Providence

Providence St. Joseph Hospital – Eureka

Oral Treatment of Covid-19 in High Risk Outpatients

Update: FDA is not authorizing use of Regeneron or bamlanivumab/etesevimab at this time.

The FDA has authorized oral Paxlovid for emergency use as treatment for COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. **There is currently a limited supply of Paxlovid in the county.**

The FDA has authorized oral Molnupiravir for emergency use as treatment for COVID-19 in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. **There is currently a limited supply of Molnupiravir in the county. **Molnupiravir is not recommended in pregnant patients – please do not order molnupiravir for pregnant patients****

What is Paxlovid: Paxlovid consists of nirmatrelvir, a SARS-CoV-2 main protease inhibitor, and ritonavir, and HIV-1 protease inhibitor and CYP3A inhibitor given orally x 5 days.

What is Molnupivir: Molnupivir is an investigational nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis given orally x 5 days.

Due to the limited supply of Paxlovid, treatment will be restricted to the following risk groups:

Tier	Risk Group
1	• Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); *or* • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
2	• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)

Immunocompromised conditions include but not limited to:

- Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab)
- Patients receiving Bruton tyrosine kinase inhibitors
- Chimeric antigen receptor T cell recipients

- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication
- Patients with hematologic malignancies who are on active therapy
- Lung transplant recipients
- Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant)
- Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents
- Patients with severe combined immunodeficiencies
- Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm^3

Where:
The MAB clinic is located on the Providence St. Joseph main hospital campus in the Conference Center, rooms 2 & 3. This area has been converted to negative pressure and separated from C1. There will be 8 recliner chairs, monitoring equipment and emergency medical equipment available. The Conference Center is located at 2710 Dolbeer, immediately behind (to the west) of the Medical Oncology/Hematology suite. See the attached map.

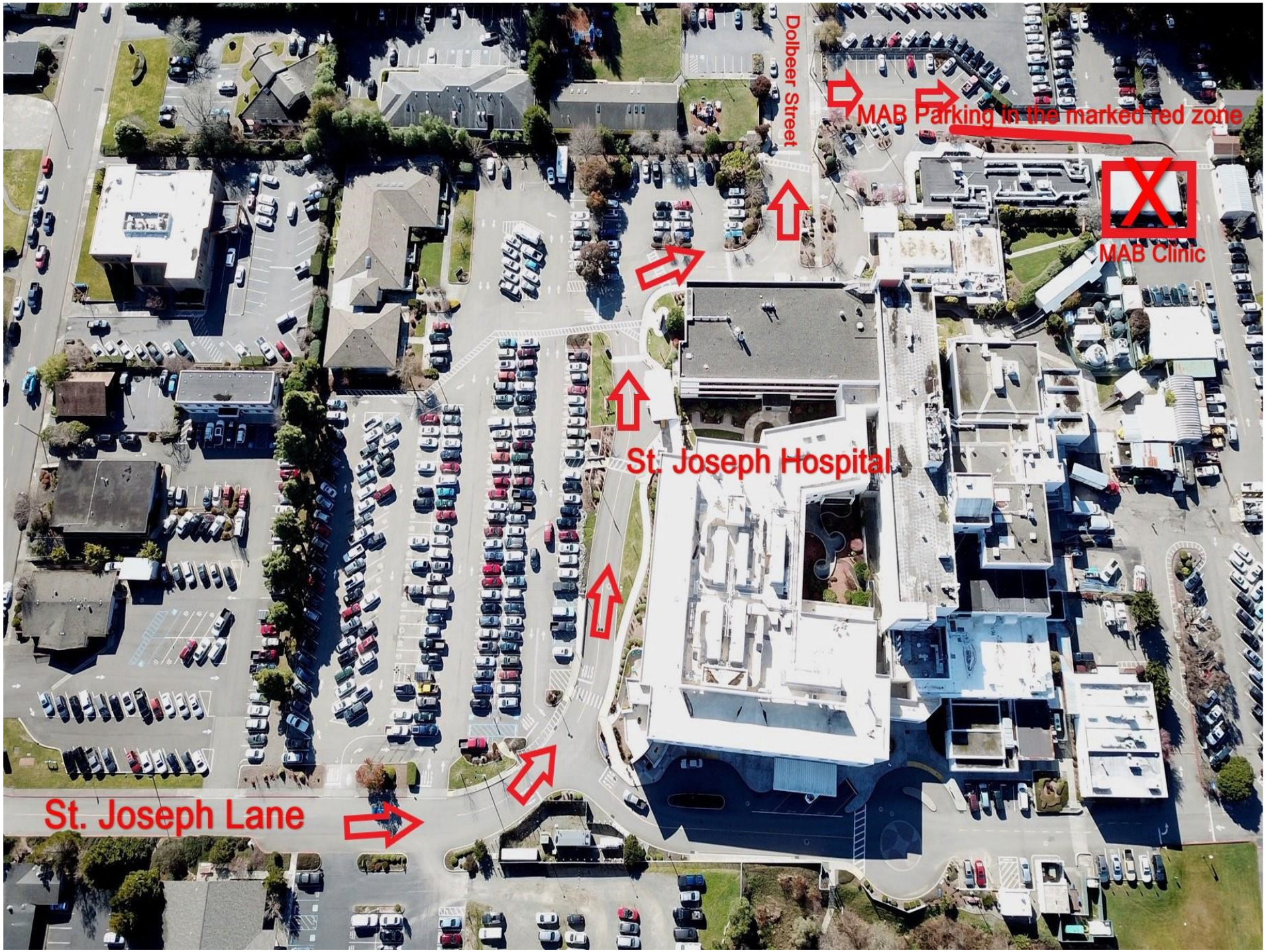
Hours of Operation:
The MAB clinic will be open from 8:00 AM to 4:00 PM Monday thru Friday.

