

# RegenCOV Infusion Playbook

Last updated: 1/13/22

## Physical space

- Minimum conditions
  - Physical barriers between other patients with a closing door
  - Ease of access to a medical provider
  - Access
- Ideal conditions
  - Room with negative pressure capabilities
  - Higher air exchange rates
  - Direct external access to space

## Supply needs

- Infusion supplies (IV start kits, tubing *with a filter*, locks)
- IV pump
- 0.9% saline flushes
- Simple dressing (bandaid/2x2/tape)
- Pulse oximeter
- Blood pressure cuff
- Stethoscope
- Thermometer
- Documentation capabilities

**Staffing:** RN capable of performing and monitoring an infusion patient on Isolation Precautions

# Ordering Regen-COV monoclonal antibodies in the *ER*

- This is an open orderable drug to all providers
  - Currently ordered through paper documentation, available on toolkit
    - “RegenCOV Casirivimab 600mg + Imdevimab 600mg IV infusion x 1”
      - When ordered in the **ER** – paper order to be faxed to facilities’ pharmacy with a call to pharmacy to alert staff on when drug should be made.
      - Can be administered subcutaneously as an alternative route when intravenous infusion is not feasible and would lead to a delay in treatment (ER use only, see slides 22- 26)
      - Option to order Regen-COV as an intravenous infusion OR a subcutaneous injection on paper order form
      - Patient EUA fact sheet to be given to all patients as well as written documentation of consent, please see documentation slide
  - Currently housed at CPH pharmacy with capacity for drug to be carried if need be (please call CPH pharmacy for drug transportation guidance, requires refrigeration)

GH pharmacy: 7a-5p week days, closed on weekends and holidays

MH pharmacy: 8a – 4p week days, 8a-1p weekends

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Ordering Regen-COV monoclonal antibodies

## *OUTPATIENT* at CPH

- This is an open orderable drug to all providers
  - Currently ordered through paper documentation, available on toolkit
    - Now can also order through eCW (refer to slides 14-21)
    - “RegenCOV Casirivimab 600mg + Imdevimab 600mg IV infusion x 1”
      1. Ordering provider to document discussion regarding risks/benefits with patient and answer any clinical questions on order form
      2. Paper order to be faxed to CPH pharmacy 315-261-5513
      3. Orders will be reviewed by pharmacy for eligibility and to confirm drug availability
      4. Patient will be contacted directly with their scheduled appointment and receive appointment day instructions
      5. RN to confirm all patient’s questions have been answered, provide patient EUA fact sheet, review and document informed consent for an EUA drug
- Currently housed at CPH pharmacy with capacity for drug to be couriered if need be (please call CPH pharmacy for drug transportation guidance, requires refrigeration)

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Ordering Regen-COV monoclonal antibodies

## *OUTPATIENT* at **MH**

- This is an open orderable drug to all providers
  - Currently ordered through paper documentation, available on toolkit
    - “RegenCOV Casirivimab 600mg + Imdevimab 600mg IV infusion x 1”
      1. Ordering provider to document discussion regarding risks/benefits with patient and answer any clinical questions (TE, virtual visit)
      2. Paper order to be faxed to MH pharmacy
      3. Call 315-769-4211 (MH infusion suite)
      4. Infusion nurse will confirm eligibility and call Pharmacy to confirm drug availability
      5. Infusion nurse will schedule infusion and contact ordering provider with date/time
      6. Provider will notify the patient of their scheduled infusion
      7. RN to confirm all patient’s questions have been answered, provide patient EUA fact sheet, review and document informed consent for an EUA drug
- Currently housed at CPH pharmacy with capacity for drug to be couriered if need be (please call CPH pharmacy for drug transportation guidance, requires refrigeration)

MH pharmacy: 8a – 4p week days, 8a-1p weekends, fax #315-769-4630

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Ordering Regen-COV monoclonal antibodies

