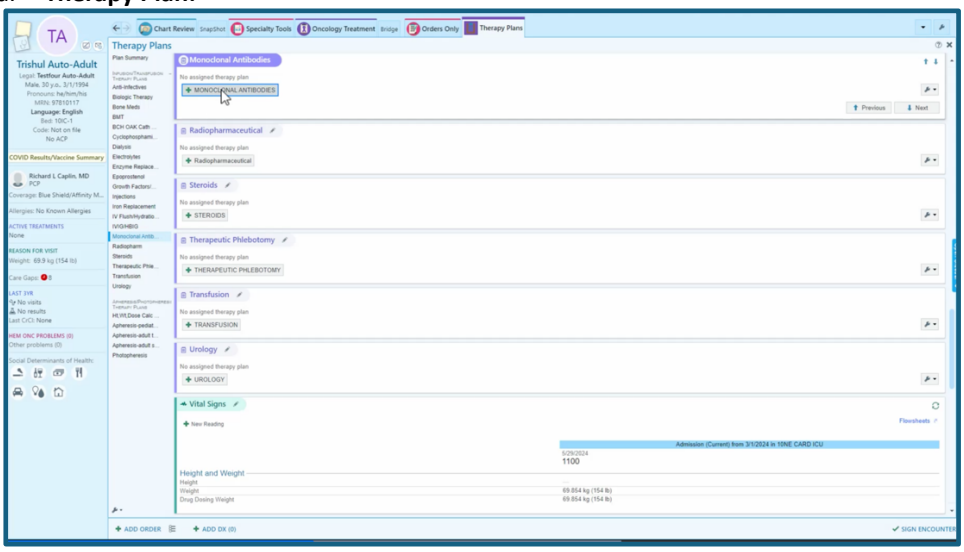
1) Send patient this useful smartphrase: "**COVIDPemivibartPatient**" or "CovidpemivibartFORpatients"
   a. This smartphrase includes a link to Patient Fact Sheet which the patient must review
   b. Counsel the pt on EUA risks/benefits/cost
   c. Inform pt that a 2-hour monitoring period is required after each infusion
   d. Educate pts that they remain at risk for COVID19 infections despite pemivibart
   e. Obtain PA (see #2)

2) REF800: order + sign
   a. Enables PA process for the required 2 authorization codes (1) **M0224 :** administration code (2) **Q0224** : product/drug code

3) Pemivibart therapy plan: order + sign
   a. Open encounter where orders can be placed > Therapy Plan tab > Monoclonal Antibodies > Pemivibart > complete + sign*

   if both are not done, the pt will not be scheduled

4) Pictures of orders
   a. **Therapy Plan:**



   b. **Pemivibart**:

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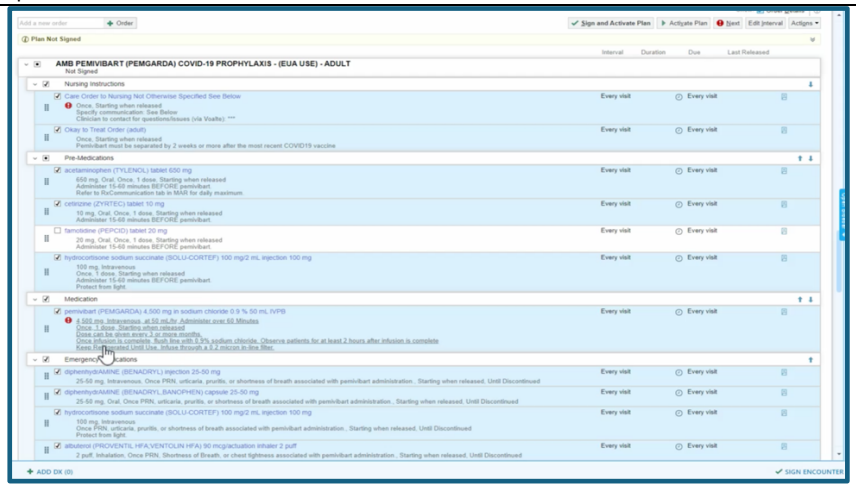
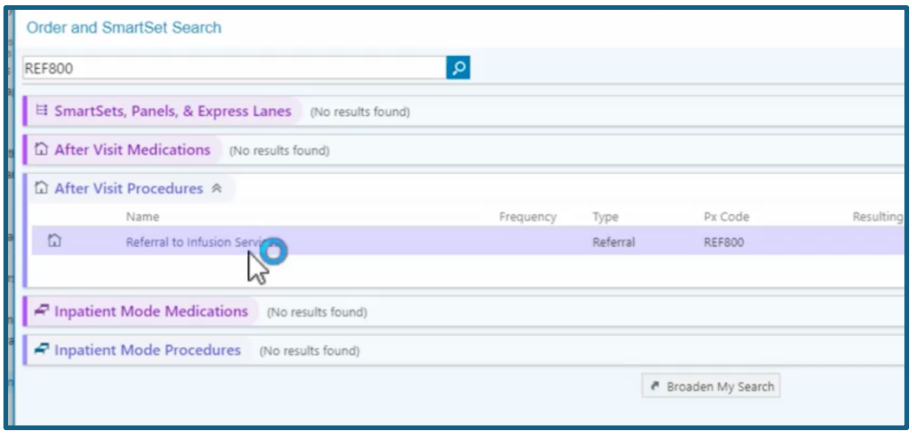
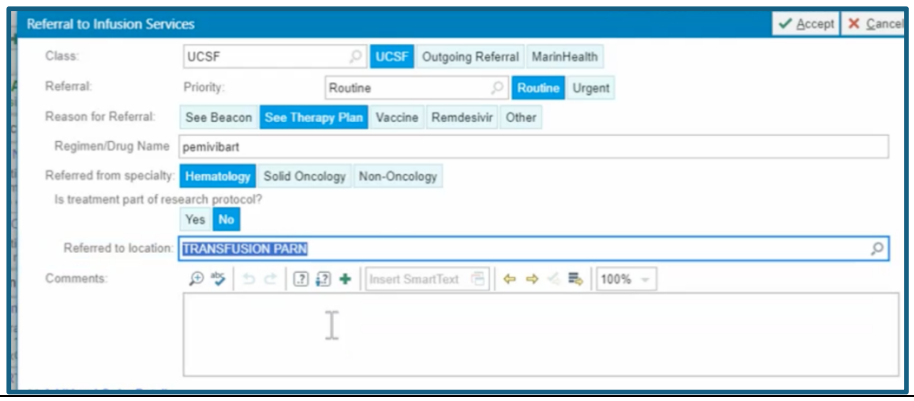


