



Summary of Clinical Process for Ordering COVID-19 Monoclonal Antibody



Patient
Identification



Therapy
Plan/Ordering



Insurance
Evaluation



Pemivibart
Infusion



Identification of Candidates for Pemivibart

Patients age 12 or older, weighing $\geq 40\text{kg}$, who meet all of the following criteria:

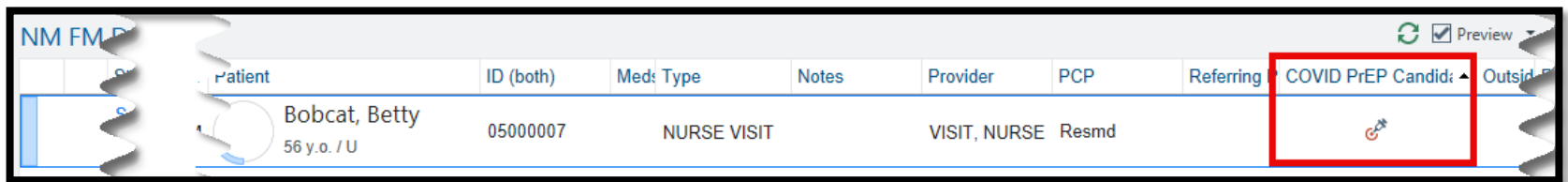
- Not currently infected with SARS-CoV-2
- No recent known exposure to an individual infected with SARS-CoV-2
- Have moderate to severe immunocompromise due to a medical condition or immunosuppressive medications, such as:
 - Solid tumor or hematologic malignancy
 - Solid organ transplant on immunosuppression
 - CAR-T therapy or HSCT
 - Primary or acquired immunodeficiency
 - Active treatment with steroids, chemotherapeutics, immunosuppressant, or immunomodulatory medications
- Unlikely to mount an adequate immune response to COVID-19 vaccination



Tools for Identification of Candidate Patients for Pemivibart

One Chart message and/or snail mail letter to eligible patients could be customized

Column titled “COVID PrEP Candidate?” can be added to your clinic schedule:



Patient	ID (both)	Med Type	Notes	Provider	PCP	Referring	COVID PrEP Candidate?	Outside
 Bobcat, Betty 56 y.o. / U	05000007	NURSE VISIT		VISIT, NURSE	Resmd			

Hovering over “COVID-19” in the Storyboard will identify qualifying criteria and identify prior doses of mAb therapy given through Nebraska Medicine:

COVID-19: Unknown
Isolation: None

COVID Treatment Risk Allocation Score

406.93	Total Score
400	Tier 1: severely immunocompromised OR never vaccinated (age >=75, >=65 years with risk factors)
2.64	BMI 35 kg/m2 or greater
1.65	Immunocompromised or on immunosuppressant therapy
0.66	Diabetes Mellitus
0.66	COPD/Pulmonary Disease
0.66	Cardiovascular Disease
0.66	Other high risk condition

COVID Pre-Exposure Prophylaxis Criteria Met

General
Seen at Nebraska Medicine in Past 18 Months

COVID-19 Pre-Exposure Prophylaxis Tier 1 Criteria
History of CAR-T Therapy , Active Bruton Tyrosine Kinase Inhibitor Therapy

COVID-19 Pre-Exposure Prophylaxis Tier 2 Criteria
Active Belatacept Outpatient Therapy , Hematopoietic Stem Cell Transplant in Past 3 Years

COVID-19 Pre-Exposure Prophylaxis Tier 3 Criteria
Active Outpatient Immunosuppressive Medication

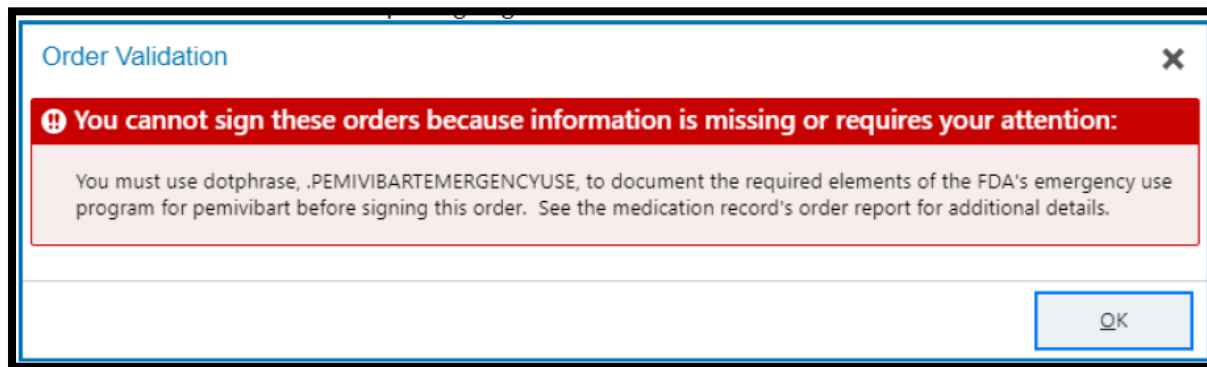
Current as of: 5/14/2024 7:02 PM ?