## *OUTPATIENT* at GH

- This is an open orderable drug to all providers (if ordering provider does not have active privileges, order will be signed by GH Hospitalist)
  - Currently ordered through paper documentation, available on toolkit
    - “RegenCOV Casirivimab 600mg + Imdevimab 600mg IV infusion x 1”
      1. Ordering provider to document discussion regarding risks/benefits with patient and answer any clinical questions (ie TE, virtual visit)
      2. Paper order to be faxed to GH ED 315-261-5738
      3. Call GH ER to discuss drug availability and scheduling
      4. Nurse will confirm eligibility and check ED fridge for RegenCOV kit
      5. Nurse will schedule infusion and contact patient with date/time of appointment
      6. RN to confirm all patient’s questions have been answered, provide patient EUA fact sheet, review and document informed consent for an EUA drug
      7. Prior to giving, contact nursing supervisor. They must text CPH Pharmacy to let them know it is being used. CPH pharmacy will report to DOH on our behalf, and will also automatically send a replacement within roughly 24 hours. The phone number is listed in the kit instructions.

\*\* As pharmacy is not open on weekends, the courier will give replacement vial to nursing supervisor if it arrives on a Saturday/Sunday. It will need to be placed in the night cabinet refrigerator for pharmacy to restock. In the event that the ED runs out over the weekend, please check the night cabinet refrigerator. Paperwork kits will be made up in the night cabinet, so the supervisor will then just need to grab the kit and the vial from fridge. M-F pharmacy will be restocking to the ED fridge.\*\*

CPH pharmacy: 7a-7p week days, 7a – 4p weekends

# Clinical Information - Contraindication/Unauthorized

- History of anaphylaxis to RegenCOV
- **Meets clinical criteria for hospitalization or anticipated to be hospitalized with COVID-19**
- Require O2 beyond baseline
- *\*Pregnancy/Lactation — there is insufficient data to evaluate drug risk should only be used if the potential benefits outweigh the potential risks for mother and child (pregnancy does not preclude use of RegenCOV but should be considered with caution)*

# Clinical Information – Eligibility Criteria

*This product may be therapeutically interchanged based on drug availability and efficacy of drug based on epidemiologic recommendations*

- Documented COVID positive test
- Age 18+ (or 12+ if >40kg in clinical coordination with pediatrician)
- Documented positive test for SARS-COV-2 within the last **7 days**
- High risk criteria
  - Non-white
  - BMI 25+
  - Diabetes
  - CKD
  - Immunosuppressive condition/treatment
  - Cardiovascular disease
  - Hypertension
  - Chronic lung disease Medical technology dependence (ie tracheostomy, gastrostomy, etc)
  - Neurodevelopmental disorders
  - Sickle cell disease
  - \*Pregnancy

*Above are the minimum eligibility criteria, prioritization for verifying orders may vary based on product availability please see next slide for current inclusion criteria. If patient is not going to be scheduled ordering office will be contacted and informed.*



## Prioritization for outpatient anti-SARS-CoV-2-specific therapies

Priority tier	Risk group description
1	<ul style="list-style-type: none"><li>Immunocompromised individuals 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 (refer to immunocompromising conditions below*)</li><li><b>or</b></li><li>Unvaccinated individuals at the highest risk of severe disease (age <math>\geq 75</math> years or age <math>\geq 65</math> years with additional risk factors).</li></ul>
2	<ul style="list-style-type: none"><li>Unvaccinated individuals at risk of severe disease not included in Tier 1 (age <math>\geq 65</math> years or age <math>&lt; 65</math> years with clinical risk factors).</li></ul>
3	<ul style="list-style-type: none"><li>Vaccinated individuals at high risk of severe disease (age <math>\geq 75</math> years or age <math>\geq 65</math> years with clinical risk factors).</li></ul> <p><b>Note:</b> Vaccinated individuals who have <b>not</b> received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment over those who have received a booster.</p>
4	<ul style="list-style-type: none"><li>Vaccinated individuals at risk of severe disease (age <math>\geq 65</math> years or age <math>&lt; 65</math> with clinical risk factors).</li></ul> <p><b>Note:</b> Vaccinated individuals who have <b>not</b> received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment over those who have received a booster.</p>

The NIH COVID-19 Treatment Guideline Panel prioritizes risk groups for anti-SARS-CoV-2-specific therapy based on 4 key elements: age, vaccination status, immune status, and clinical risk factors. The groups are listed by tier in descending order of priority.

