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Monoclonal Antibody Information Sheet

Casirivimab/imdevimab are potent antispike neutralizing monoclonal antibodies designed to mimic the body's natural immune response by binding to the receptor-binding domain of SARS-CoV-2. Monoclonal antibody (mAB) therapy is indicated for the treatment of mildly symptomatic COVID-19 outpatients who are at high risk of progressing to moderate or severe disease. These patients also should not require any supplemental oxygen or require higher level of oxygen compared to their baseline. There are currently 2 combination therapies available under FDA emergency use authorization (EUA) which are casirivimab/imdevimab (Regeneron) and sotrovimab (GlaskoSmithKline).

- Casirivimab/imdevimab vs. Placebo
  - 3% vs 9% progressed to ED/hospitalization
- Sotrovimab
  - 1% vs 7% progressed to hospitalization/death

Under the EUA, eligible patients are outpatients with mild and moderate COVID-19 with no more than 10 days of symptoms. Ideally, mAb therapies should be administered as soon as possible after positive viral test for COVID-19. These patients must be at high-risk for progression to severe COVID-19 and/or hospitalization due to age, elevated BMI, or specified chronic conditions. Notably, the EUA is not an approval but a determination that potential benefits outweigh potential risks.

Adverse Events: There are limited clinical data available for the monoclonal antibodies. Serious and unexpected adverse events may occur that have not been previously reported with their use.

- Infusion-related reactions have been observed with administration. These reactions may be severe or life threatening. If an infusion-related reaction occurs, consider slowing or stopping the infusion.
- Signs and symptoms of infusion related reactions may include: fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia (e.g., atrial fibrillation, sinus tachycardia, bradycardia), chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, dizziness and diaphoresis
- Most common: nausea, vomiting
- Less common: anaphylaxis, hypersensitivity reaction, infusion-related reaction

General take away about the role of these therapies:
Key findings showed symptom improvement compared to placebo group.
Patients with higher viral loads have higher rates of hospitalizations.
In summary, patients who received these therapies had fewer hospitalizations and lower symptom burden than those who did not, with the most pronounced effects in those who are at high risk of developing severe COVID-19 disease.

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Talking Points for Ordering Provider for Patients Eligible for mAb Therapy:

1. Inform patient that COVID test is positive.

2. Let them know that there is a drug available in limited quantities that has recently been given emergency authorization by the FDA for the treatment of early COVID in patients like them.

3. Because of their condition (tell them which risk factor – age, diabetes, hypertension, immunosuppressed, etc.), they are at higher risk of progressing to severe disease.

4. This medication has been shown to reduce the risk of hospitalization and decrease severity of symptoms.

5. This medication is administered through a vein. The process takes over an hour with an additional hour of observation.

6. Based on studies and our own experience, the treatment appears to be safe, but full side effects are not known.

7. Possible side effects include:

    a. Nausea and vomiting – most common (each occurring in 1% of subjects)

    b. An allergic reaction – hives, difficulty breathing, fall in blood pressure – which will be treated with emergency medications

    c. Pain, bleeding, bruising at the IV site

    d. If they ask what other possible side effects there could be, can mention that it MAY affect efficacy of a future vaccine or it MAY prevent them from developing natural immunity from this infection.

8. The CDC recommends deferring COVID vaccination for at least 90 days after this therapy as otherwise it may interfere with vaccine efficacy. Remind them that reinfection with COVID-19 during this 90 day period is very unlikely.

9. The decision on whether to take this treatment is theirs. Deciding not to take it will not affect the care they are given.

10. The standard care for COVID is supportive therapy. They can be enrolled in a home monitoring program, rest and drink plenty of fluids, and take medications such as acetaminophen or ibuprofen for fever and body aches.

11. The key is to get the therapy ASAP. Must be infused by (tell them the date for them based off their symptom onset – must be within 10 days of that).

