

WHAT TO EXPECT ON THE  
DAY OF INFUSION

**REGEN-COV**<sup>TM</sup>  
(casirivimab with imdevimab)



*REGENERON*

# HERE'S WHAT YOU NEED TO KNOW ABOUT REGEN-COV™ (casirivimab with imdevimab)

If you've recently tested positive for coronavirus disease 2019 (COVID-19), a new treatment option called REGEN-COV (REE-jen-cove) may be right for you.

In this guide, you'll learn about REGEN-COV, including what it is, who it is for, what to expect on the day of infusion, its possible benefits, and important safety information. REGEN-COV is investigational, which means it's a new drug that is still being studied, so there's a lot that experts still don't know about it. And remember, it's always important to discuss possible treatment options with your healthcare provider.

REGEN-COV is a combination monoclonal antibody treatment for COVID-19. "Combination" means that it contains two different monoclonal antibodies, casirivimab (CASS-uh-RIV-uh-mab) and imdevimab (im-DEV-uh-mab) that work together to help fight the infection. REGEN-COV is a one-time intravenous infusion—so no need for multiple doses.

**Know your options. If you received a positive COVID-19 test, talk to your healthcare provider right away about REGEN-COV.**

## Important notes about REGEN-COV

REGEN-COV (casirivimab with imdevimab) is an investigational medicine 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. 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.

- REGEN-COV has not been approved, but has been authorized for emergency use by FDA
- This use is 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
- For additional information on REGEN-COV, please see the [FDA Letter of Authorization](#), [Fact Sheet for Healthcare Providers](#), and [Fact Sheet for Patients, Parents and Caregivers](#)

## What is REGEN-COV and how does it work?

When you get infected with a virus, such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, your immune system creates antibodies to fight it off. It takes time for your body to make these antibodies, which allows the infection to get worse and make you sicker.

REGEN-COV contains two monoclonal antibodies that neutralize SARS-CoV-2 to help patients fight and recover from COVID-19. Being treated with REGEN-COV antibodies as soon as you are diagnosed with COVID-19 may limit the amount of virus that develops in your body, which may help you recover from the infection.

# WHO IS ELIGIBLE FOR REGEN-COV™ (casirivimab with imdevimab)?

REGEN-COV is an investigational medicine used to treat mild to moderate symptoms of COVID-19 in non-hospitalized persons who are:

- at least 12 years old AND
- at least 88 pounds (40 kg) AND
- at high risk of developing severe COVID-19 symptoms or the need for hospitalization



## **Am I at high risk?:**

You should speak to your healthcare provider about your risk factors. These are the risk factors that might make you eligible for treatment with REGEN-COV:

- Have a body mass index (BMI)  $\geq 35$
- Have chronic kidney disease
- Have diabetes
- Have immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are  $\geq 65$  years of age
- Are  $\geq 55$  years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/ other chronic respiratory disease
- Are 12-17 years of age AND have
  - BMI  $\geq 85$ th percentile for their age and gender based on CDC growth charts, [https://www.cdc.gov/growthcharts/clinical\\_charts.htm](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 COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control

# WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS?

## Warnings and important possible side effects of REGEN-COV™ (casirivimab with imdevimab)

**Allergic reactions:** Allergic reactions can happen during and after infusion with REGEN-COV. 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 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 and itching
- Muscle aches
- Dizziness
- Sweating

These reactions may be severe or life threatening.

**Worsening symptoms after treatment:** You may experience new or worsening symptoms after infusion, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness, or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

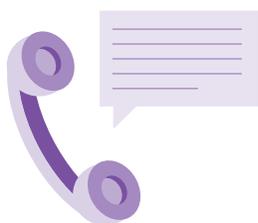
The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site.

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.

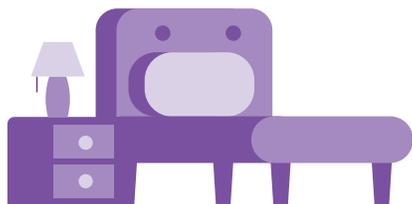
# PREPPING FOR YOUR INFUSION APPOINTMENT

After your healthcare provider has prescribed REGEN-COV™ (casirivimab with imdevimab), you may be able to receive the infusion immediately, or you may need an appointment. Consider the following tips to make yourself comfortable and reduce the likelihood of spreading COVID-19 to others.



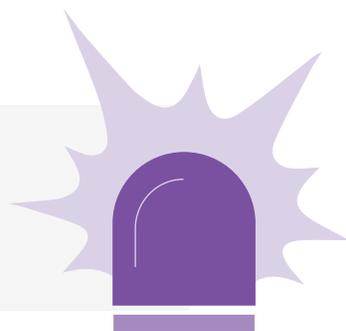
Call your healthcare provider to discuss the best self-care strategies for managing your COVID-19 symptoms.

Stay at home and avoid visiting public areas unless you are seeking medical care.



Take care of yourself by getting rest and staying hydrated.

Stay in touch with your healthcare provider and get care immediately if you have trouble breathing or any other emergency warning signs.



