TOP TOPICS

Monthly Spotlights

Just for HPSJ Providers

January 29, 2021 – **COVID-19 Special Issue**

Health Plan of San Joaquin

Monoclonal antibody infusion

This a reminder that the FDA has approved for EUA (emergency use authorization) several monoclonal antibody treatments.

Please consider for your mild-to-moderate COVID-19 patients that are not hospitalized – so they can get the antibodies early in their COVID course, have a milder form of the disease and avoid hospitalizations plus poor outcomes.

Attached is a sample from San Joaquin General Hospital - eligibility information, a referral form and patient/parents/caregivers fact sheets from Eli Lilly and Regeneron. An SJGH contact is at 209-468-6820.

Virtual Briefing COVID-19 Vaccinations

February 17 (6-7PM)

Hosted by HPSJ for ALL Providers

Maggie Park, MD, San Joaquin County Public Health Officer

Julie Vaishampayan, MD, MPH, FIDSA, Stanislaus County Public Health Officer

Introductions
Lakshmi Dhanvanthari, MD
HPSJ Chief Medical Officer

Best County Sites

Testing – COVID Vaccines – Vaccinators – & More

As of January 29, 2021

San Joaquin County https://www.sjready.org/
Stanislaus County http://schsa.org/coronavirus/vaccine/

COMING NEXT WEEK

REVAMPED PROVIDERS' HPSJ COVID-UPDATES WEB PAGE

hpsj.com/covid-19-provider-information/

Licensees Authorized to Administer Vaccines in California (as of January 25, 2021)

www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/Authorized-Licensees.aspx

HPSJ Alert (1/7/21): DHCS Guidance on COVID-19 Vaccinations & Vaccination Administration. A carve-out Medi-Cal benefit

https://www.hpsj.com/alerts/

https://us13.admin.mailchimp.com/campaigns/show?id=4985862 – **Download infographic**

Community & Consumer Alerts

For Health Plan of San Joaquin Members

Members, Do Not Be Fooled! No-Cost COVID-19 tests available

There is no cost to HPSJ members for medically-needed COVID-19 screening and testing

Questions or Concerns? Members (and Providers), please call your local public health department or HPSJ at (888) 936-7526 or visit hpsj.com/covid.

San Joaquin General Hospital
And
San Joaquin County Clinics

Bamlanivimab; Casirivmab/imdevimab Referral Form

Dear Provider,

Thank you for referring your patient for monoclonal antibody infusion as an outpatient treatment for Covid 19. SJGH has defined patients eligible for treatment as those meeting the following criteria:

I. Have laboratory confirmed SARS-CoV-2 infection either by antigen or molecular PCR Test. **AND**

II. Have at least one symptom of mild or moderate Covid-19 **AND**

III. Onset of symptoms ≤ 10 days **PLUS** one of the following:
   A. Age ≥ 65 **or**
   B. BMI≥ 35 **or**
   C. CKD **or**
   D. Diabetes
   E. Age ≥ 55 with at least one of the following conditions
      1. Cardiovascular disease **or**
      2. COPD or other chronic respiratory disease **or**
      3. HTN **or**
      4. Immunosuppressive disease **or**
      5. Currently receiving immunosuppressive medications

IV. Patients with any of the following exclusion criteria **will not** be eligible for treatment:

   A. Onset of symptoms > 10 days prior to start of treatment
   B. Need for hospital admission
   C. Requiring supplemental oxygen OR requiring increase in baseline oxygen flow rate if on chronic oxygen supplementation
   F. Presence of any condition likely to predict poor clinical outcome with SARs-Covid-19

San Joaquin General Hospital
And
San Joaquin County Clinics

Bamlanivimab; Casirivmab/imdevimab Referral Form

Basic demographic information

Patient Name: _____

Date of Birth: _____Age:_____Telephone: _____

Preferred Language: _____

Referring Provider's name: _____

Referring Provider's phone number: _____

Referring Provider's address: _____

Provider has reviewed FDA EUA with patient for Bamlanivimab; Casirivmab/imdevimab and patient consents to proceed. ☐ Yes

COVID19 related information

Date of symptom onset: _____

Date of positive test for SARS-CoV-2 (COVID-19): _____

Is the patient on home oxygen at baseline? ☐ Yes ☐ No

If yes, what is the patient's baseline oxygen requirement? _____L/min

What is the patient's current oxygen requirement? ☐ None (room air) ☐ _____ L/min

