MAUI HEALTH
Community hospitals affiliated with KAISER PERMANENTE®

Monoclonal Antibody Treatment at Kaiser Permanente Maui Lani, in partnership with Maui Health

Physician Referral Packet*

Referring MDs:

- Please discuss the treatment with your patient to confirm they understand the treatment and would like to receive it.
- Follow the **Candidate Submission Checklist** located on the first page of the referral packet to ensure you have all necessary forms and information sheets.
- Fill out the referral packet (attached) and sign appropriate pages.
- Email the referral form to MHS-Covidmab-requests@kp.org.
- Once referred for treatment, patients may call (808) 600-2785 to schedule an appointment. (Monday through Saturday from 8 a.m. to 5 p.m.)

If you have any questions, please call the MAB appointment line at (808) 600-2785 (Monday through Saturday from 8 a.m. to 5 p.m.).

Not part of the medical record

Casirivimab-Imdevimab Candidate Submission Checklist

- ☐ Patient Referral Form
- ☐ MMMC Consent Form
- ☐ Casirivimab-Imdevimab Prioritization Scoring Sheet
- ☐ NIH COVID-19 Treatment Guidelines Panel Statement on Casirivimab-Imdevimab Treatment
- ☐ EUA Fact Sheet for Patients (Separate PDF)
- ☐ EUA Fact Sheet for Healthcare Providers (Separate PDF)
- ☐ Casirivimab-Imdevimab Dose Update Letter (Separate PDF)

Not part of the medical record

CASIRIVIMAB-IMDEVIMAB MEDICATION REQUEST

MAUI MEMORIAL MEDICAL CENTER	Email required forms to MHS-Covidmab-requests@kp.org	Required Documents 1. Casirivimab-Imdevimab Medication Request 2. Consent for Casirivimab-Imdevimab treatment 3. Prioritization scoring sheet

A. ORDERING PHYSICIAN

Print Name:	Office Phone:	Office Fax:

B. PATIENT INFORMATION

Last Name:	First :	M.I.	**SEX:** ☐ Male ☐ Female
	PHONE #s		
Birth Date:	Home:	Work:	Cell :

C. INSURANCE INFORMATION

1.	Plan Number: #	Group Number: #
2.	Plan Number: #	Group Number: #

D. PROCEDURAL DIAGNOSIS

E. PRIMARY PROCEDURE/TREATMENT/TEST/INFUSION

Procedure/Treatment: _____

Additional Requests / Information / Special Instructions for Clinical Team:

Additional services requested on the same day of treatment? CPT:

Requisition Completed by (Print Name): _____ Date: _____ Time: _____

MMMC Scheduler: ☐ **Confirmed Date:** **Time**:
☐ **Date Unavailable please reschedule**

MAUI MEMORIAL MEDICAL CENTER
A community hospital affiliated with KAISER PERMANENTE.

CONSENT TO OPERATION, POST OPERATIVE CARE, MEDICAL TREATMENT, ANESTHESIA, OR OTHER PROCEDURE

You have the right and obligation to make decisions concerning your health care. Your physician will provide you with the necessary information and advice to help you in the decision- making process. This form has been designed to acknowledge your understanding and acceptance of the treatment recommended by your physician. Please feel free to ask any questions.

(1) I hereby authorize Dr. _____
(and any associate or assistant involved in my care) to treat the following condition(s) which have been explained to me.

PROFESSIONAL: _____

ORDINARY OR LAY LANGUAGE: _____

(2) The procedures(s) planned for treatment of my condition(s) has/have been explained to me by my physician as follows:

PROFESSIONAL: _____

ORIDNARY OR LAY LANGUAGE: _____

(3) I recognize that, during the course of the operation, postoperative care, medical treatment, anesthesia or other procedure, unforeseen conditions may require the above-named physician and his or her assistants to perform additional or different surgical or other procedures necessary to preserve my life or bodily functions.

(4) I have been informed that there are many significant risks, such as severe loss of blood, infection, cardiac arrest and other consequences that can lead to death or permanent or partial disability which can result from any procedure.

Any following sections that do not apply to the proposed treatment may be crossed out. Both physician and patient must initial all sections crossed out.

(5) No promise or guarantee bas been or can be made to me regarding a result of this procedure or cure for my condition.

(6) I consent to the administration of general, spinal, regional, and/or local anesthesia or procedural sedation by my attending Physician, by an Anesthesiologist, a nurse Anesthetist, or other qualified party under the direction of a Physician as may be deemed necessary. I understand that all anesthetics involve risks that may result in complications and possible serious damage to such vital organs as the brain, heart, lungs, liver and kidney. These complications may result in paralysis, cardiac arrest and related consequences or death from both known and unknown causes.
☐ Procedural Sedation

(7) I consent to the use of transfusion of blood and blood products as deemed necessary. I have been informed of the benefits, alternatives and risks such as transmissions of disease, allergic reactions and other unusual reactions.