\* If anti-SARS-CoV-2-specific therapy cannot be provided to all moderately to severely immunocompromised individuals, the Panel suggests prioritizing their use for those who are least likely to mount an adequate response to COVID-19 vaccination or SARS-CoV-2 infection and who are at risk for severe outcomes, including (but not limited to) the following: patients who are within 1 year of receiving B-cell depleting therapies (eg, 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<sup>3</sup>. If supplies are extremely limited, the Panel suggests prioritizing those who are more severely immunocompromised (refer to above list) and who also have additional risk factors for severe disease for the outpatient therapies.

# Clinical Information – Adverse Reactions

- Allergic reactions
- Worsening symptoms after treatment
- Infusion site reactions
  - Pain
  - Burning
  - Bleeding
  - Infusion site infection
- May reduce immune function/increase risk for other infections
- May negatively impact response to SARS-COV-2 and guidance on administration of vaccination after infusion should be based on [https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC\\_AA\\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#antiviral-therapy](https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#antiviral-therapy)

# Documentation Criteria

- Date of first positive SARS-COV-2 test
- Which high risk criteria are met
- Documentation that patient does not meet inpatient criteria and does not have additional O2 demand beyond baseline
- Standard EUA drug consent form (performed on date of service) to be included in chart
- Documentation of drug order (scan of paper documentation or written documentation of drug dose and infusion rate)
- *\*For outpatient providers: documentation of conversation regarding risk/benefits of using EUA drug*

# ***REGEN-COV***

Casirivimab 600mg + Imdevimab 600mg

single IV infusion

or \*subq infusion/injection

*\*specific clinical scenario required*

Cited from REGENERON administration recommendations

**RECOMMENDED ADMINISTRATION RATE FOR 600 MG OF CASIRIVIMAB AND 600 MG OF IMDEVIMAB FOR INTRAVENOUS INFUSION**

Size of Prefilled 0.9% Sodium Chloride Infusion Bag	Maximum Infusion Rate	Minimum Infusion Time
50 mL <sup>a</sup>	180 mL/hr	20 minutes
100 mL	310 mL/hr	21 minutes
150 mL	310 mL/hr	31 minutes
250 mL	310 mL/hr	50 minutes

<sup>a</sup> The minimum infusion time for patients administered casirivimab and imdevimab together using the 50-mL prefilled 0.9% Sodium Chloride infusion bag must be at least 20 minutes to ensure safe use.

In June 2021, the maximum infusion rate when using the 50 mL infusion bag was adjusted down. The minimum infusion times for the other bag sizes were also lowered. These adjustments were made due to the change in authorized dose.

Regeneron guidance recommended **1 HOUR OBSERVATION PERIOD**

- EUA Fact Sheet for PATIENTS
  - <https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf>
- EUA Fact Sheet for PROVIDERS
  - <https://www.regeneron.com/downloads/treatment-covid19-eua-fact-sheet-for-hcp.pdf>
- A consent form written consent needed
  - [https://www.strac.org/files/RIC/PatientConsentForm\\_BamRegen%20Bam\\_Ete\\_03.30.21.pdf](https://www.strac.org/files/RIC/PatientConsentForm_BamRegen%20Bam_Ete_03.30.21.pdf)

# Ordering Process for eCW

\*please note that the following screenshots are for the older version of eCW

# Under lab section

- Although it is not a lab, it was built under the lab section to allow the use of a questionnaire
1. Under the lab section you will search “RegenCOV (casirivimab 600 mg + imdevimab 600 mg) IV infusion x1”