12. If they are interested, tell them they will get a call from one of Health Park Pharmacy's Team Members. Stress that they should expect the call as time is of the essence.

13. Give the caveat that they may NOT be able to receive the therapy:

    a. if drug is not available

    b. if they are not able to get infused within the critical time frame (due to scheduling limitations on the part of the site or the patient)

    c. if their condition deteriorates to the point that they require oxygen/hospitalization as this medication cannot be given to patients who have severe disease.

Monoclonal Antibody Screening Questionnaire & Physician's Order Sheet

Patient Name: _____ DOB: _____
Allergies: _____ Patient Contact Number: _____

Diagnosis and ICD-10: _____

Monoclonal Antibody Screening Questions

Qualifications to receive REGEN-COVTM (casirivimab and imdevimab) Intravenous (IV/SQ) Therapy

Patient has a positive COVID-19 test? (If the answer is NO, the patient cannot receive this treatment)

- ☐ YES, Date of Positive Test: _____
- ☐ NO

Inclusion Criteria: (All criteria must be met to qualify for treatment)

- ☐ The patient is within 10 days of the onset of symptoms. Date of symptom onset: _____
- ☐ The patient is at least 12 years of age
- ☐ Patient weighs more than 40 kg
- ☐ Patient is NOT fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV2 Vaccination
- ☐ Patient NOT on oxygen therapy or has not required increasing levels of baseline oxygen
- ☐ Patient is NOT pregnant, lactating or breastfeeding Qualifying Conditions: (Must have AT LEAST ONE to qualify; select all that apply):
- ☐ Older age (> 65)
- ☐ Body Mass Index (BMI) ≥ 25
- ☐ Chronic Kidney Disease
- ☐ Diabetes
- ☐ Immunosuppressive Disease or Immunosuppressive Treatment
- ☐ Cardiovascular Disease or Hypertension
- ☐ Chronic Lung Disease
- ☐ Sickle Cell Disease
- ☐ Neurodevelopmental Disorders or other conditions that confer medical complexity
- ☐ Having a medical-related technological dependence (i.e. trach, gastrostomy or positive pressure ventilation)
- ☐ Other medical conditions or factors that place patient at high risk for progressive to severe COVID-19

Has the patient been provided a copy of the Fact Sheet for Patients, Parents and Caregivers EUA sheet?

- ☐ YES
- ☐ NO

Physician's Orders

Patient is a candidate to receive REGEN-COV (casirivimab and imdevimab) IV Therapy:

- ☐ Administer Monoclonal IV Therapy per protocol

Provider Signature: _____ Date: _____ Time:_____
Provider Printed Name: _____ Office Number: _____

Fax this completed order form, a copy of the patient's positive COVID-19 test and a signed informed consent to 919.847.7641 to schedule patient for therapy

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FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COVTM (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 COVID19. 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: o 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, o are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising Page 2 of 5 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-aresick/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 Page 3 of 5 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. o If your healthcare provider determines that you are unable to receive REGENCOV 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. o 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. Page 4 of 5 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/emergencypreparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-useauthorization 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. Page 5 of 5 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). Manufactured by: Regeneron Pharmaceuticals, Inc. 777 Old Saw Mill River Road Tarrytown, NY 10591-6707

Revised: 07/2021

PATIENT CONSENT FORM FOR COVID-19 TREATMENT PURPOSE OF INFORMED CONSENT

Casirivimab/Imdevimab (Regeneron) As your physician has discussed with you, you have been diagnosed with COVID-19 (or SARS-CoV-2). At the present time, there are few Food and Drug Administration (FDA) approved, or clinically proven therapies for treatment of COVID-19. As new clinical data emerges, local treatment guidelines have been developed and will be updated as new information becomes available. CDC guidelines reflect what is known about therapies that may work against the SARS-CoV-2 virus, have been used to treat other coronaviruses, or may theoretically target the underlying causes of virus- related severe lung conditions that make breathing difficult.