Relevant Medical History

Patient's weight (kg):_____ Patient's height (inches):_____ BMI: _____

Current medications: _____

Allergies _____

Is the patient pregnant? ☐ Yes ☐ No

San Joaquin General Hospital
And
San Joaquin County Clinics

Bamlanivimab; Casirivmab/imdevimab Referral Form

Please check if patient has history of any of the following

- ☐ Age ≥ 65
- ☐ Body Mass Index (BMI) ≥ 35
- ☐ Cardiovascular disease
- ☐ Hypertension
- ☐ Chronic obstructive pulmonary disease or other chronic lung disease
- ☐ Chronic kidney disease
- ☐ Diabetes
- ☐ Immunosuppressive disease (not including diabetes)
- ☐ Use of immunosuppressive agents

Referring Provider will obtain patient consent for treatment:

- Provide patient with fact sheet for Bamlanivimab; Casirivmab/imdevimab
- Inform of alternatives to Bamlanivimab; Casirivmab/imdevimab
- Must inform that Bamlanivimab; Casirivmab/imdevimab is authorized for Emergency Use only and is not approved by FDA to treat Covid 19.

If patient meets inclusion criteria and consents to treatment Provider or representative will call:
(209) 468- 6820 to schedule next available appointment.

Patient is to bring a copy of signed consent and referral documents to infusion appointment.

San Joaquin General Hospital
And
San Joaquin County Clinics

Bamlanivimab; Casirivmab/imdevimab Emergency Use Authorization Form

1. Patient meets inclusion criteria for the infusion of Bamlanivimab or Casirivmab/imdevimab. ☐

2. Patient has been given a copy of the Fact Sheet for Patients, Parents and Caregivers on the Emergency Use Authorization of Bamlanivimab; Casirivmab/imdevimab. ☐

3. Patient has been informed of the potential risks and benefits of Bamlanivimab or Casirivmab/imdevimab. ☐

4. Patient has been informed that the infusion of Bamlanivimab or Casirivmab is for emergency use only and is not approved by the FDA to treat Covid 19. ☐

5. Patient Consents to receiving treatment. ☐

_____

(Patient) (Date & Time)

_____

(Physician) (Date & Time)

_____

(Witness) (Date & Time)

Fact Sheet for Patients, Parents and Caregivers
Emergency Use Authorization (EUA) of Bamlanivimab for Coronavirus Disease 2019 (COVID-19)

You are being given a medicine called **bamlanivimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking bamlanivimab, which you may receive.

Receiving bamlanivimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about bamlanivimab. Talk to your healthcare provider if you have questions. It is your choice to receive bamlanivimab or stop it at any time.

What is COVID-19?
COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

What are the symptoms of COVID-19?
The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is bamlanivimab?
Bamlanivimab is an investigational medicine used for the treatment of COVID-19 in non-hospitalized adults and adolescents 12 years of age and older with mild to moderate symptoms who weigh 88 pounds (40 kg) or more, and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Bamlanivimab is investigational because it is still being studied. There is limited information known about the safety or effectiveness of using bamlanivimab to treat people with COVID-19.

The FDA has authorized the emergency use of bamlanivimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the section "**What is an Emergency Use Authorization (EUA)?**" at the end of this Fact Sheet.

What should I tell my healthcare provider before I receive bamlanivimab?
Tell your healthcare provider about all of your medical conditions, including if you:
- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

How will I receive bamlanivimab?
- Bamlanivimab is given to you through a vein (intravenous or IV) for at least 1 hour.
- You will receive one dose of bamlanivimab by IV infusion.

What are the important possible side effects of bamlanivimab?
Possible side effects of bamlanivimab are:
- Allergic reactions. Allergic reactions can happen during and after infusion with bamlanivimab. Tell your healthcare provider right away if you get any of the following signs and symptoms of allergic reactions: fever,

chills, nausea, headache, shortness of breath, low blood pressure, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, and dizziness.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of bamlanivimab. Not a lot of people have been given bamlanivimab. Serious and unexpected side effects may happen. Bamlanivimab is still being studied so it is possible that all of the risks are not known at this time.

It is possible that bamlanivimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, bamlanivimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

What other treatment choices are there?
Like bamlanivimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on the emergency use of other medicines that are not approved by FDA to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with bamlanivimab. Should you decide not to receive bamlanivimab or stop it at any time, it will not change your standard medical care.