Lookup: regen By: Order Name Contains Type: Both Lab DI

Lab Company: -Meditech All Prev

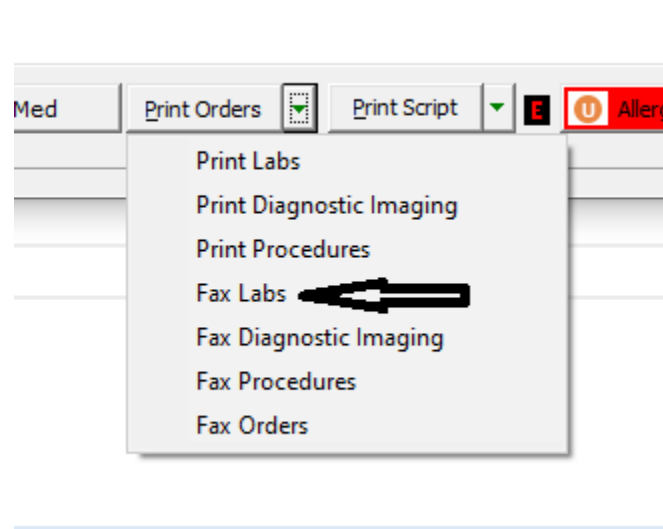
	Order Name	Alias Name	Lab Companies
public	Regen-COV (casirivimab 600mg + imdevimab 600mg) IV infusion ...		-Meditech



- Once you try to exit the treatment screen the questionnaire will pop up and you will fill in the required information and click “OK”

Lab Company	-Meditech
Regen-COV (casirivimab 600mg + imdevimab 600mg) IV infusion x1	
Weight in Kilograms	<input type="text"/>
Allergies:	<input type="text"/>
First COVID positive date	<input type="text"/>
High risk criteria	<input type="checkbox"/> Age 65 or older <input type="checkbox"/> BMI 25 or more <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Chronic kidney disease <input type="checkbox"/> Immunosuppressive disease/treatment <input type="checkbox"/> Cardiovascular disease <input type="checkbox"/> Hypertension <input type="checkbox"/> Chronic lung disease <input type="checkbox"/> Medical related technological dependence (ie tracheostomy, gastrostomy etc.) <input type="checkbox"/> Neurodevelopmental disorders <input type="checkbox"/> Non-white race <input type="checkbox"/> Sickle Cell disease <input type="checkbox"/> Pregnancy
Regen-COV (casirivimab 600mg + imdevimab 600mg) IV infusion x1	<input type="radio"/> ED immediate use <input type="radio"/> Scheduled out-patient use
Was the EUA consent performed?	<input type="radio"/> Yes <input type="radio"/> No

3. Fax the order to the necessary pharmacy CPH Pharmacy, MH Pharmacy, or GH ED Fax. All three are built into the system to search and do not need to be hand entered.
4. In the EXE version (old version) → From the treatment screen, click the arrow next to Print order and select fax labs.