For more tips to help prevent the spread of COVID-19 if you are sick, visit <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/steps-when-sick.html>

**PLEASE SEE IMPORTANT SAFETY  
INFORMATION THROUGHOUT THIS GUIDE.**

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# WHAT TO EXPECT FROM THE INFUSION

## **You may receive your treatment at a hospital, infusion center, or clinic.**

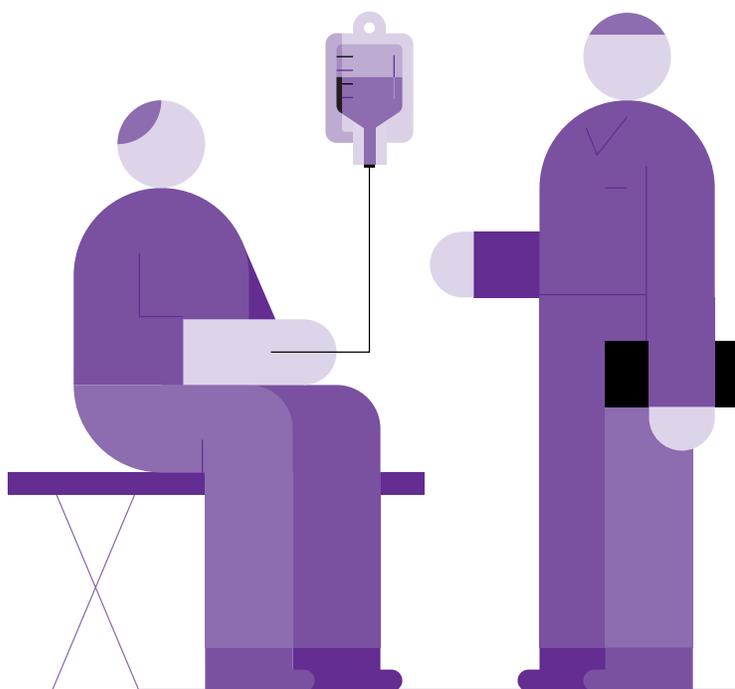
Upon arrival, you will be shown to your chair and a nurse will insert a small needle into your arm to prepare for your intravenous (IV) infusion. REGEN-COV™ (casirivimab with imdevimab) is given as one IV infusion by a doctor or nurse who is able to treat any reactions that may occur. The infusion will take 20 to 52 minutes or longer. Your healthcare provider will determine the duration of your infusion. After the infusion is complete, you will be monitored for at least 1 hour.

Ask your healthcare provider where to go to get your infusion. If you and your healthcare provider are looking for an infusion center near you, visit <https://locator.infusioncenter.org/>.



## **Before receiving REGEN-COV, 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 (prescriptions, over-the-counter drugs, vitamins, and herbal products)



PLEASE SEE IMPORTANT SAFETY INFORMATION THROUGHOUT THIS GUIDE.

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# TIPS FOR YOUR INFUSION

This may be the first time you have ever received an infusion. Consult your infusion center to learn if they have any guidelines or advice for your visit.

## **What happens after my treatment?**

After you finish your infusion, there is a monitoring period that will last at least 60 minutes. In the days following infusion, your healthcare provider may check in with you to see how you feel and which COVID-19 symptoms still persist. You still may be able to infect others after receiving REGEN-COV™ (casirivimab with imdevimab), so continue to follow safety guidelines and any additional instructions from your healthcare provider. **Speak to your healthcare provider right away or seek medical attention immediately if your symptoms get worse.**



## **Important Safety Information**

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 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.

# WHAT ELSE SHOULD I CONSIDER BEFORE RECEIVING REGEN-COV™ (casirivimab with imdevimab)?

## **What other treatment options are there?**

As with REGEN-COV, the 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.

## **What if my healthcare provider prescribes REGEN-COV, but I don't want to receive it?**

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 do I need to know about getting both REGEN-COV and a COVID-19 vaccine?**

### **What if I've received a COVID-19 vaccine? Can I still receive REGEN-COV?**

Even if you've received a COVID-19 vaccine, you can still receive REGEN-COV if your healthcare provider thinks it is appropriate.

### **If I've received REGEN-COV, can I still get vaccinated for COVID-19?**

Talk to your healthcare provider about when you should receive the COVID-19 vaccine if you have received REGEN-COV.

REGEN-COV is not a vaccine and will not replace receiving the vaccine. 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.

Please see [Understanding Your COVID-19 Treatment Options](#) to learn more.



# AUTHORIZED USE AND **IMPORTANT SAFETY INFORMATION**

REGEN-COV™ (casirivimab with imdevimab) is an investigational medicine 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. 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.

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## **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 (prescriptions, over-the-counter drugs, vitamins, and herbal products)

## **Receiving REGEN-COV (casirivimab with imdevimab)**

REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together as a single intravenous infusion (through a vein). You will receive one dose of REGEN-COV by intravenous infusion. The infusion will take 20 to 52 minutes or longer. Your healthcare provider will determine the duration of your infusion.

## **Warnings and important possible side effects of REGEN-COV (casirivimab with imdevimab)**

- **Allergic reactions:** Allergic reactions can happen during and after infusion with REGEN-COV. 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 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, dizziness and sweating. These reactions may be severe or life threatening.

# AUTHORIZED USE AND **IMPORTANT SAFETY INFORMATION (CONT'D)**

- **Worsening symptoms after treatment:** You may experience new or worsening symptoms after infusion, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these occur, contact your healthcare provider or seek immediate medical attention as some of these events have required hospitalization. It is unknown if these events are related to treatment or are due to the progression of COVID-19.

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## **Pregnancy and breastfeeding**

There is limited experience treating pregnant women or breastfeeding mothers with REGEN-COV (casirivimab with imdevimab). For a mother and unborn baby, the benefit of receiving REGEN-COV 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.

**Please see the [Fact Sheet for Patients, Parents and Caregivers](#) for more information.**