What if I am pregnant or breastfeeding?
There is limited experience treating pregnant women or breastfeeding mothers with bamlanivimab. For a mother and unborn baby, the benefit of receiving bamlanivimab may be greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

How do I report side effects with bamlanivimab?
Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch, call 1-800-FDA-1088, or contact Eli Lilly and Company at 1-855-LillyC19 (1-855-545-5921).

How can I learn more?

- Ask your healthcare provider
- Visit www.bamlanivimab.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?
The United States FDA has made bamlanivimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Bamlanivimab has not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for bamlanivimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the product may no longer be used).

Literature issued November 2020

Eli Lilly and Company, Indianapolis, IN 46285, USA

BAM-0001-EUA PAT-20201109

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF CASIRIVIMAB AND IMDEVIMAB FOR CORONAVIRUS DISEASE 2019
(COVID-19)

You are being given a medicine called **casirivimab** and **imdevimab** for the treatment of coronavirus disease 2019 (COVID-19). This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking casirivimab and imdevimab, which you may receive.

Receiving casirivimab and imdevimab may benefit certain people with COVID-19.

Read this Fact Sheet for information about casirivimab and imdevimab. Talk to your healthcare provider if you have questions. It is your choice to receive casirivimab and imdevimab or stop at any time.

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can occur and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, seem to be at higher risk of being hospitalized for COVID-19.

WHAT ARE THE SYMPTOMS OF COVID-19?

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

WHAT IS CASIRIVIMAB AND IMDEVIMAB?

Casirivimab and imdevimab are investigational medicines used to treat mild to moderate symptoms of COVID-19 in non-hospitalized adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)), and who are at high risk for developing severe COVID-19 symptoms or the need for hospitalization. Casirivimab and imdevimab are investigational because they are still being studied. There is limited information known about the safety and effectiveness of using casirivimab and imdevimab to treat people with COVID-19.

The FDA has authorized the emergency use of casirivimab and imdevimab for the treatment of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the **"What is an Emergency Use Authorization (EUA)?"** section at the end of this Fact Sheet.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE CASIRIVIMAB AND IMDEVIMAB?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies

- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE CASIRIVIMAB AND IMDEVIMAB?

- Casirivimab and imdevimab are two investigational medicines given together as a single intravenous infusion (through a vein) for at least 1 hour.
- You will receive one dose of casirivimab and imdevimab by intravenous infusion.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF CASIRIVIMAB AND IMDEVIMAB?

Possible side effects of casirivimab and imdevimab are:

- Allergic reactions. Allergic reactions can happen during and after infusion with casirivimab and imdevimab. Tell your healthcare provider or nurse, or get medical help right away if you get any of the following signs and symptoms of allergic reactions: fever, chills, low blood pressure, changes in your heartbeat, shortness of breath, wheezing, swelling of your lips, face, or throat, rash including hives, itching, headache, nausea, vomiting, sweating, muscle aches, dizziness and shivering.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

These are not all the possible side effects of casirivimab and imdevimab. Not a lot of people have been given casirivimab and imdevimab. Serious and unexpected side effects may happen. Casirivimab and imdevimab are still being studied so it is possible that all of the risks are not known at this time.

It is possible that casirivimab and imdevimab could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, casirivimab and imdevimab may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

WHAT OTHER TREATMENT CHOICES ARE THERE?

Like casirivimab and imdevimab, FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.covid19treatmentguidelines.nih.gov/ for information on other medicines used to treat people with COVID-19.

It is your choice to be treated or not to be treated with casirivimab and imdevimab. Should you decide not to receive casirivimab and imdevimab or stop it at any time, it will not change your standard medical care.

WHAT IF I AM PREGNANT OR BREASTFEEDING?

There is limited experience treating pregnant women or breastfeeding mothers with casirivimab and imdevimab. For a mother and unborn baby, the benefit of receiving casirivimab and imdevimab may be

greater than the risk from the treatment. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH CASIRIVIMAB AND IMDEVIMAB?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or call 1-844-734-6643.

HOW CAN I LEARN MORE?

- Ask your health care provider.
- Visit www.REGENCOV2.com
- Visit https://www.covid19treatmentguidelines.nih.gov/
- Contact your local or state public health department.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?

The United States FDA has made casirivimab and imdevimab available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Casirivimab and imdevimab have not undergone the same type of review as an FDA-approved or cleared product. The FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for casirivimab and imdevimab is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

REGENERON

Manufactured by:
Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
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