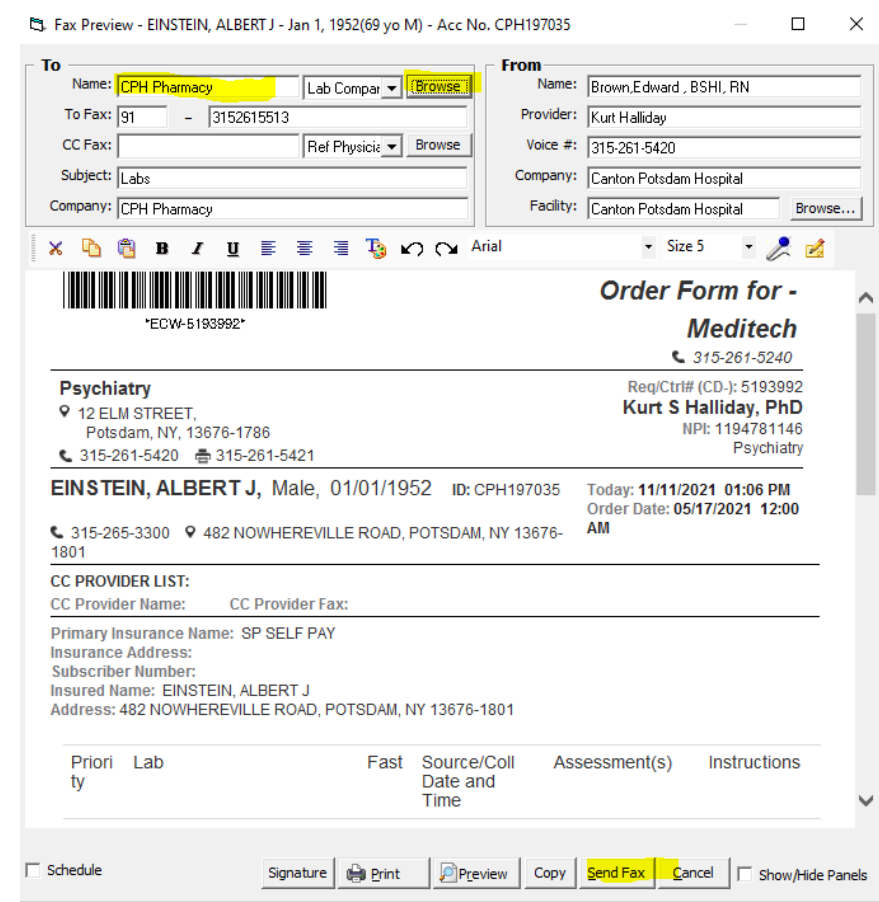
5. On the pop up screen assure that the Regen order is checked and click ok



The 'Print/Fax' dialog box contains the following elements:

- All Orders
- Regen-COV (casirivimab 600mg + imdevir)
- Facility: Psychiatry
- Lab Company: -Meditech
- Comments: Browse...
- Buttons: OK, Cancel

6. Change lab company to the correlating Pharmacy and click send fax



The 'Fax Preview' window displays the following information:

