Information about the COVID-19 REGEN-COV Monoclonal Antibody Treatment

Disclaimer: as of January 24, 2022, the U.S. Food and Drug Administration has revoked approval of the COVID-19 monoclonal antibody (mAb) treatment called REGEN-COV in all U.S. states and territories. This is due to an increase in COVID-19 cases caused by the Omicron variant and data showing that REGEN-COV is unlikely to be as effective against it.[1]

Like many other viruses, the SARS-CoV-2 virus that causes COVID-19 is evolving and changing over time. This means that what made the virus susceptible to certain treatments or vaccines may change. As COVID-19 becomes an endemic disease, meaning that it is still present but not causing significant disruption in our daily lives, the virus will continue to change and new variants will arise.

In the future, new variants may arise that may once again be treatable with REGEN-COV.

Authorization of REGEN-COV

On November 21, 2020, the US Food and Drug Administration authorized a COVID-19 cocktail monoclonal antibody (mAb) treatment called REGEN-COV made by Regeneron Pharmaceutical, Inc. for emergency use during the current pandemic. On August 10, 2021, this authorization was updated to include post-exposure prophylaxis for those who have been exposed to the SARS-CoV-2 virus and are at high risk of developing serious complications. It is still authorized for the treatment of mild to moderate COVID-19 in those at high risk of developing serious complications.[2] REGEN-COV is considered a cocktail because it is made up of two mAbs called casirivimab and imdevimab that are given together as a single treatment.

This fact sheet contains information about the REGEN-COV treatment to help you make informed decisions about treatments for COVID-19 that may help reduce your risk of severe illness.

How does REGEN-COV work?

REGEN-COV provides your immune system with antibodies to protect you from COVID-19. The antibodies recognize and attack the SARS-CoV-2 virus and stop it from entering the cells in your body. **The treatment is given to you immediately after testing positive for COVID-19 or being exposed to the SARS-CoV-2 virus.**

Monoclonal antibody treatments are most effective in the 10 days from when you first started showing COVID-19 symptoms. It is incredibly important that you are tested and contact your health care provider as soon as possible if you are experiencing COVID-19 symptoms.[3]

When used for post-exposure prophylaxis, REGEN-COV stops the virus from replicating in your body before you get sick so you may not experience severe or any symptoms.

Who is the REGEN-COV for?

REGEN-COV has been authorized for the treatment of mild to moderate cases of COVID-19. Those that receive the treatment must be 12 years of age and older, weigh at least 40kg/88lbs, and be at high risk for progressing to severe COVID-19 and/or hospitalization.[4]

You are considered high-risk if you meet at least one of the following criteria[4]:

- Have a body mass index (BMI) equal to or over 35
- Have a chronic kidney disease
- Have diabetes
- Have an immunosuppressive disease
- Are currently receiving immunosuppressive treatment
- Are 65 years of age or older
- Are 55 years of age or older AND have any of the following:
  - cardiovascular disease
  - hypertension
  - chronic obstructive pulmonary disease/other chronic respiratory disease
- Are 12–17 years of age AND have any of the following:
  - BMI in the 85th percentile or over for their age and gender based on CDC growth charts
  - sickle cell disease
  - congenital or acquired heart disease
  - neurodevelopmental disorders, such as cerebral palsy
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
  - asthma, reactive airway, or other chronic respiratory diseases that require daily medication for control

REGEN-COV's revised authorization for post-exposure prophylaxis is for those that are at high risk of progressing to severe COVID-19 as previously defined[2] AND:

- are not fully vaccinated or expected to mount an adequate immune response (are immunocompromised or immunosuppressed)
- have been exposed to an individual infected with SARS-CoV-2 through close contact or
- are at high risk of close contact exposure to an individual infected with SARS-CoV-2 in the same institutional setting (such as a nursing home or prison)

Before receiving REGEN-COV, you should talk with your provider to discuss potential risks and benefits if you[5]:

- Have any allergies
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Have any serious illnesses
- Are taking any medications (prescription, over the counter, vitamins, and herbal products)

REGEN-COV is not authorized for use in people who[4]:

- Are already hospitalized due to COVID-19
- Require oxygen therapy due to COVID-19
- Require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy because of a pre-existing medical condition

How is REGEN-COV given?

The two mAbs (casirivimab and imdevimab) that make up REGEN-COV are administered together as a single dose through an intravenous (IV) infusion or a subcutaneous (under the skin) injection.[2] The treatment takes at least 60 minutes to deliver but can take longer. Patients are monitored during the infusion and for at least one hour afterward.[4]

What are the possible benefits of receiving REGEN-COV?

Possible benefits of receiving REGEN-COV treatment include[5]:

- Reduced risk of severe COVID-19 symptoms
- Reduced risk of hospitalization
- Reduced risk of death from COVID-19

What are the possible risks of receiving REGEN-COV?

Possible temporary side effects of REGEN-COV treatment include[3]:

- Nausea
- Diarrhea
- Dizziness
- Headache
- Itching
- Vomiting
- Allergic reaction
- Worsening of already existing symptoms of COVID-19

Possible temporary side effects of getting any medicine by infusion include[3]:

- Brief pain at the infusion site
- Bleeding
- Bruising of the skin
- Soreness
- Swelling
- Possible infection at the infusion site

It is also possible that REGEN-COV could interfere with your body's ability to fight off a future COVID-19 infection.[2] Similarly, REGEN-COV may reduce your body's immune response to a COVID-19 vaccine.[2]

Although not all side effects are currently known, the known and potential benefits of REGEN-COV outweigh the known and potential risks. The FDA will continue to monitor for any additional side effects.

Can I be vaccinated for COVID-19 if I am treated with REGEN-COV for COVID-19?

Currently, there is no data on the safety and effectiveness of COVID-19 vaccines in people who received a COVID-19 mAb treatment like REGEN-COV. The Advisory Committee on Immunization Practice recommends that you wait 90 days after receiving a COVID-19 mAb treatment to get vaccinated to avoid any possible interactions between the treatment and vaccine.[6] This is the recommended wait time because data suggest that reinfection of COVID-19 is uncommon within 90 days.[6]

Should I continue to follow CDC guidelines?

You should continue to practice all safety measures, even if you have received the REGEN-COV treatment. This is important because receiving this treatment does not protect you against future COVID-19 infections. To protect yourself and your community we recommend:

- Continuing to wear a mask
- Continuing to social distance
- Continuing to wash your hands
- Following local public health recommendations

Resources

1. Coronavirus (COVID-19) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant. U.S. Food and Drug Administration. Updated January 24, 2022. Accessed April 15, 2022. www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron
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6. Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC. CDC. Published September 17, 2021. Accessed September 20, 2021. www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html