Monoclonal Antibody Therapy

NCH Healthcare System

NCH is pleased to offer Monoclonal antibody therapy to our community. We currently have the Regeneron combination (casirivimab and imdevimab) available. This regimen is used for the treatment of mild to moderate coronavirus disease in adults and pediatric patients with positive results of direct SARS-CoV2 viral testing who are 12 years of age and older weighting at least 40KG and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Treatment is to be administered as soon as possible after positive results and within 10 days of symptom onset.

Providers with NCH ordering privileges:

Complete the attached order set and fax to the NCH Outpatient Infusion Center at **(239) 624-4371**.

For Pediatric Patients, fax the order set to **(239) 624-0061**.

Providers who do <u>NOT</u> have NCH ordering privileges:

Contact NCH at **(239) 624-0940** for patient evaluation and treatment orders.

For additional information on this process, please contact Ellison Warner at **(239) 982-4200** Monday-Friday from 8am-5pm

FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™
(casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

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

WHAT IS COVID-19?

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. 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, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people 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 REGEN-COV (casirivimab and imdevimab)?

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
    - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
    - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising

conditions, including someone who is taking immunosuppressive medications), **and**

- have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html, **or**
- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention 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.

WHO SHOULD NOT TAKE REGEN-COV?

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?

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

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?

- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the

tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
    - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
    - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?

Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.
- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

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. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

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

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV 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 REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization for information on the emergency use of other medicines that are not approved by FDA that are used 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 REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

WHAT OTHER PREVENTION CHOICES ARE THERE?
Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (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.REGENCOV.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 REGEN-COV (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.

REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic.

The EUA for REGEN-COV 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
Tarrytown, NY 10591-6707

Revised: 07/2021

Patient Name _____ **Date:**_____
Address:_____
Phone:_____
Date of Birth_____
Height _____ **Weight** _____
Allergies _____
ICD-10 DIAGNOSIS CODES:

Bamlanivimab and etesevimab/ casirivimab and imdevimab **Infusion Orders (for Outpatient Infusion Services only). OPIS FAX 239.624.4371**

REFERRAL TO NCH CREDENTIALED PROVIDER (if ordering provider not privileged at NCH)- **CALL**(239) 624-0940

AUTHORIZED USE The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product **bamlanivimab and etesevimab** or **casirivimab and imdevimab** for the treatment of mild to moderate coronavirus disease 2019 (COVID19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing or those with known exposure who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

LIMITATIONS OF AUTHORIZED USE

- **Bamlanivimab and etesevimab or casirivimab and imdevimab are not authorized for use in patients:**
  - o who are hospitalized due to COVID-19, OR
  - o who require oxygen therapy due to COVID-19, OR
  - o who require 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.
- Benefit of treatment with **bamlanivimab and etesevimab** or **casirivimab and imdevimab** has not been observed in patients hospitalized due to COVID-19. Monoclonal antibodies, such as **bamlanivimab and etesevimab** or **casirivimab and imdevimab** may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

BAMLANIVIMAB AND ETESEVIMAB/ CASIRIVIMAB AND IMDEVIMAB CRITERIA:

Date of positive viral test for SARS-CoV-2 _____ □ **NA**
Administration **of bamlanivimab and etesevimab** or **casirivimab and imdevimab** to be administered as soon as possible after positive test or exposure within 10 days of symptom onset. If positive SARS-CoV-2 was completed outside of the NCH Healthcare System, please attach confirmation of positive SARS-CoV-2 test with this order.
Optimal infusion date(s) between _____ and _____.

This EUA is for the use of the unapproved product bamlanivimab and etesevimab or **casirivimab and imdevimab** for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Check high risk criteria. High risk is defined as patients who meet the criteria discussed in the EAU statement such as:

- ❑ Body mass index (BMI) ≥ 35
- ❑ Chronic kidney disease- indicate stage _____
- ❑ Diabetes
- ❑ Immunosuppressive disease
- ❑ Pregnancy
- ❑ ≥ 65 years of age with additional risk factors/comorbitities: _____
- ❑ Significant Cardiovascular disease OR chronic obstructive pulmonary disease/other chronic respiratory disease
- ❑ Exposure and risk for progressing to severe disease or hospitalization
- ❑ Patient is 12-17 years of age AND
  - ❑ BMI ≥ 85th percentile for their age and gender based on CDC growth charts https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - ❑ sickle cell disease OR

- ❑ congenital or acquired heart disease OR
- ❑ neurodevelopmental disorders, for example, cerebral palsy OR
- ❑ a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COIVD-19) OR
- ❑ asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

INFUSIONS:

1. Ensure the patient is provided with the Emergency Use Authorization fact sheet.
2. 0.9% Sodium Chloride IV **250 ml bag** @ 20ml/hr to keep vein open. Flush with 10ml – 30ml before and after medication administration and as needed.
3. Monitor patient including vital signs and oxygenation pre-infusion; q 30 minutes during infusion; and for at least one hour after infusion.
4. Once infusion is complete, flush the infusion line to ensure delivery of the required dose.

***Pharmacy may substitute infusion product based allocated product availability.

❑ ***** BAMLANIVIMAB AND ETESEVIMAB INFUSION (USE IS ON HOLD IN FLORIDA AS OF 5/28/21 DUE TO VARIANTS)**

❑ **CASIRIVIMAB & IMDEVIMAB INFUSION ORDERS**

1. casirivimab 600 mg and imdevimab 600 mg administered together as an intravenous infusion over at least 21 minutes via pump or gravity. Use polyvinylchloride infusion set containing a 0.2-0.22 micron in-line polyethersulfone filter.

❑ **ADVERSE REACTION ORDERS**

The following orders should be followed if a patient experiences the following:

A) A sudden drop in Systolic BP less than 90 mm Hg
B) Pulse Rate less than 50 beats per minute
C) Shortness of breath
D) Any signs or symptoms of a transfusion reaction
   1) Stop the Infusion
   2) Sodium Chloride 0.9% at 100 ml/hr
   3) Start Oxygen @ 2 liters/nasal cannula to keep O2 sat >90%
   4) Call SWAT
   5) Call Physician for follow-up orders
   6) Notify pharmacy for FDA MedWatch submission

ADDITIONAL REACTION ORDERS (attn: must be reviewed / ordered prior to infusion being scheduled)

❑ Give Diphenhydramine (Benadryl) 25 mg IVP x 1 dose
❑ Acetaminophen 650 mg po (if not given as a premedication)
❑ Give Methylprednisolone (Solu-Medrol) 125 mg IV x 1 dose

PHYSICIAN SIGNATURE _____ **DATE/TIME**_____

PHYSICIAN NAME PRINTED_____(Ordering physician must have NCH privileges)

By signing, physician attests to personally reviewing risks, benefits and alternative therapy options with the patient regarding the emergency use authorization for bamlanivimab and etesevimab/ CASIRIVIMAB & IMDEVIMAB.
Scheduling will be completed based on availability of the allocated product (bamlanivimab and etesevimab or CASIRIVIMAB & IMDEVIMAB)
References:
CMS guide: https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf

Fact sheet for health care providers: http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-hcp.pdf Fact Sheet for Heatlh Care Providers: Emergency Use Authorization (EUA) of Casirivimab and Imdevimab (fda.gov)