Summary of Clinical Process for Ordering COVID-19 Monoclonal Antibody

Identification of Candidates for Pemivibart

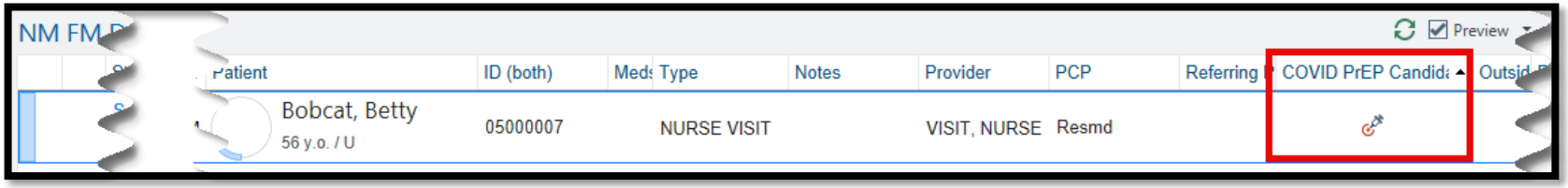
Patients age 12 or older, weighing ≥40kg, who meet all of the following criteria:

- 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

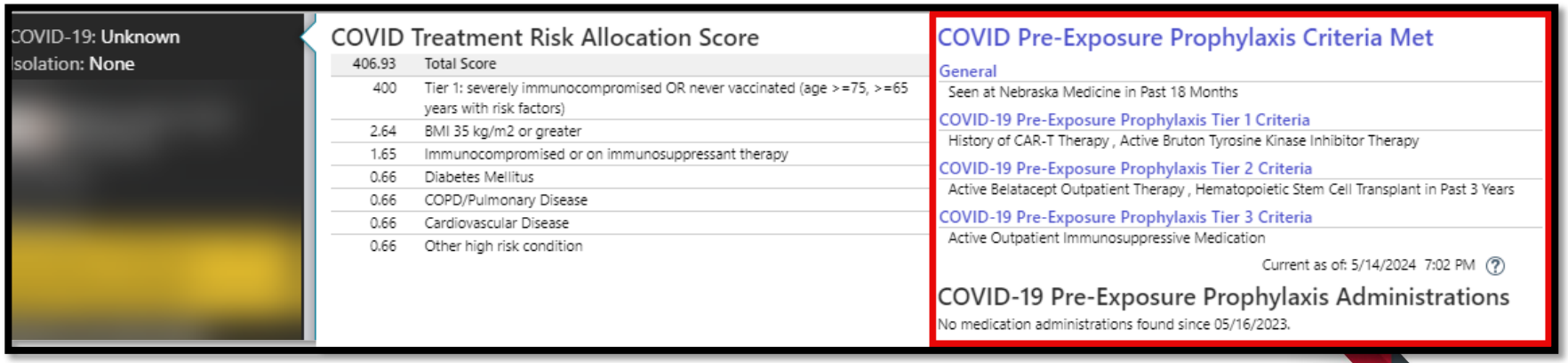
Tools for Identification of Candidate Patients for Pemivibart

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:

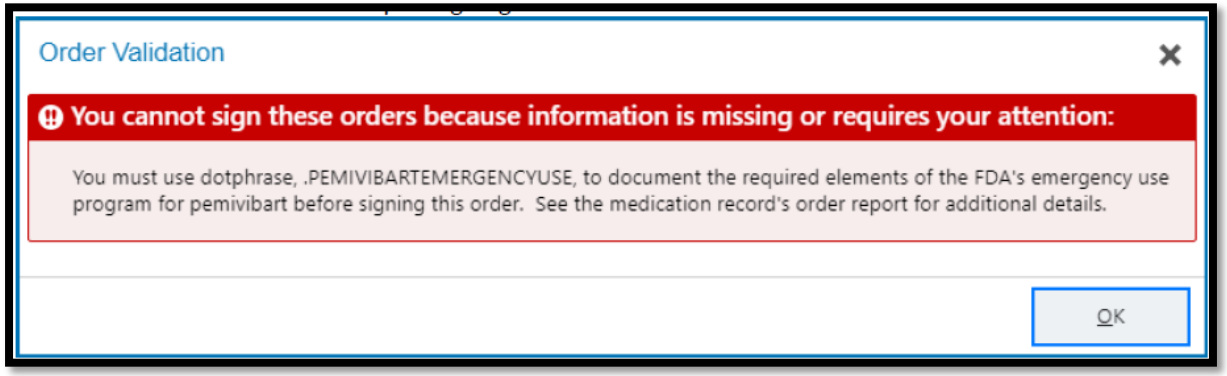


Hovering over “COVID-19” in the Storyboard will identify qualifying criteria and identify prior doses of mAb therapy given through Nebraska Medicine:



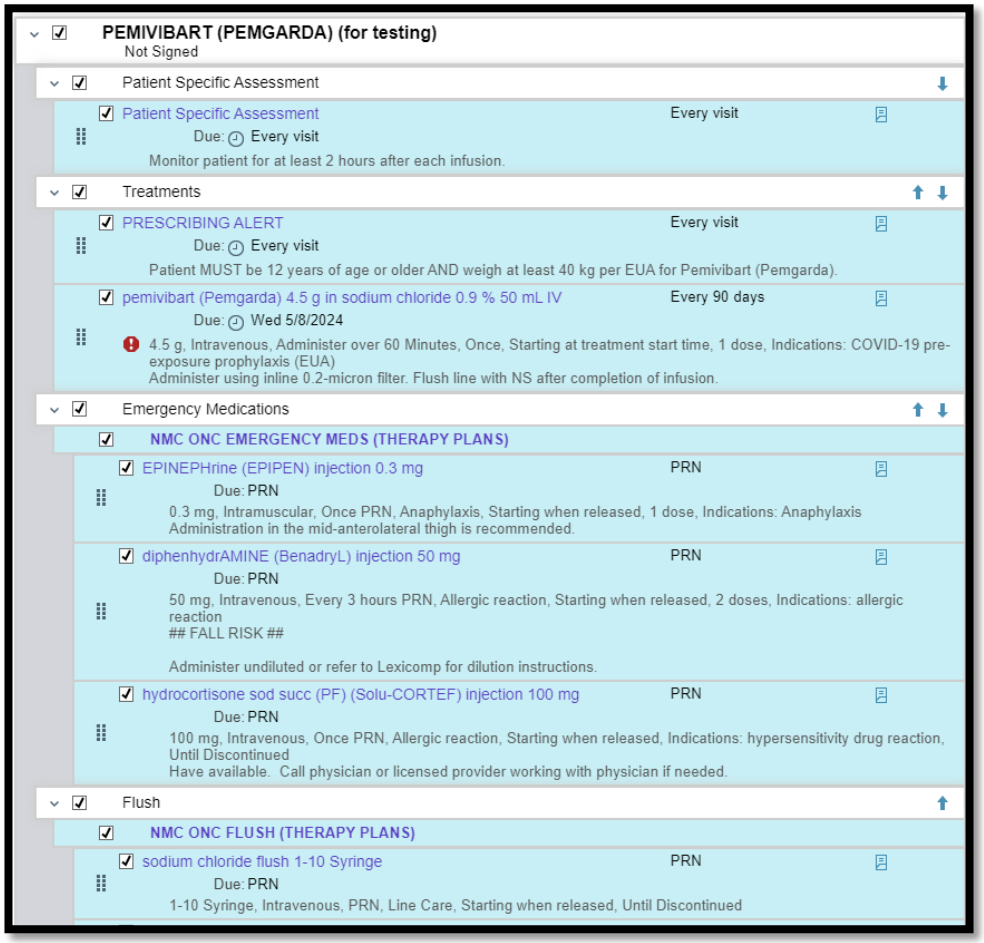
EUA Documentation Prior to Ordering Pemivibart

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 pended 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:



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

Nebraska Medicine