(8) Any tissues or parts surgically removed may be disposed of by the Medical Center or physician in accordance with accustomed practice.

(9) I consent to the photographing or video monitoring or storing on other media of the operation or procedure to be performed, including appropriate portions of my body, for the internal purpose of performance improvement, provided that my identity is not revealed by the picture or by descriptive texts accompanying them.

(10) I consent to the observation of the operative procedure for the purpose of advancing medical education.

(11) My physician has also discussed with me the following:

RISKS: _____

BENEFITS: _____

ALTERNATIVES: _____

(12) I have had the opportunity to ask questions and have them answered.

MY PHYSICIAN INFORMED ME OF:

a. My diagnosis or probable diagnosis.
b. The nature of the proposed care, treatment, services, interventions, medications and procedures.
c. The potential benefits, risks or side effects including problems related to recuperation.
d. The likelihood of achieving care, treatment, and service goals.
e. Reasonable alternatives to the proposed care, treatment, and services.
f. The relevant risks, benefits, and side effects related to alternatives, including the possible results of not receiving care, treatment, and services.
g. Any limitations on the confidentiality of information learned from or about me.

PATIENT CERTIFICATION AND CONSENT

I certify that I have read this consent or have had it read to me in a language I understand. I have had an opportunity to ask questions. All my questions have been answered to my satisfaction. I knowingly and willingly give consent to have this surgery or procedure.

X_____ _____ _____ _____ _____ _____
Signature of patient or legal representative | Date | Time | Signature of Witness OR Translator | Date | Time

_____ _____
Print Patient Name | Print Witness or Translator Name

PHYSICIAN/PROVIDER CERTIFICATION

I have fully discussed this information consent with the patient/representative using language that is appropriate and understandable. I believe that the patient/representative understands the above and our discussion. I certify that I have encouraged questions and that all questions were answered.

_____ _____ _____ _____
Physician Signature/Printed Name | Date | Time | Place

Not part of the medical record

CASIRIVIMAB-IMDEVIMAB MEDICATION REQUEST

Patient Name: DOB:	
Risk Factor and Prioritization Scoring Sheet for Monoclonal Ab. Circle all that apply	Points
≥ 65 years of age	2
BMI ≥ 25 kg/m2	1
Pregnancy	1
Chronic kidney disease	1
Diabetes Mellitus	1
Immunosuppressive disease or Immunosuppressant medication	1
Cardiovascular disease (including congenital heart disease or hypertension)	1
Chronic Lung diseases (COPD/Asthma/other respiratory disease)	1
Sickle Cell Disease	1
Neurodevelopmental disorders (e.g. Cerebral Palsy, severe congenital abnormalities)	1
Medical-related technological dependence (e.g. tracheostomy, gastrostomy)	1
12-17 years AND BMI ≥ 85th percentile for age and gender	1
12-17 years AND sickle cell disease	1
12-17 years AND congenital or acquired heart disease	1
12-17 years AND neurodevelopmental disorder (e.g. cerebral palsy)	1
12-17 years AND medical-related technology dependence	1
12-17 years AND chronic respiratory disease that requires daily medication	1
TOTAL	

Prioritization Grid Clinical Considerations for Monoclonal Antibody to reduce progression of disease

Initial appropriate boxes	Initials
My patient is at least 12 years of age or older weighing at least 40kg. DOB _____ weight _____kg	
My patient has a positive SARS-CoV-2 viral test with NAAT or PCR test. If NAAT or PCR test was not done patient is not eligible. Date of positive NAAT or PCR test: _____	
My patient has developed symptoms related to COVID-19 less than 10 days ago. Symptom onset date: _____ (Asymptomatic patients are not eligible)	
My patient does NOT require hospitalization and has mild to moderate COVID-19 infection , but is at high risk for progressing to severe COVID-19 and or hospitalization (see risk factor and prioritization scoring sheet above)	
My patient does NOT require oxygen therapy due to COVID-19, or does not require an increase in baseline oxygen flow rate due to COVID- 19 if already on chronic oxygen therapy due to another non-COVID-19 related comorbidity.	
I have communicated with my patient or parent/caregiver information consistent with the “Fact sheet for Patients, Parents and Caregivers: Emergency Use Authorization of Casirivimab-Imdevimab for COVID-19” and provided a copy of the fact sheet to the patient.	
Physician Signature	Date

The COVID-19 Treatment Guidelines Panel's Statement on the Updated Emergency Use Authorization of the Anti-SARS-CoV-2 Monoclonal Antibody Combination Casirivimab Plus Imdevimab for the Treatment of COVID-19