c. REF800





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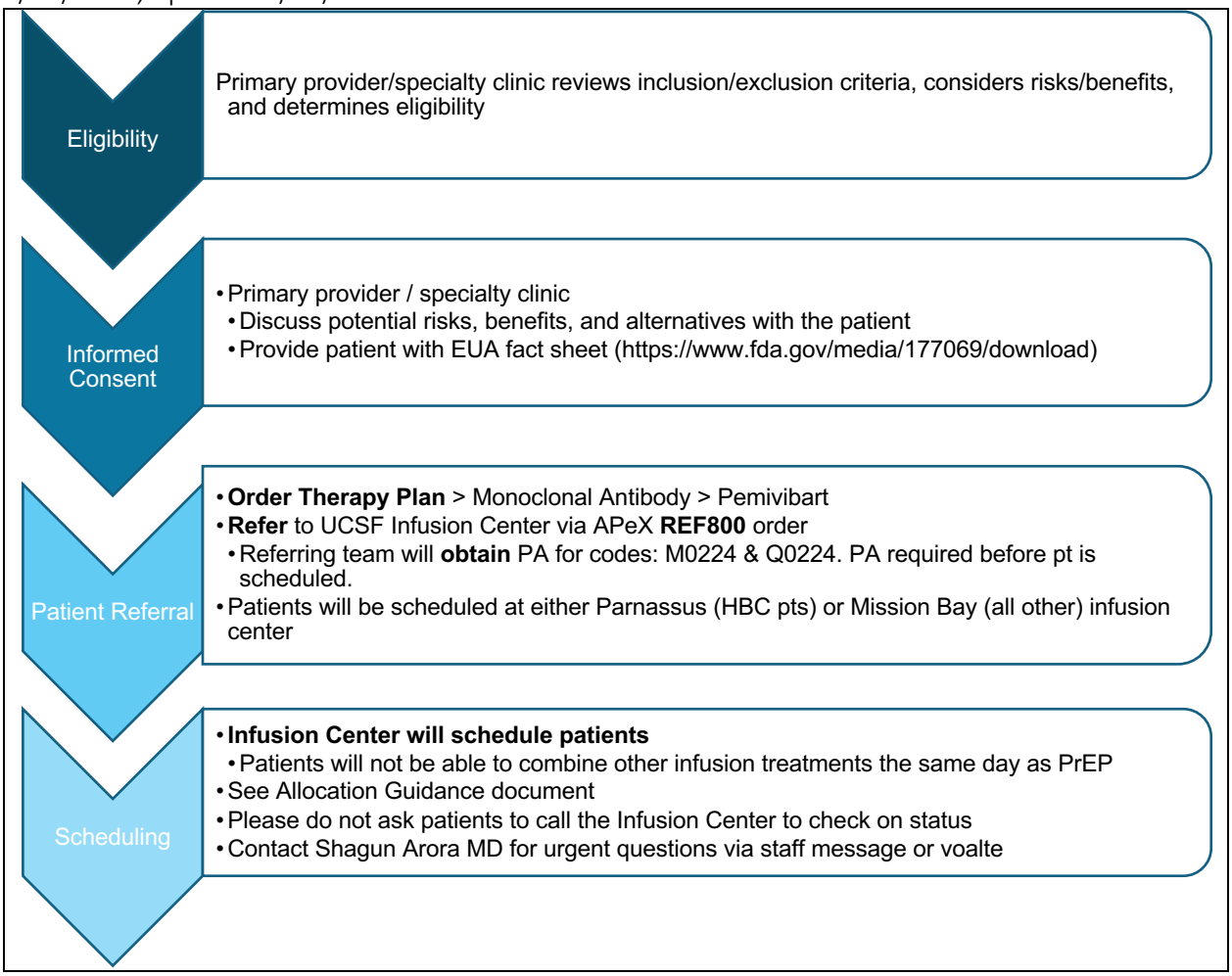

Allocation
Guiding principles
• No patient should be denied access to pre-exposure prophylaxis based on age, disability, religion, race, ethnicity, national origin, immigration status, gender/gender identity, perceived quality of life, or sexual orientation • Patients eligible for pre-exposure prophylaxis via clinical trials should be offered participation in the trials (if available) but should not be compelled to participate in trials for the sole purpose of accessing the drug. Patients who opt not to participate in trials shall be offered pre-exposure prophylaxis via the EUA if eligible
Process
Among individuals eligible for receipt of the agent by the guidelines above, allocation will occur as outlined in the detailed COVID Monoclonals Allocation Guidance document when drug supply is limited *need to get this document