Scheduling:
Patients will be given prescriptions by appointment only. To schedule an appointment, call the Ambulatory Infusion department at 707-269-3607. Orders (see attached) are to be faxed to the Ambulatory Infusion department. The fax number is 707-269- 3755.

Parking:
Curb side patient parking is available in designated/identified spaces immediately outside the MAB clinic. Signs will be posted identifying parking. Signs will also be posted directing patients to the MAB clinic check-in. **Patients are asked not to enter the main hospital or the Medical Oncology (Peals Cancer Center) seeking directions. See attached map.**

Further information:
Following are links to more detailed information regarding medications listed in this letter:

- https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/?utm_campaign=highlights
- https://www.fda.gov/media/155050/download
- https://www.fda.gov/media/155054/download
- https://www.covid19treatmentguidelines.nih.gov/
- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron


Dolbeer Street
MAB Parking in the marked red zone
MAB Clinic
St. Joseph Hospital
St. Joseph Lane

PAXLOVID inclusion checklist	❑ Laboratory-confirmed SARS-CoV-2 infection ❑ NOT requiring oxygen supplement due to COVID-19 ❑ NOT requiring an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity. ❑ Age 18 years or older and weight is 40kg or more ❑ Either: • Immunocompromised and not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to underlying conditions, regardless of vaccine status • Unvaccinated and ≥ 65 years or < 65 years with additional risk factor ❑ At high risk of progressing to severe COVID-19 and/or hospitalization by meeting at least one of the following criteria: • Have a body mass index (BMI) ≥35 kg/m^2 • Have chronic kidney disease • Have diabetes • Have immunosuppressive disease/treatment • Are currently receiving immunosuppressive treatment • Are pregnant • Have cardiovascular disease including hypertension • Have Sickle cell disease • Have chronic lung disease such as chronic obstructive pulmonary disease/other chronic respiratory disease • Have neurodevelopmental disorders or other conditions that confer medical complexities • Have medical-related technological dependence not related to COVID-19 Patient needs to meet all the above criteria for Paxlovid treatment.
Patient/family consent	Provide the following education to patient and document on education record: ❑ Patient/family has provided consent and a copy of the FDA EUA sheet has been provided to the patient/family.
Order	❑ 300mg nirmatrelvir and 100mg ritonavir orally by mouth twice daily x 5 days for eGFR ≥ 60 mL/min ❑ 150mg nirmatrelvir and 100mg ritonavir orally by mouth twice daily x 5 days for eGFR 30-60 mL/min *Paxlovid not recommended for eGFR < 30 mL/min or severe hepatic impairment.*
	MD/DO Signature: **Date:** **Time:**

2700 Dolbeer Street, Eureka CA 95503 •

Providence St. Joseph Hospital

PAXLOVID TREATMENT
PHYSICIAN PRESCRIPTION

(rev 01/22)

Patient identification

Molnupiravir inclusion checklist	❑ Laboratory-confirmed SARS-CoV-2 infection (PCR) less than 4 days from time of order ❑ Either: — At least 1 pre-existing risk factor for progression to hospitalization (chronic lung disease, hypertension, cardiovascular or cerebrovascular disease, diabetes, obesity (BMI ≥30), immunocompromised, chronic kidney disease, chronic liver disease, current cancer, or sickle cell disease) — OR aged ≥ 60 years ❑ Presence of ≥ 1 symptom(s) consistent with COVID-19 for less than or equal to 7 days prior to order (such as fever, cough, fatigue, shortness of breath, sore throat, headache, myalgia/arthralgia) ❑ Age 18 years or older ❑ Oxygen saturation (SpO2) greater than 94% on room air ❑ Not currently requiring hospitalization ❑ Not currently pregnant. Patient needs to meet all the above criteria for Molnupiravir treatment.
Order	Molnupiravir 800mg orally by mouth every 12 hours X 5 days.
	MD/DO Signature: **Date:** **Time:**