Last Updated: June 17, 2021

On June 3, 2021, the Food and Drug Administration (FDA) updated the Emergency Use Authorization (EUA) of the anti-SARS-CoV-2 monoclonal antibody combination casirivimab plus imdevimab for the treatment of nonhospitalized individuals with COVID-19.[1] The authorized dosage has been reduced from a single intravenous (IV) infusion of casirivimab 1,200 mg plus imdevimab 1,200 mg to casirivimab 600 mg plus imdevimab 600 mg. In addition, the same doses of casirivimab and imdevimab may now be administered by subcutaneous (SQ) injection when IV infusion is not feasible or may delay treatment. It should be noted that SQ administration requires four injections (2.5 mL per injection) at four different sites (see the FDA EUA for details).

The COVID-19 Treatment Guidelines Panel (the Panel) currently recommends that nonhospitalized patients with COVID-19 who are at high risk for disease progression receive one of three authorized anti-SARS-CoV-2 monoclonal antibody regimens (see the Panel's Statement on the Emergency Use Authorizations of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19). The Panel has reviewed the data that were provided in the updated EUA for casirivimab plus imdevimab and reported publicly.[2,3] For the casirivimab plus imdevimab combination regimen (if selected from the three authorized regimens), the Panel recommends:

- Using the dose of **casirivimab 600 mg plus imdevimab 600 mg (AIIa)**.
- Using IV infusion of **casirivimab plus imdevimab (AIIa)**.
- When IV infusion is not feasible or would lead to delay in treatment, SQ injection of **casirivimab plus imdevimab** can be used as an alternative route of administration **(BIII)**.

Rationale

The recommendation for the use of the lower dose of casirivimab 600 mg plus imdevimab 600 mg IV is based on the Phase 3 results from the R10933-10987-COV-2067 study (*ClinicalTrials.gov* Identifier NCT04425629). This study is a double-blind, placebo-controlled randomized trial in outpatients with mild to moderate COVID-19. This trial included 4,057 participants; 736 received IV casirivimab 600 mg plus imdevimab 600 mg and 748 received placebo.[2,3]

The modified full analysis set included participants aged ≥18 years who had a positive SARS-CoV-2 polymerase chain reaction result from a nasopharyngeal swab at randomization and had one or more risk factors for disease progression to severe COVID-19. The primary outcome was COVID-19-related hospitalizations or death from any cause, which was reported in 7 of 736 participants (1.0%) in the IV casirivimab 600 mg plus imdevimab 600 mg arm and in 24 of 748 participants (3.2%) in the placebo arm ($P = 0.0024$), a 2.2% absolute reduction and a 70% relative reduction in hospitalization or death among the casirivimab plus imdevimab recipients compared to the placebo recipients. These results are comparable to IV infusion of casirivimab 1,200 mg plus imdevimab 1,200 mg in which COVID-19-related hospitalizations or death from any cause were reported in 18 of 1,355 participants (1.3%) in the casirivimab plus imdevimab arm and in 62 of 1,341 participants (4.6%) in the placebo arm ($P < 0.0001$), a 3.3% absolute reduction and a 71% relative reduction in hospitalization or death among the casirivimab plus imdevimab recipients compared to the placebo recipients.

The recommendation for the use of SQ injection is based on the Phase 1 R10933-10987-HV-2093 study (*ClinicalTrials.gov* Identifier NCT04519437), a double-blind, placebo-controlled randomized trial that compared casirivimab plus imdevimab administered SQ to placebo in healthy volunteers. Injection site reactions were observed in 12% of the 729 casirivimab plus imdevimab participants and 4% of the 240 placebo participants. According to the FDA EUA, in a separate trial among symptomatic participants, there were similar reductions in viral load between the IV and SQ arms, but neither a preprint nor a published report is currently available, and clinical outcomes data have not been reported.[1] Because the safety and efficacy data for casirivimab plus imdevimab administered SQ is limited, this route of administration should only be used when IV infusion is not feasible or would lead to a delay in treatment **(BIII)**.

References

1. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization (EUA) of REGEN-COV (casirivimab and imdevimab). 2020. Available at: https://www.fda.gov/media/145611/download.
2. Weinreich DM, Sivapalasingam S, Norton T, et al. REGEN-COV antibody cocktail clinical outcomes study in COVID-19 outpatients. *medRxiv*. 2021;Preprint. Available at: https://www.medrxiv.org/content/10.1101/2021.05.19.21257469v2.
3. Regeneron. COV-2067 Phase 3 trial in high-risk outpatients shows that REGEN-COV (2400 mg and 1200 mg IV doses) significantly reduces risk of hospitalization or death while also shortening symptom duration. 2021. Available at: https://newsroom.regeneron.com/index.php/static-files/a7173b5a-28f3-45d4-bede-b97370bd03f8.