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed or suspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization

TREATMENT

In order for you to be treated with the therapy by the Infusion Team, you must sign this form to show that you agree to the use of investigational or off label treatments, that you have been informed of the benefits and risks of taking such therapies as well as the benefits and risks of declining or refusing such use. The Infusion team will annotate the monoclonal therapy available below for your encounter and the particular therapy chosen is based upon availability. You will be provided a patient informational handout regards the specific monoclonal antibody infusion before the infusion begins. You have the right to refuse to take this treatment(s) for any reason.

Attention Health Care Professional:

The Medication Checked Below is the One You will Receive for your Subcutaneous Treatment.

☐ Casirivimab/Imdevimab (Regeneron)

BACKGROUND

Regeneron is an investigational medicine which is monoclonal antibodies 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. The FDA has issued an Emergency Use Authorization (EUA) to permit the use of this unapproved medication. Clinical trials are ongoing to study its safety and efficacy. POSSIBLE BENEFITS It is possible that the medications listed above may help to control your symptoms, slow or stop the growth of the virus, shorten the duration or lessen the severity of the illness in you. Possible benefits primarily include improvement in lung function (ability to breathe without assistance) and normalization of blood pressure. However, there is the possibility that these medications may be of NO direct medical benefit to you. Your condition may get worse. POSSIBLE RISKS AND KNOWN SIDE EFFECTS It is possible that the medication prescribed may not improve your symptoms and not shorten the duration nor severity of the illness. It is possible that the medication will unexpectedly interfere with your ability to improve, hasten damage to the lungs or other organs, and shorten your life. Regeneron. There is limited clinical data available for this treatment and unexpected adverse events may occur that have not been previously reported. Side effects may include allergic reactions and injection site reactions. It is possible that these treatments could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. This treatment may also reduce your body's immune response to a vaccine for SARS-CoV-2. If you receive this therapy, it could reduce or delay your response to any COVID-19 vaccine for up to 90 days following the infusion and should consider waiting 90 days for a COVID-19 vaccine. Alternatives: There are

few approved therapies for the treatment of COVID-19 specifically. Medical care relies on helping the patient through the many complications. Most hospitalized patients survive their disease with standard medical care

List side effects/risks: Nausea (3%)* Dizziness (3%) Headache (3%) Pruritus (2%) Immediate nonserious hypersensitivity (2%) Diarrhea (1%)* Vomiting (1%). Serious side effects: anaphylaxis (s (<1%), Low Blood Pressure (<1%), Wheezing (<1%)

For more information about risks and side effects, please ask your physician. Please be advised that not all risks and side effects in the context of COVID-19 are known. Your physician may give you medication to help lessen the side effects. Some side effects are temporary. In some cases, side effects can be serious and can last a long time. Sometimes they never go away.

CERTIFICATION AND SIGNATURES

I have read this informed consent form and all of my questions have been answered to my satisfaction by my physician. I understand that I have the right to refuse to take this medication(s) for any reason. If I choose not to take this medication(s), this decision will not otherwise affect my status as a patient. I voluntarily consent to take the monoclonal antibody medication by subcutaneous route as discussed with my physician, and Health Park Pharmacy team members as described in this consent form.

CONSENT

The FDA has granted Emergency Use Authorization (EUA) to permit investigational therapies in patients with confirmed or suspected COVID-19. Investigational therapies are not approved for any indication. They are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. If checked below and signed, you consent to the use under this authorization.

Patient Name: _____

Patient Signature: _____Date:_____Time:_____

If patient is a minor; or is unable to sign, Indicate reason (ex: patient in COVID isolation):

Name of Person Signing for Patient:_____

Signature of Person Signing for Patient:_____Date:_____Time:_____

Monoclonal Antibody Administered	Date of Administration	Route & Site of Administration	Hpp Team Member that administers mAb
RegenCOV		SC R ABD / L ABD / R QUAD / L QUAD / L TRICEPT / R TRICEPT	