COVID-19 Pre-Exposure Prophylaxis Administrations

No medication administrations found since 05/16/2023.

EUA Documentation Prior to Ordering Pemivibart

As pemivibart is not FDA approved and only under an EUA at this time, patients must be educated on and provided a copy of the Fact Sheet for Patients prior to administration. Specifically, this must be documented in One Chart via the SmartPhrase “.pemivibartemergencyuse” in a pending or signed note prior to ordering:



Pemivibart Therapy Plan

For outpatient ordering, a pemivibart therapy plan has been generated which is pre-populated with the proper ordering instructions, medication order, redosing interval, and associated rescue medications:

✓	PEMIVIBART (PEMGARDA) (for testing) Not Signed	
✓	Patient Specific Assessment	↓
✓	Patient Specific Assessment Due: ⌚ Every visit Monitor patient for at least 2 hours after each infusion.	📄
✓	Treatments	↑ ↓
✓	PRESCRIBING ALERT Due: ⌚ Every visit Patient MUST be 12 years of age or older AND weigh at least 40 kg per EUA for Pemivibart (Pemgarda).	📄
✓	pemivibart (Pemgarda) 4.5 g in sodium chloride 0.9 % 50 mL IV Due: ⌚ Wed 5/8/2024 4.5 g, Intravenous, Administer over 60 Minutes, Once, Starting at treatment start time, 1 dose, Indications: COVID-19 pre-exposure prophylaxis (EUA) Administer using inline 0.2-micron filter. Flush line with NS after completion of infusion.	📄
✓	Emergency Medications	↑ ↓
✓	NMC ONC EMERGENCY MEDS (THERAPY PLANS)	
✓	EPINEPHrine (EPIPEN) injection 0.3 mg Due: PRN 0.3 mg, Intramuscular, Once PRN, Anaphylaxis, Starting when released, 1 dose, Indications: Anaphylaxis Administration in the mid-anterolateral thigh is recommended.	📄
✓	diphenhydrAMINE (BenadryL) injection 50 mg Due: PRN 50 mg, Intravenous, Every 3 hours PRN, Allergic reaction, Starting when released, 2 doses, Indications: allergic reaction ## FALL RISK ## Administer undiluted or refer to Lexicomp for dilution instructions.	📄
✓	hydrocortisone sod succ (PF) (Solu-CORTEF) injection 100 mg Due: PRN 100 mg, Intravenous, Once PRN, Allergic reaction, Starting when released, Indications: hypersensitivity drug reaction, Until Discontinued Have available. Call physician or licensed provider working with physician if needed.	📄
✓	Flush	↑
✓	NMC ONC FLUSH (THERAPY PLANS)	
✓	sodium chloride flush 1-10 Syringe Due: PRN 1-10 Syringe, Intravenous, PRN, Line Care, Starting when released, Until Discontinued	📄





Insurance Evaluation and Appointment Setup

- Generation of a pemivibart therapy plan in a new One Chart encounter will trigger a referral to Patient Financial Services for an insurance coverage and out-of-pocket cost estimate
 - This can sometimes take weeks depending on the timeliness of responses from the insurance providers involved
 - **Therapy plans should be entered as soon as this therapy is planned to allow time for this process to be completed**
- Discussion with the patient of insurance disposition and details for scheduling infusion
 - Pemivibart can be scheduled for administration at any of the three Nebraska Medicine infusion centers
- It is understood that each team will have an individualized approach for managing the workflow surrounding these elements of the process





Pemivibart Infusion Logistics

- Administered via IV infusion over 1 hour
- A central line is not necessary for infusion
- No pre-medications are populated as a default, as this and other COVID-19 mAb infusions have produced very low rates of reactions
- Patients should be monitored for infusion reactions for 2 hours following infusion
 - This can be done outside of the infusion room, in a nearby area where there is ready access to emergency care and medications
- Any adverse event reporting can be done through the standard SOS reporting system to meet EUA/FDA requirements





Summary

- COVID-19 PrEP is again available for our immunosuppressed patients, however, data on degree of mitigation of severe disease are not yet available
- Pemivibart may be cost prohibitive for some patients and requires pre-evaluation
- Informatics tools are available to support teams in identifying patients and operationalizing this therapy
- Pemivibart should be available for ordering beginning on May 20th, or shortly thereafter



