

YOUR GUIDE TO

REGEN-COV™
(casirivimab and imdevimab)



REGENERON

Authorized Use

REGEN-COV (casirivimab and 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

Please see the [Fact Sheet for Patients, Parents and Caregivers](#) or visit regencov.com for more information.

WHAT INFORMATION IS IN THIS GUIDE?

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

In this guide, you will learn about REGEN-COV, including what it is, who it is for, what to expect on the day of your infusion or injection, its possible benefits, and important safety information. REGEN-COV is investigational, which means it's a 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.

What should I know about REGEN-COV?	3
What is COVID-19?	4
Who is eligible for REGEN-COV?	5
What are the important possible side effects?	6
When should I seek treatment with REGEN-COV?	7
How will REGEN-COV be administered?	8
What should I expect on the day of treatment?	9
What should I expect after my treatment?	10
What else should I consider before receiving REGEN-COV?	11
Authorized Use and Important Safety Information	12

WHAT SHOULD I KNOW ABOUT REGEN-COV?

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

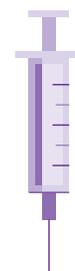
When you get infected with a virus, such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19, your immune system creates antibodies to fight it off. It takes time for your body to make these antibodies, during which the infection may get worse and make you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

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. The two monoclonal antibodies neutralize the virus, SARS-CoV-2, to help certain 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. REGEN-COV has been tested against clinical variants of SARS-CoV-2. In these tests, REGEN-COV was still able to neutralize the virus, including the Delta clinical variant.

REGEN-COV is given as a single intravenous infusion (through a vein), which will take 20 to 50 minutes or longer. 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 injection (medicine is injected in the tissue just under the skin). One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

Regardless of the means of administration, your healthcare provider will monitor you for one hour following treatment.

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



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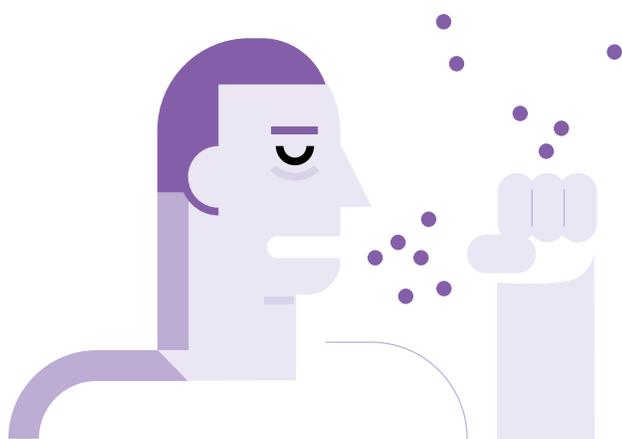
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WHAT IS COVID-19?

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, 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. For more information on high risk factors for COVID-19, see the following page.



| What are the symptoms?

Each person may experience different symptoms. The most commonly reported symptoms of COVID-19, which may appear 2 to 14 days after exposure, include:

- Fever
- Cough
- Shortness of breath
- Fatigue
- Muscle or body aches
- Headache
- New loss of taste or smell
- Sore throat
- Congestion or runny nose
- Nausea or vomiting
- Diarrhea

This list does not include all possible symptoms. For more information and updates, please visit the CDC website at <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

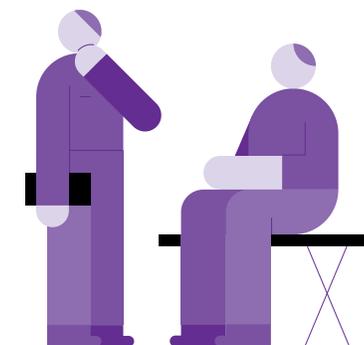
If you tested positive for COVID-19, talk to your healthcare provider right away to see if REGEN-COV is right for you.



WHO IS ELIGIBLE FOR REGEN-COV?

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



I Am I at high risk?

The following medical conditions or other factors may place adults and pediatric patients (age 12-17 years and weighing at least 88 pounds [40 kg]) at higher risk for progression to severe COVID-19:

- Older age (for example, age ≥ 65 years of age)
- Obesity or being overweight (for example, BMI > 25 kg/m², or if age 12-17, have BMI ≥ 85 th percentile for their age and gender based on [CDC growth charts](#))
- Pregnancy
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis and pulmonary hypertension)
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Having a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID 19))

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above.

For additional information on medical conditions and factors associated with increased risk for progression to severe COVID, see the [CDC website](#).

WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS?

I Warnings and important possible side effects of REGEN-COV (casirivimab and 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
- Feeling faint
- 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. 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.



WHEN SHOULD I SEEK TREATMENT WITH REGEN-COV?

If you have recently tested positive for COVID-19 and are at high risk, it is important to know what to do next, as REGEN-COV should be administered as soon as possible.

If you have tested positive or think you may have COVID-19, talk to your healthcare provider right away to see if REGEN-COV may be right for you.

Getting treated early may help prevent your symptoms from becoming severe and possibly life-threatening.

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)

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



HOW WILL REGEN-COV BE ADMINISTERED?

REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, that can be administered via intravenous (IV) infusion or subcutaneous injection. Subcutaneous injection can be used if your healthcare provider determines that you are unable to receive REGEN-COV as an IV infusion.

IV Infusion

When given intravenously, REGEN-COV is given as a single IV infusion (through a vein). The infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.