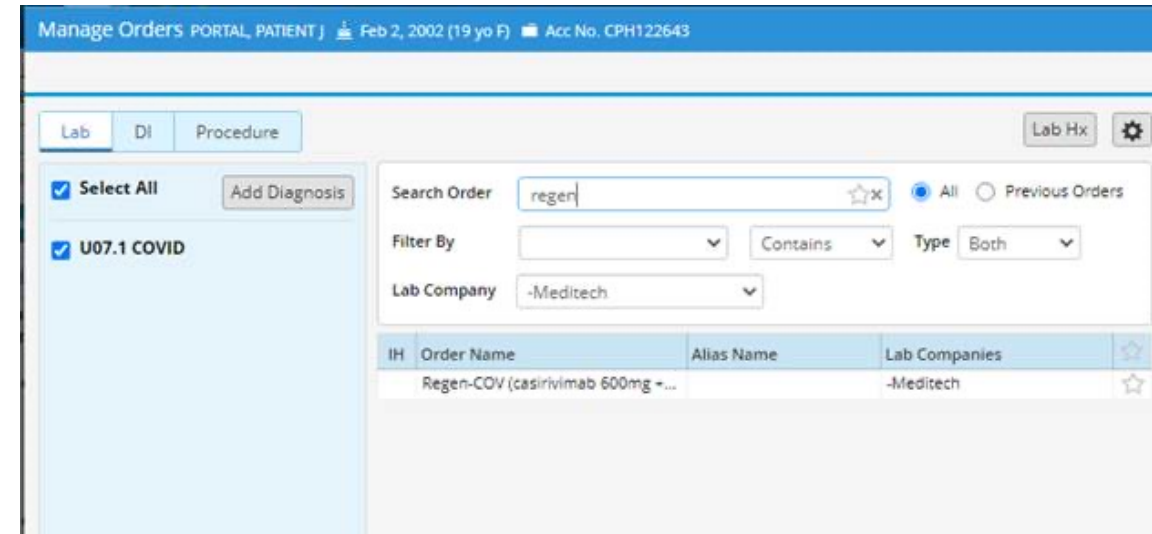
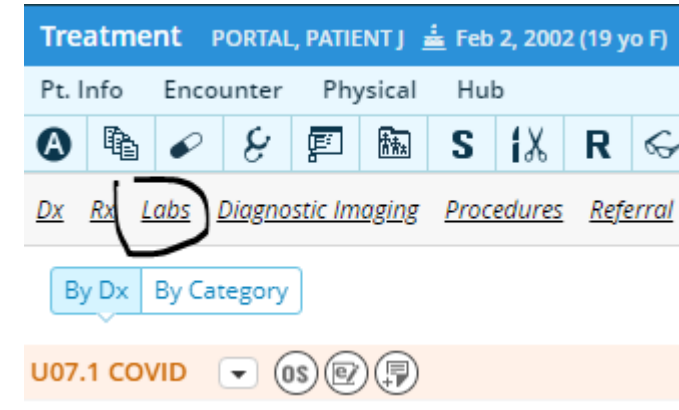
- To:** Name: CPH Pharmacy, Lab Compar: [Browse...], To Fax: 91 - 3152615513, CC Fax: [Ref Physic: Browse], Subject: Labs, Company: CPH Pharmacy
- From:** Name: Brown,Edward , BSHI, RN, Provider: Kurt Halliday, Voice #: 315-261-5420, Company: Canton Potsdam Hospital, Facility: Canton Potsdam Hospital [Browse...]
- Barcode: \*ECW-5193992\*
- Order Form for - Meditech**  
315-261-5240
- Psychiatry**  
12 ELM STREET, Potsdam, NY, 13676-1786  
315-261-5420 315-261-5421
- Req/Ctrl# (CD-): 5193992  
**Kurt S Halliday, PhD**  
NPI: 1194781146  
Psychiatry
- EINSTEIN, ALBERT J, Male, 01/01/1952** ID: CPH197035 Today: 11/11/2021 01:06 PM  
Order Date: 05/17/2021 12:00 AM
- 315-265-3300 482 NOWHEREVILLE ROAD, POTSDAM, NY 13676-1801
- CC PROVIDER LIST:**  
CC Provider Name: CC Provider Fax:
- Primary Insurance Name: SP SELF PAY  
Insurance Address:  
Subscriber Number:  
Insured Name: EINSTEIN, ALBERT J  
Address: 482 NOWHEREVILLE ROAD, POTSDAM, NY 13676-1801

Priori ty	Lab	Fast	Source/Coll Date and Time	Assessment(s)	Instructions
-----------	-----	------	---------------------------	---------------	--------------

- Buttons: Schedule, Signature, Print, Preview, Copy, Send Fax, Cancel, Show/Hide Panels

# Cloud Version

1. Click labs in the treatment section.
2. Search and add “Regen-COV (casirivimab 600mg + imdevimab 600mg) IV infusion x1” then click close.



3. AOE questionnaire will open. Fill out the details and click ok.
4. You will return to the treatment screen. Click the arrow next to send and select fax labs.