2700 Dolbeer Street, Eureka CA 95503 ●

MOLNUPIRAVIR TREATMENT
PHYSICIAN PRESCRIPTION

(rev 01/22)

Patient identification

Remdesivir inclusion checklist	❑ Laboratory-confirmed SARS-CoV-2 infection (PCR) less than 4 days from time of order ❑ Either: — At least 1 pre-existing risk factor for progression to hospitalization (chronic lung disease, hypertension, cardiovascular or cerebrovascular disease, diabetes, obesity (BMI ≥30), immunocompromised, chronic kidney disease, chronic liver disease, current cancer, or sickle cell disease) — OR aged ≥ 60 years ❑ Presence of ≥ 1 symptom(s) consistent with COVID-19 for less than or equal to 7 days prior to order (such as fever, cough, fatigue, shortness of breath, sore throat, headache, myalgia/arthralgia) ❑ Age 18 years or older ❑ Oxygen saturation (SpO2) greater than 94% on room air ❑ Not currently requiring hospitalization Patient needs to meet all the above criteria for remdesivir treatment X 3 days and in appropriate negative-pressure room as an outpatient treatment.
Order	❑ Remdesivir 200mg IV in 250ml NS over 30 min day 1, then remdesivir 100mg IV in 250ml NS over 30 min days 2-3. Lab: BMP if no serum creatinine value available in the last 30 days.
	MD/DO Signature: **Date:** **Time:**

2700 Dolbeer Street, Eureka CA 95503 ●

Providence
St. Joseph Hospital

REMDESIVIR OUTPATIENT TREATMENT
PHYSICIAN ORDER

(rev 01/22)

Patient identification

Sotrovimab inclusion checklist	❑ Laboratory-confirmed SARS-CoV-2 infection ❑ NOT requiring oxygen supplement due to COVID-19 ❑ NOT requiring an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity. ❑ Age 18 years or older and weight is 40kg or more ❑ Either: • Immunocompromised and not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to underlying conditions, regardless of vaccine status • Unvaccinated and ≥ 65 years or < 65 years with additional risk factor ❑ At high risk of progressing to severe COVID-19 and/or hospitalization by meeting at least one of the following criteria: • Have a body mass index (BMI) ≥35 kg/m^2 • Have chronic kidney disease • Have diabetes • Have immunosuppressive disease/treatment • Are currently receiving immunosuppressive treatment • Are pregnant • Have cardiovascular disease including hypertension • Have Sickle cell disease • Have chronic lung disease such as chronic obstructive pulmonary disease/other chronic respiratory disease • Have neurodevelopmental disorders or other conditions that confer medical complexities • Have medical-related technological dependence not related to COVID-19 Patient needs to meet all the above criteria for sotrovimab treatment X 1 dose and in appropriate negative-pressure room as an outpatient treatment.
Patient/family consent	Provide the following education to patient and document on education record: ❑ Patient/family has provided consent and a copy of the FDA EUA sheet has been provided to the patient/family.
Order	❑ 500mg sotrovimab in 50-100 ml NS infused over 30 min intravenously. Observe patient for 1 hour after infusion has completed for side effect.
	MD/DO Signature: **Date:** **Time:**

2700 Dolbeer Street, Eureka CA 95503 ●

Providence St. Joseph Hospital

Patient identification

SOTROVIMAB TREATMENT
PHYSICIAN ORDER

(rev 01/22)

Tixagevimab and Cilgavimab inclusion checklist	❑ NOT currently infected with SARS-CoV-2 ❑ Have NOT had a known recent exposure to an individual infected with SARS-CoV-2 ❑ Age 18 years or older and weight is 40kg or more ❑ Have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications/treatments and may not mount adequate immune response to COVID-19 or for whom vaccination with any available COVID-19 vaccine is not recommended due a history of severe adverse reaction. Medical conditions or treatments that may result in moderate/severe immune compromise include but are not limited to: • Active treatment for solid tumor and hematologic malignancies • Receipt of solid-organ 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 immunosuppression therapy) • Moderate or severe primary immunodeficiency (e.g., 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, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)
Patient/family consent	Provide the following education to patient and document on education record: ❑ Patient/family has provided consent and a copy of the FDA EUA sheet has been provided to the patient/family.
Order	❑ 150 mg Tixagevimab (1.5 ml) IM x 1 dose and 150 mg Cilgavimab (1.5 ml) IM x 1 dose. Administer the IM injections at different injection sites, preferably one in each of the gluteal muscles, one after the other. Observe patient for 1 hour after infusion has completed for side effect. Evushield should be administered at least two weeks after COVID-19 vaccine if vaccinated recently.
	MD Signature: **Date:** **Time:**

2700 Dolbeer Street, Eureka CA 95503 ●

Providence St. Joseph Hospital

TIXAGEVIMAB AND CILGAVIMAB (EVUSHELD) TREATMENT

(rev 01/22)

Patient identification