- You will receive one dose of REGEN-COV by IV infusion
- You will then be monitored for at least 1 hour after the infusion is complete

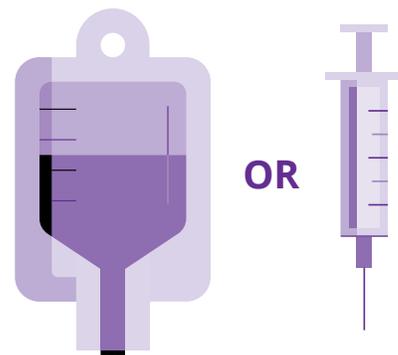
Subcutaneous Injection

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 injection (medicine is injected in the tissue just under the skin).

- You will receive 4 subcutaneous injections given in separate locations around the same time
- Injection sites may include the thighs, upper arms, or either side of the abdomen
- You will then be monitored for at least 1 hour after the injections

Where can I receive REGEN-COV?

REGEN-COV can be available in several treatment facilities, including a doctor's office, a hospital, a clinic, an urgent care center, or an infusion center. Ask your healthcare provider where you can receive treatment. **If you and your healthcare provider are looking for an infusion center near you, visit <https://locator.infusioncenter.org/>.**



WHAT SHOULD I EXPECT ON THE DAY OF TREATMENT?

You may receive your treatment at a variety of treatment facilities, including a doctor's office, a hospital, a clinic, an urgent care center, or an infusion center. Treatment may last between 1 hour and 45 minutes to 3 hours and 30 minutes. Your healthcare provider will guide and prepare you for each step of the process.

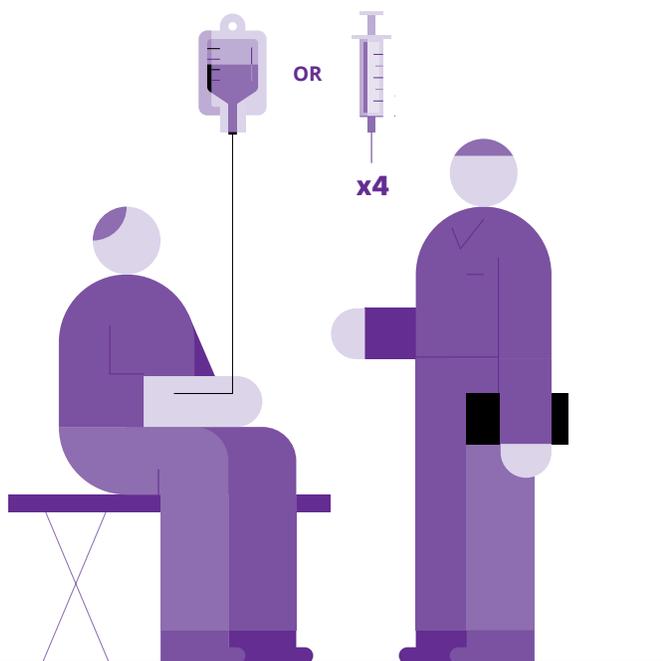
IV Infusion

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 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 50 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.

Subcutaneous Injection

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 injection (medicine is injected in the tissue just under the skin). One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

Injections will be administered to 4 different injection sites that may include the thighs, upper arms, or either side of the abdomen. After the injections, you will be monitored for at least 1 hour.



WHAT SHOULD I EXPECT AFTER MY TREATMENT?

I How soon might I feel better?

In a clinical study, the average time for symptoms to improve was 10 days for those who took REGEN-COV compared to 14 days for those who didn't.

You still may be able to infect others after receiving REGEN-COV, 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.**

I How much does REGEN-COV cost?

The federal government is working with Regeneron, the manufacturer of REGEN-COV, to make it easier for you to get this important treatment. The federal government purchased the first 1.5 million doses to ensure the medicine is free and accessible to those who need it. However, healthcare facilities may charge fees related to administering the infusion. If you have insurance, it may cover some or all of these fees. You should contact your insurance provider if you have any questions.



I Important Safety Information

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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?

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.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> 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 current 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?

Yes. 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.

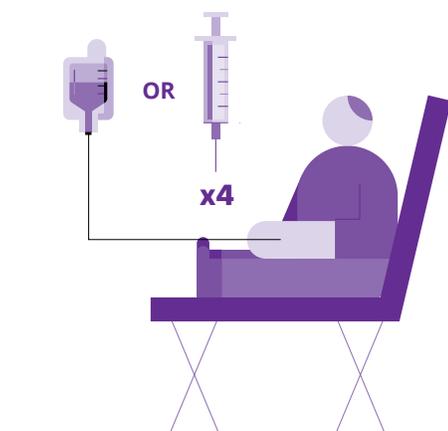
REGEN-COV is not a vaccine and will not replace receiving the vaccine. REGEN-COV may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks.

What is the difference between receiving REGEN-COV by intravenous infusion versus subcutaneous injection?

In clinical trials, there was no difference in treatment outcomes between the intravenous infusion and subcutaneous injection of REGEN-COV. 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 injection (medicine is injected in the tissue just under the skin). One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

Can you receive REGEN-COV to prevent getting COVID-19 if exposed to someone that has tested positive for COVID-19?

REGEN-COV is not authorized for patients that have not tested positive for COVID-19. If you think you may have contracted COVID-19, it is important to talk to your doctor.



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

AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION

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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 and imdevimab)

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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 injection (medicine is injected in the tissue just under the skin). One dose will consist of 4 subcutaneous injections given in separate locations around the same time.

AUTHORIZED USE AND IMPORTANT SAFETY INFORMATION (CONT'D)

Warnings and important possible side effects of REGEN-COV (casirivimab and 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, 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, 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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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.

Pregnancy and breastfeeding

There is limited experience treating pregnant women or breastfeeding mothers with REGEN-COV. 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.

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