Order Details PORTAL, PATIENT J Feb 2, 2002 (19 yo F) Acc No. CPH122643

Regen-COV (casirivimab 600mg + imdevimab 600mg) IV infusion x1

-Meditech

Weight in Kilograms  
66

Allergies:  
nkda

First COVID positive date  
11/9/21

High risk criteria

<input checked="" type="checkbox"/> Age 65 or older	<input type="checkbox"/> BMI 25 or more
<input checked="" type="checkbox"/> Diabetes mellitus	<input type="checkbox"/> Chronic kidney disease
<input checked="" type="checkbox"/> Immunosuppressive disease/treatment	<input type="checkbox"/> Cardiovascular disease

5. In the Common Send screen deselect everything but the Regen order and hit send in the lower right.

Common Send PORTAL, PATIENT J Feb 2, 2002 (19 yo F) Acc No. CPH122643

Lab Company: -Meditech  
Assigned To: [Search] [Star] [More]  
Clinical Info: [Text Field]  
Comment: [Text Field] [Print Label]

Specimen Source: [Dropdown]  
Volume: [Text Field] Unit: [Text Field] Fasting: [Dropdown]  
Collection Date: 11/15/2021 [Calendar] Time: 05:45 PM [Clock]  
CC Results To: [Search] [Star] [Apply to Selected]  
Ordering Facility: CPH Pain Management [Dropdown]

<input checked="" type="checkbox"/>	Mode	Lab	Configured For	Send To	Collection Date/Time	SP	IH	[Icon]	[Icon]	[Icon]
<input type="checkbox"/>	Fax	Pregnancy Test, Urine	-Meditech	-Meditech	08/05/2021	<input checked="" type="checkbox"/>	IH	<input type="checkbox"/>	[Info]	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	Fax	Regen-COV (casirivimab 600mg + Imdevimab 600mg) IV infusion x1	-Meditech	-Meditech		<input checked="" type="checkbox"/>		<input type="checkbox"/>	[Info]	<input checked="" type="checkbox"/>

Only  items will be sent through the transmit mode selected for each item. **Send**

6. Order was faxed to the lab.

# Subcutaneous Regen-COV Workflow

For Emergency Department Use Only

# Subcutaneous Regen-COV

- Can be administered **subcutaneously** as an alternative route when intravenous infusion is not feasible and would lead to a delay in treatment
- Requirements for use remain the same as for the intravenous preparation
  - EUA consent, two high-risk factors, <7 days since symptom onset, etc.
- Dose:
  - Casirivimab 600 mg and imdevimab 600 mg administered together by subcutaneous injection as soon as possible after positive SARS-CoV-2 viral testing and within 10 days of symptom onset



# Administration

- For the administration of 600 mg of casirivimab and 600 mg of imdevimab, gather 4 syringes (see Table 5 on next slide) and prepare for subcutaneous injections
- Administer the subcutaneous injections consecutively, each at a different injection site
  - Into the thigh, back of the upper arm, or abdomen, except for 2 inches (5 cm) around the navel
  - The waistline should be avoided
- Recommended that providers use different quadrants of the abdomen or upper thighs or back of the upper arms to space apart each 2.5 mL subcutaneous injection of casirivimab and imdevimab
  - DO NOT inject into skin that is tender, damaged, bruised, or scarred
- Clinically monitor patients after injections and observe patients for at least 1 hour

**Table 5: Preparation of 600 mg of Casirivimab and 600 mg of Imdevimab for Subcutaneous Injections**

<b>Prepare 600 mg of Casirivimab and 600 mg of Imdevimab</b>	<b>Preparation of 4 Syringes</b>
<b>Using Casirivimab and Imdevimab Co-formulated Vial</b>	Withdraw 2.5 mL solution per syringe into FOUR separate syringes.
<b>Using Casirivimab and Imdevimab Individual Vials</b>	<ul style="list-style-type: none"> <li>• <b>Casirivimab:</b> Withdraw 2.5 mL solution per syringe into TWO separate syringes.</li> <li>• <b>Imdevimab:</b> Withdraw 2.5 mL solution per syringe into TWO separate syringes.</li> </ul> <p style="text-align: center;">For total of 4 syringes.</p>

# Warnings

- Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions
  - Serious hypersensitivity reactions, including anaphylaxis, have been observed with administration of REGEN-COV. If signs or symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy.
- Signs & Symptoms of Infusion-Related Reactions:
  - Fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions (e.g., pre-syncope, syncope), dizziness, and diaphoresis